2.7.6.2　　付表

付表 2.7.6.2- 1　すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団） 2

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例） 47

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Number of subjects (%) with at least one adverse event		1959 (81.2%)	1928 (80.2%)	781 (32.4%)	804 (33.4%)
Blood and lymphatic system disorders	血液およびリンパ系障害	94 (3.9%)	91 (3.8%)	29 (1.2%)	24 (1.0%)
Anaemia	貧血	57 (2.4%)	42 (1.7%)	18 (0.7%)	11 (0.5%)
Anaemia folate deficiency	葉酸欠乏性貧血	1 (<0.1%)	1 (<0.1%)		
Anaemia of chronic disease	慢性疾患の貧血	1 (<0.1%)	0	1 (<0.1%)	0
Coagulopathy	凝血異常	0	2 (<0.1%)	0	2 (<0.1%)
Disseminated intravascular coagulation	播種性血管内凝固	1 (<0.1%)	0		
Eosinophilia	好酸球増加症	0	2 (<0.1%)	0	1 (<0.1%)
Febrile neutropenia	発熱性好中球減少症	2 (<0.1%)	1 (<0.1%)		
Haemolytic anaemia	溶血性貧血	1 (<0.1%)	0		
Haemorrhagic anaemia	出血性貧血	1 (<0.1%)	3 (0.1%)	1 (<0.1%)	3 (0.1%)
Haemorrhagic diathesis	出血性素因	1 (<0.1%)	0	1 (<0.1%)	0
Heparin-induced thrombocytopenia	ヘパリン起因性血小板減少症	1 (<0.1%)	0	1 (<0.1%)	0
Hypercoagulation	凝固亢進	1 (<0.1%)	3 (0.1%)	0	1 (<0.1%)
Hypochromic anaemia	低色素性貧血	0	1 (<0.1%)		
Hypocoagulable state	凝固低下状態	0	1 (<0.1%)	0	1 (<0.1%)
Idiopathic thrombocytopenic purpura	特発性血小板減少性紫斑病	0	1 (<0.1%)		
Iron deficiency anaemia	鉄欠乏性貧血	6 (0.2%)	9 (0.4%)	4 (0.2%)	2 (<0.1%)
Leukocytosis	白血球増加症	0	4 (0.2%)	0	1 (<0.1%)
Leukopenia	白血球減少症	4 (0.2%)	4 (0.2%)	0	1 (<0.1%)
Lymph node fibrosis	リンパ節線維症	1 (<0.1%)	0		
Lymph node pain	リンパ節痛	1 (<0.1%)	0		
Lymphadenitis	リンパ節炎	0	1 (<0.1%)		
Lymphadenopathy	リンパ節症	4 (0.2%)	6 (0.2%)		
Lymphadenopathy mediastinal	縦隔リンパ節腫脹	2 (<0.1%)	0		
Lymphocytosis	リンパ球増加症	0	1 (<0.1%)		
Microcytic anaemia	小球性貧血	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Neutropenia	好中球減少症	2 (<0.1%)	4 (0.2%)		
Neutrophilia	好中球増加症	1 (<0.1%)	0		
Normochromic normocytic anaemia	正色素性正球性貧血	1 (<0.1%)	0	1 (<0.1%)	0
Pancytopenia	汎血球減少症	0	1 (<0.1%)		
Pernicious anaemia	悪性貧血	1 (<0.1%)	0		
Spleen disorder	脾臓障害	1 (<0.1%)	0		
Splenic haemorrhage	脾臓出血	0	1 (<0.1%)	0	1 (<0.1%)
Splenic infarction	脾臓梗塞	0	1 (<0.1%)		
Splenic lesion	脾臓病変	0	2 (<0.1%)		
Splenomegaly	脾腫	3 (0.1%)	2 (<0.1%)		
Spontaneous haematoma	特発性血腫	0	1 (<0.1%)	0	1 (<0.1%)
Thrombocytopenia	血小板減少症	7 (0.3%)	8 (0.3%)	1 (<0.1%)	1 (<0.1%)
Thrombocytosis	血小板増加症	2 (<0.1%)	2 (<0.1%)	0	1 (<0.1%)
Cardiac disorders	心臓障害	223 (9.2%)	209 (8.7%)	14 (0.6%)	3 (0.1%)

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Acute coronary syndrome	急性冠動脈症候群	0	1 (<0.1%)		
Acute left ventricular failure	急性左室不全	1 (<0.1%)	0		
Acute myocardial infarction	急性心筋梗塞	6 (0.2%)	12 (0.5%)		
Angina pectoris	狭心症	8 (0.3%)	4 (0.2%)		
Angina unstable	不安定狭心症	10 (0.4%)	3 (0.1%)	2 (<0.1%)	0
Aortic valve incompetence	大動脈弁閉鎖不全症	10 (0.4%)	6 (0.2%)		
Arrhythmia	不整脈	4 (0.2%)	4 (0.2%)		
Arteriosclerosis coronary artery	冠動脈硬化症	2 (<0.1%)	0		
Atrial fibrillation	心房細動	26 (1.1%)	26 (1.1%)		
Atrial flutter	心房粗動	1 (<0.1%)	4 (0.2%)		
Atrial tachycardia	心房頻脈	1 (<0.1%)	0		
Atrial thrombosis	心房血栓症	1 (<0.1%)	1 (<0.1%)		
Atrioventricular block	房室ブロック	0	1 (<0.1%)		
Bradycardia	徐脈	4 (0.2%)	5 (0.2%)		
Bundle branch block left	左脚ブロック	2 (<0.1%)	1 (<0.1%)		
Bundle branch block right	右脚ブロック	0	1 (<0.1%)		
Cardiac aneurysm	心臓瘤	1 (<0.1%)	1 (<0.1%)		
Cardiac arrest	心停止	1 (<0.1%)	0		
Cardiac disorder	心障害	1 (<0.1%)	0		
Cardiac failure	心不全	15 (0.6%)	16 (0.7%)		
Cardiac failure acute	急性心不全	5 (0.2%)	2 (<0.1%)	1 (<0.1%)	0
Cardiac failure chronic	慢性心不全	2 (<0.1%)	2 (<0.1%)		
Cardiac failure congestive	うっ血性心不全	5 (0.2%)	6 (0.2%)	1 (<0.1%)	0
Cardiac hypertrophy	心肥大	2 (<0.1%)	0		
Cardiac valve disease	心臓弁膜疾患	1 (<0.1%)	1 (<0.1%)		
Cardio-respiratory arrest	心肺停止	1 (<0.1%)	0		
Cardiogenic shock	心原性ショック	1 (<0.1%)	0		
Cardiomegaly	心拡大	1 (<0.1%)	1 (<0.1%)		
Cardiomyopathy	心筋症	0	4 (0.2%)		
Cardiovascular disorder	心血管障害	0	1 (<0.1%)		
Cardiovascular insufficiency	心血管不全	1 (<0.1%)	0		
Congestive cardiomyopathy	うっ血性心筋症	2 (<0.1%)	0	1 (<0.1%)	0
Cor pulmonale	肺性心	3 (0.1%)	2 (<0.1%)		
Cor pulmonale acute	急性肺性心	1 (<0.1%)	0		
Cor pulmonale chronic	慢性肺性心	1 (<0.1%)	1 (<0.1%)		
Coronary artery disease	冠動脈疾患	2 (<0.1%)	8 (0.3%)	1 (<0.1%)	1 (<0.1%)
Coronary artery dissection	冠動脈解離	0	1 (<0.1%)		
Coronary artery occlusion	冠動脈閉塞	1 (<0.1%)	0		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Coronary artery stenosis	冠動脈狭窄	0	2 (<0.1%)		
Cyanosis	チアノーゼ	6 (0.2%)	0		
Diastolic dysfunction	拡張機能障害	3 (0.1%)	0		
Dilatation ventricular	心室拡張	2 (<0.1%)	4 (0.2%)		
Extrasystoles	期外収縮	4 (0.2%)	3 (0.1%)		
Hepatojugular reflux	肝頚静脈逆流	1 (<0.1%)	0		
Hypertensive heart disease	高血圧性心疾患	2 (<0.1%)	0		
Hypertrophic cardiomyopathy	肥大型心筋症	1 (<0.1%)	0		
Ischaemic cardiomyopathy	虚血性心筋症	0	1 (<0.1%)		
Left atrial dilatation	左房拡張	8 (0.3%)	3 (0.1%)		
Left ventricular dysfunction	左室機能不全	3 (0.1%)	0		
Left ventricular failure	左室不全	2 (<0.1%)	1 (<0.1%)		
Left ventricular hypertrophy	左室肥大	4 (0.2%)	1 (<0.1%)		
Mitral valve incompetence	僧帽弁閉鎖不全症	26 (1.1%)	23 (1.0%)		
Myocardial infarction	心筋梗塞	0	1 (<0.1%)		
Myocardial ischaemia	心筋虚血	0	3 (0.1%)		
Myocarditis	心筋炎	0	1 (<0.1%)		
Palpitations	動悸	20 (0.8%)	27 (1.1%)	5 (0.2%)	0
Paroxysmal arrhythmia	発作性不整脈	0	1 (<0.1%)		
Pericardial effusion	心嚢液貯留	2 (<0.1%)	7 (0.3%)		
Pericardial haemorrhage	心嚢内出血	1 (<0.1%)	2 (<0.1%)	0	2 (<0.1%)
Pericarditis	心膜炎	3 (0.1%)	0		
Right atrial dilatation	右房拡張	1 (<0.1%)	0		
Right ventricular dysfunction	右室機能不全	0	1 (<0.1%)		
Right ventricular failure	右室不全	4 (0.2%)	0	1 (<0.1%)	0
Sick sinus syndrome	洞不全症候群	0	1 (<0.1%)		
Sinus bradycardia	洞性徐脈	2 (<0.1%)	0		
Sinus tachycardia	洞性頻脈	4 (0.2%)	6 (0.2%)		
Supraventricular extrasystoles	上室性期外収縮	2 (<0.1%)	2 (<0.1%)		
Supraventricular tachycardia	上室性頻脈	3 (0.1%)	6 (0.2%)		
Tachyarrhythmia	頻脈性不整脈	1 (<0.1%)	1 (<0.1%)		
Tachycardia	頻脈	50 (2.1%)	40 (1.7%)	5 (0.2%)	0
Tricuspid valve incompetence	三尖弁閉鎖不全症	7 (0.3%)	12 (0.5%)	1 (<0.1%)	0
Ventricular extrasystoles	心室性期外収縮	0	2 (<0.1%)		
Ventricular fibrillation	心室細動	1 (<0.1%)	0		
Ventricular hypertrophy	心室肥大	4 (0.2%)	3 (0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Ventricular hypokinesia	心室壁運動低下	0	1 (<0.1%)		
Ventricular tachycardia	心室性頻脈	3 (0.1%)	4 (0.2%)		
Congenital, familial and genetic disorders	先天性、家族性および遺伝性障害	33 (1.4%)	23 (1.0%)		
Anomalous pulmonary venous connection	肺静脈還流異常	1 (<0.1%)	0		
Antithrombin III deficiency	アンチトロンビンＩＩＩ欠乏症	1 (<0.1%)	0		
Atrial septal defect	心房中隔欠損症	1 (<0.1%)	0		
Cardiac septal defect	心中隔欠損	1 (<0.1%)	0		
Coagulation factor mutation	凝固因子変異	1 (<0.1%)	0		
Congenital cystic kidney disease	先天性嚢胞性腎疾患	0	1 (<0.1%)		
Congenital renal cyst	先天性腎嚢胞	0	2 (<0.1%)		
Double ureter	重複尿管	1 (<0.1%)	0		
Eisenmenger's syndrome	アイゼンメンゲル症候群	1 (<0.1%)	0		
Factor II mutation	第ＩＩ因子突然変異	3 (0.1%)	2 (<0.1%)		
Factor V Leiden mutation	第Ｖ因子ライデン変異	13 (0.5%)	13 (0.5%)		
Factor V deficiency	第Ｖ因子欠乏症	0	1 (<0.1%)		
Factor VIII deficiency	第ＶＩＩＩ因子欠乏症	1 (<0.1%)	0		
Gene mutation	遺伝子突然変異	3 (0.1%)	2 (<0.1%)		
Hydrocele	陰嚢水瘤	2 (<0.1%)	0		
Kidney duplex	重複腎	0	1 (<0.1%)		
Phimosis	包茎	0	1 (<0.1%)		
Platelet glycoprotein gene mutation	血小板糖蛋白遺伝子突然変異	0	1 (<0.1%)		
Protein C deficiency	プロテインＣ欠乏症	1 (<0.1%)	1 (<0.1%)		
Protein S deficiency	プロテインＳ欠乏症	2 (<0.1%)	0		
Type V hyperlipidaemia	５型高脂血症	3 (0.1%)	0		
Ear and labyrinth disorders	耳および迷路障害	74 (3.1%)	69 (2.9%)	5 (0.2%)	11 (0.5%)
Auricular perichondritis	耳介軟骨膜炎	1 (<0.1%)	0		
Deafness	難聴	3 (0.1%)	0		
Deafness unilateral	片耳難聴	0	1 (<0.1%)		
Ear canal erythema	外耳道紅斑	0	1 (<0.1%)		
Ear discomfort	耳不快感	1 (<0.1%)	5 (0.2%)		
Ear disorder	耳の障害	0	1 (<0.1%)		
Ear haemorrhage	耳出血	2 (<0.1%)	10 (0.4%)	2 (<0.1%)	8 (0.3%)
Ear pain	耳痛	0	5 (0.2%)		
Ear pruritus	耳そう痒症	0	2 (<0.1%)		
Eustachian tube obstruction	耳管閉塞	1 (<0.1%)	0		
Hypoacusis	聴力低下	2 (<0.1%)	4 (0.2%)	0	1 (<0.1%)
Meniere's disease	メニエール病	1 (<0.1%)	0		
Otosalpingitis	耳管炎	1 (<0.1%)	0		
Sudden hearing loss	突発難聴	1 (<0.1%)	1 (<0.1%)		
Tinnitus	耳鳴	18 (0.7%)	6 (0.2%)	2 (<0.1%)	1 (<0.1%)

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Tympanic membrane perforation	鼓膜穿孔	0	1 (<0.1%)		
Vertigo	回転性めまい	41 (1.7%)	38 (1.6%)	1 (<0.1%)	1 (<0.1%)
Vertigo positional	頭位性回転性めまい	3 (0.1%)	1 (<0.1%)		
Endocrine disorders	内分泌障害	24 (1.0%)	26 (1.1%)	2 (<0.1%)	1 (<0.1%)
Addison's disease	アジソン病	1 (<0.1%)	0	1 (<0.1%)	0
Adrenal haemorrhage	副腎出血	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Adrenal insufficiency	副腎機能不全	1 (<0.1%)	1 (<0.1%)		
Adrenal mass	副腎腫瘤	2 (<0.1%)	2 (<0.1%)		
Autoimmune thyroiditis	自己免疫性甲状腺炎	1 (<0.1%)	1 (<0.1%)		
Basedow's disease	バセドウ病	1 (<0.1%)	0		
Diabetes insipidus	尿崩症	0	1 (<0.1%)		
Goitre	甲状腺腫	5 (0.2%)	4 (0.2%)		
Hyperparathyroidism	副甲状腺機能亢進症	0	1 (<0.1%)		
Hyperparathyroidism primary	原発性副甲状腺機能亢進症	1 (<0.1%)	1 (<0.1%)		
Hyperthyroidism	甲状腺機能亢進症	4 (0.2%)	7 (0.3%)	1 (<0.1%)	0
Hypothyroidism	甲状腺機能低下症	6 (0.2%)	5 (0.2%)		
Inappropriate antidiuretic hormone secretion	抗利尿ホルモン不適合分泌	0	1 (<0.1%)		
Steroid withdrawal syndrome	ステロイド離脱症候群	1 (<0.1%)	0		
Thyroid cyst	甲状腺嚢腫	2 (<0.1%)	1 (<0.1%)		
Thyroid mass	甲状腺腫瘤	0	1 (<0.1%)		
Eye disorders	眼障害	101 (4.2%)	102 (4.2%)	36 (1.5%)	38 (1.6%)
Abnormal sensation in eye	眼の異常感	1 (<0.1%)	0		
Age-related macular degeneration	加齢黄斑変性	1 (<0.1%)	1 (<0.1%)		
Amaurosis	黒内障	0	1 (<0.1%)		
Arteriosclerotic retinopathy	動脈硬化性網膜症	0	1 (<0.1%)		
Blepharitis	眼瞼炎	0	1 (<0.1%)		
Cataract	白内障	10 (0.4%)	7 (0.3%)		
Conjunctival haemorrhage	結膜出血	29 (1.2%)	32 (1.3%)	21 (0.9%)	28 (1.2%)
Conjunctival hyperaemia	結膜充血	1 (<0.1%)	0		
Conjunctivitis	結膜炎	9 (0.4%)	8 (0.3%)		
Conjunctivitis allergic	アレルギー性結膜炎	0	1 (<0.1%)		
Diplopia	複視	3 (0.1%)	1 (<0.1%)		
Dry eye	眼乾燥	6 (0.2%)	2 (<0.1%)	2 (<0.1%)	0
Eye allergy	眼のアレルギー	0	1 (<0.1%)		
Eye disorder	眼の障害	0	1 (<0.1%)		
Eye haemorrhage	眼出血	7 (0.3%)	13 (0.5%)	7 (0.3%)	6 (0.2%)
Eye inflammation	眼の炎症	2 (<0.1%)	2 (<0.1%)		
Eye irritation	眼刺激	0	2 (<0.1%)		
Eye pain	眼痛	2 (<0.1%)	4 (0.2%)		
Eye pruritus	眼そう痒症	1 (<0.1%)	2 (<0.1%)	0	1 (<0.1%)
Eyelid bleeding	眼瞼出血	1 (<0.1%)	0		
Eyelid oedema	眼瞼浮腫	4 (0.2%)	2 (<0.1%)	1 (<0.1%)	0
Eyelid pain	眼瞼痛	1 (<0.1%)	0		

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Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Eyelid skin dryness	眼瞼皮膚乾燥	1 (<0.1%)	0	1 (<0.1%)	0
Eyelids pruritus	眼瞼そう痒症	2 (<0.1%)	0		
Foreign body sensation in eyes	眼の異物感	1 (<0.1%)	0		
Glaucoma	緑内障	3 (0.1%)	4 (0.2%)		
Heterophoria	眼球斜位	1 (<0.1%)	0		
Iridocyclitis	虹彩毛様体炎	0	1 (<0.1%)		
Keratitis	角膜炎	1 (<0.1%)	1 (<0.1%)		
Lacrimal haemorrhage	涙器出血	0	1 (<0.1%)		
Lacrimation increased	流涙増加	2 (<0.1%)	0		
Lens disorder	水晶体障害	1 (<0.1%)	0		
Lenticular opacities	水晶体混濁	1 (<0.1%)	0		
Myopia	近視	0	1 (<0.1%)		
Ocular hyperaemia	眼充血	2 (<0.1%)	5 (0.2%)	1 (<0.1%)	2 (<0.1%)
Ocular hypertension	高眼圧症	1 (<0.1%)	2 (<0.1%)		
Optic disc hyperaemia	視神経乳頭充血	1 (<0.1%)	0		
Optic ischaemic neuropathy	虚血性視神経症	1 (<0.1%)	0		
Panophthalmitis	全眼球炎	0	1 (<0.1%)		
Papilloedema	視神経乳頭浮腫	1 (<0.1%)	0		
Photopsia	光視症	0	2 (<0.1%)		
Presbyopia	老視	0	1 (<0.1%)		
Pupils unequal	瞳孔不同	0	1 (<0.1%)	0	1 (<0.1%)
Retinal degeneration	網膜変性	0	1 (<0.1%)		
Retinal detachment	網膜剥離	0	2 (<0.1%)		
Retinal haemorrhage	網膜出血	0	1 (<0.1%)	0	1 (<0.1%)
Retinopathy hypertensive	高血圧性網膜症	1 (<0.1%)	0		
Scleral haemorrhage	強膜出血	1 (<0.1%)	0	1 (<0.1%)	0
Scleral hyperaemia	強膜充血	2 (<0.1%)	0	2 (<0.1%)	0
Scleritis	強膜炎	1 (<0.1%)	0		
Scotoma	暗点	0	2 (<0.1%)	0	1 (<0.1%)
Vision blurred	霧視	4 (0.2%)	2 (<0.1%)		
Visual acuity reduced	視力低下	5 (0.2%)	1 (<0.1%)	1 (<0.1%)	0
Visual impairment	視力障害	1 (<0.1%)	2 (<0.1%)		
Vitreous detachment	硝子体剥離	2 (<0.1%)	0		
Vitreous floaters	硝子体浮遊物	0	2 (<0.1%)		
Vitreous haemorrhage	硝子体出血	1 (<0.1%)	0		
Gastrointestinal disorders	胃腸障害	765 (31.7%)	703 (29.2%)	217 (9.0%)	182 (7.6%)
Abdominal discomfort	腹部不快感	17 (0.7%)	15 (0.6%)	5 (0.2%)	1 (<0.1%)
Abdominal distension	腹部膨満	11 (0.5%)	5 (0.2%)		
Abdominal hernia	腹部ヘルニア	1 (<0.1%)	1 (<0.1%)		
Abdominal mass	腹部腫瘤	0	1 (<0.1%)	0	1 (<0.1%)
Abdominal pain	腹痛	46 (1.9%)	42 (1.7%)	5 (0.2%)	1 (<0.1%)
Abdominal pain lower	下腹部痛	3 (0.1%)	6 (0.2%)		
Abdominal pain upper	上腹部痛	55 (2.3%)	44 (1.8%)	5 (0.2%)	1 (<0.1%)
Abdominal tenderness	腹部圧痛	1 (<0.1%)	0		
Abdominal wall haematoma	腹壁血腫	0	7 (0.3%)	0	3 (0.1%)
Abdominal wall mass	腹壁腫瘤	0	1 (<0.1%)		
Acute abdomen	急性腹症	0	1 (<0.1%)		
Aerophagia	空気嚥下	1 (<0.1%)	1 (<0.1%)		
Anal fissure	裂肛	2 (<0.1%)	2 (<0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Anal haemorrhage	肛門出血	5 (0.2%)	3 (0.1%)	2 (<0.1%)	1 (<0.1%)
Anal inflammation	肛門の炎症	0	1 (<0.1%)		
Anal prolapse	肛門脱	0	1 (<0.1%)		
Anal pruritus	肛門そう痒症	1 (<0.1%)	1 (<0.1%)		
Anorectal disorder	肛門直腸障害	0	1 (<0.1%)		
Aphthous stomatitis	アフタ性口内炎	3 (0.1%)	1 (<0.1%)		
Apical granuloma	根尖肉芽腫	0	1 (<0.1%)		
Ascites	腹水	3 (0.1%)	2 (<0.1%)		
Barrett's oesophagus	バレット食道	1 (<0.1%)	1 (<0.1%)		
Breath odour	呼気臭	1 (<0.1%)	0		
Change of bowel habit	便習慣変化	1 (<0.1%)	0		
Chapped lips	口唇のひび割れ	1 (<0.1%)	0		
Cheilitis	口唇炎	1 (<0.1%)	0		
Coeliac artery stenosis	腹腔動脈狭窄	1 (<0.1%)	0		
Coeliac disease	セリアック病	2 (<0.1%)	0		
Colitis	大腸炎	2 (<0.1%)	2 (<0.1%)		
Colitis ischaemic	虚血性大腸炎	1 (<0.1%)	0		
Colitis ulcerative	潰瘍性大腸炎	1 (<0.1%)	2 (<0.1%)	1 (<0.1%)	0
Colonic polyp	結腸ポリープ	15 (0.6%)	14 (0.6%)		
Colonic stenosis	結腸狭窄	1 (<0.1%)	0		
Constipation	便秘	147 (6.1%)	143 (5.9%)	4 (0.2%)	2 (<0.1%)
Dental caries	齲歯	9 (0.4%)	9 (0.4%)		
Diarrhoea	下痢	129 (5.3%)	133 (5.5%)	12 (0.5%)	6 (0.2%)
Diarrhoea haemorrhagic	血性下痢	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Disbacteriosis	細菌叢異常症	0	2 (<0.1%)		
Diverticular perforation	憩室穿孔	1 (<0.1%)	0		
Diverticulitis intestinal haemorrhagic	出血性腸憩室炎	0	1 (<0.1%)	0	1 (<0.1%)
Diverticulum	憩室	5 (0.2%)	8 (0.3%)		
Diverticulum gastric	胃憩室	0	1 (<0.1%)		
Diverticulum intestinal	腸憩室	16 (0.7%)	7 (0.3%)		
Diverticulum oesophageal	食道憩室	1 (<0.1%)	0		
Dry mouth	口内乾燥	10 (0.4%)	4 (0.2%)	2 (<0.1%)	1 (<0.1%)
Duodenal ulcer	十二指腸潰瘍	2 (<0.1%)	2 (<0.1%)		
Duodenitis	十二指腸炎	3 (0.1%)	1 (<0.1%)		
Duodenogastric reflux	十二指腸胃逆流	1 (<0.1%)	0		
Dyspepsia	消化不良	43 (1.8%)	40 (1.7%)	9 (0.4%)	3 (0.1%)
Dysphagia	嚥下障害	4 (0.2%)	7 (0.3%)		
Enteritis	小腸炎	2 (<0.1%)	1 (<0.1%)		
Enterocolitis	腸炎	0	2 (<0.1%)		
Epigastric discomfort	心窩部不快感	0	4 (0.2%)		
Erosive duodenitis	びらん性十二指腸炎	1 (<0.1%)	1 (<0.1%)		
Eructation	おくび	0	2 (<0.1%)		
Faecal incontinence	便失禁	1 (<0.1%)	0		
Faecaloma	糞塊	1 (<0.1%)	2 (<0.1%)	1 (<0.1%)	0
Faeces discoloured	変色便	1 (<0.1%)	1 (<0.1%)		
Flatulence	鼓腸	5 (0.2%)	5 (0.2%)	0	1 (<0.1%)
Food poisoning	食中毒	2 (<0.1%)	1 (<0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Frequent bowel movements	排便回数増加	0	1 (<0.1%)		
Gastric disorder	胃障害	1 (<0.1%)	1 (<0.1%)		
Gastric haemorrhage	胃出血	0	1 (<0.1%)	0	1 (<0.1%)
Gastric mucosa erythema	胃粘膜紅斑	1 (<0.1%)	1 (<0.1%)		
Gastric mucosal hypertrophy	胃粘膜肥厚	0	1 (<0.1%)		
Gastric perforation	胃穿孔	1 (<0.1%)	0		
Gastric polyps	胃ポリープ	5 (0.2%)	2 (<0.1%)		
Gastric ulcer	胃潰瘍	5 (0.2%)	2 (<0.1%)		
Gastric ulcer haemorrhage	出血性胃潰瘍	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Gastric varices	胃静脈瘤	1 (<0.1%)	0		
Gastritis	胃炎	27 (1.1%)	25 (1.0%)	2 (<0.1%)	1 (<0.1%)
Gastritis atrophic	萎縮性胃炎	1 (<0.1%)	0		
Gastritis erosive	びらん性胃炎	10 (0.4%)	3 (0.1%)		
Gastritis haemorrhagic	出血性胃炎	1 (<0.1%)	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Gastroduodenitis	胃十二指腸炎	1 (<0.1%)	0		
Gastrointestinal disorder	胃腸障害	8 (0.3%)	1 (<0.1%)	2 (<0.1%)	0
Gastrointestinal dysplasia	胃腸異形成	1 (<0.1%)	0		
Gastrointestinal fistula	胃腸管瘻	0	1 (<0.1%)		
Gastrointestinal haemorrhage	胃腸出血	13 (0.5%)	6 (0.2%)	9 (0.4%)	5 (0.2%)
Gastrointestinal pain	消化器痛	0	4 (0.2%)	0	1 (<0.1%)
Gastrointestinal telangiectasia	胃腸毛細血管拡張症	1 (<0.1%)	0		
Gastrointestinal tract mucosal discolouration	消化管粘膜変色	1 (<0.1%)	0		
Gastrointestinal ulcer	胃腸潰瘍	0	1 (<0.1%)	0	1 (<0.1%)
Gastrooesophageal reflux disease	胃食道逆流性疾患	30 (1.2%)	29 (1.2%)	3 (0.1%)	1 (<0.1%)
Gastrooesophageal sphincter insufficiency	胃食道括約筋機能不全	3 (0.1%)	0		
Gingival bleeding	歯肉出血	60 (2.5%)	79 (3.3%)	47 (1.9%)	65 (2.7%)
Gingival disorder	歯肉障害	1 (<0.1%)	0		
Gingival oedema	歯肉浮腫	0	1 (<0.1%)		
Gingival pain	歯肉痛	2 (<0.1%)	2 (<0.1%)		
Gingivitis	歯肉炎	11 (0.5%)	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Glossitis	舌炎	1 (<0.1%)	0		
Glossodynia	舌痛	1 (<0.1%)	0		
Haematemesis	吐血	12 (0.5%)	6 (0.2%)	8 (0.3%)	3 (0.1%)
Haematochezia	血便排泄	10 (0.4%)	12 (0.5%)	7 (0.3%)	9 (0.4%)
Haemorrhoidal haemorrhage	痔出血	26 (1.1%)	12 (0.5%)	14 (0.6%)	9 (0.4%)
Haemorrhoids	痔核	21 (0.9%)	18 (0.7%)	2 (<0.1%)	0
Hiatus hernia	裂孔ヘルニア	22 (0.9%)	16 (0.7%)		
Hyperchlorhydria	胃酸過多	1 (<0.1%)	0		
Hypoaesthesia oral	口の感覚鈍麻	3 (0.1%)	0	2 (<0.1%)	0
Ileus	イレウス	0	1 (<0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Ileus paralytic	麻痺性イレウス	0	2 (<0.1%)		
Impaired gastric emptying	胃排出不全	0	1 (<0.1%)		
Inflammatory bowel disease	炎症性腸疾患	0	1 (<0.1%)		
Infrequent bowel movements	排便回数減少	2 (<0.1%)	0		
Inguinal hernia	鼠径ヘルニア	2 (<0.1%)	3 (0.1%)		
Intestinal fistula	腸管瘻	1 (<0.1%)	0		
Intestinal haemorrhage	腸出血	3 (0.1%)	4 (0.2%)	3 (0.1%)	4 (0.2%)
Intestinal infarction	腸梗塞	1 (<0.1%)	0		
Intestinal obstruction	腸閉塞	1 (<0.1%)	1 (<0.1%)		
Intestinal polyp	腸管ポリープ	1 (<0.1%)	3 (0.1%)		
Irritable bowel syndrome	過敏性腸症候群	4 (0.2%)	1 (<0.1%)	1 (<0.1%)	0
Large intestinal haemorrhage	大腸出血	0	1 (<0.1%)		
Large intestinal obstruction	大腸閉塞	1 (<0.1%)	0		
Large intestine perforation	大腸穿孔	1 (<0.1%)	2 (<0.1%)		
Lip dry	口唇乾燥	1 (<0.1%)	0	1 (<0.1%)	0
Lip haematoma	口唇血腫	1 (<0.1%)	0		
Lip haemorrhage	口唇出血	3 (0.1%)	2 (<0.1%)	2 (<0.1%)	1 (<0.1%)
Lip pain	口唇痛	1 (<0.1%)	0		
Loose tooth	弛緩歯	1 (<0.1%)	0		
Lower gastrointestinal haemorrhage	下部消化管出血	10 (0.4%)	10 (0.4%)	6 (0.2%)	9 (0.4%)
Lumbar hernia	腰ヘルニア	1 (<0.1%)	0		
Melaena	メレナ	8 (0.3%)	16 (0.7%)	4 (0.2%)	14 (0.6%)
Mouth haemorrhage	口腔内出血	9 (0.4%)	4 (0.2%)	6 (0.2%)	1 (<0.1%)
Mouth ulceration	口腔内潰瘍形成	4 (0.2%)	6 (0.2%)	0	1 (<0.1%)
Nausea	悪心	115 (4.8%)	133 (5.5%)	18 (0.7%)	8 (0.3%)
Odynophagia	嚥下痛	1 (<0.1%)	1 (<0.1%)		
Oesophageal disorder	食道障害	1 (<0.1%)	0		
Oesophageal irritation	食道刺激症状	1 (<0.1%)	0		
Oesophageal pain	食道痛	1 (<0.1%)	0		
Oesophageal ulcer	食道潰瘍	1 (<0.1%)	0	1 (<0.1%)	0
Oesophageal ulcer haemorrhage	食道潰瘍出血	0	1 (<0.1%)	0	1 (<0.1%)
Oesophagitis	食道炎	11 (0.5%)	4 (0.2%)		
Oesophagitis ulcerative	潰瘍性食道炎	1 (<0.1%)	0		
Oral discomfort	口腔内不快感	0	1 (<0.1%)		
Oral pain	口腔内痛	1 (<0.1%)	0	1 (<0.1%)	0
Pancreas lipomatosis	膵脂肪腫症	6 (0.2%)	10 (0.4%)		
Pancreatic atrophy	膵萎縮	1 (<0.1%)	0		
Pancreatic cyst	膵嚢胞	1 (<0.1%)	0		
Pancreatitis	膵炎	1 (<0.1%)	1 (<0.1%)		
Pancreatitis acute	急性膵炎	0	1 (<0.1%)		
Papilla of Vater stenosis	ファーター乳頭狭窄	1 (<0.1%)	0		
Paraesthesia oral	口の錯感覚	0	2 (<0.1%)	0	1 (<0.1%)

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Parotid gland enlargement	耳下腺腫大	0	1 (<0.1%)		
Peptic ulcer	消化性潰瘍	2 (<0.1%)	1 (<0.1%)		
Periodontitis	歯周炎	3 (0.1%)	0		
Peritoneal cyst	腹膜嚢胞	1 (<0.1%)	0		
Plicated tongue	ひだ舌	1 (<0.1%)	0		
Poor dental condition	歯状態不良	2 (<0.1%)	0		
Portal hypertensive gastropathy	門脈圧亢進性胃障害	1 (<0.1%)	0	1 (<0.1%)	0
Post-tussive vomiting	咳嗽後嘔吐	0	2 (<0.1%)	0	1 (<0.1%)
Proctalgia	肛門周囲痛	3 (0.1%)	0		
Proctitis	直腸炎	1 (<0.1%)	0		
Rectal haemorrhage	直腸出血	58 (2.4%)	44 (1.8%)	42 (1.7%)	34 (1.4%)
Rectal polyp	直腸ポリープ	3 (0.1%)	6 (0.2%)		
Rectal prolapse	直腸脱	3 (0.1%)	0		
Rectal tenesmus	直腸しぶり	1 (<0.1%)	0		
Retroperitoneal haematoma	後腹膜血腫	0	3 (0.1%)	0	2 (<0.1%)
Retroperitoneal haemorrhage	後腹膜出血	0	1 (<0.1%)	0	1 (<0.1%)
Salivary gland enlargement	唾液腺腫大	1 (<0.1%)	1 (<0.1%)		
Sigmoiditis	Ｓ状結腸炎	3 (0.1%)	0		
Small intestinal haemorrhage	小腸出血	1 (<0.1%)	0		
Small intestinal obstruction	小腸閉塞	1 (<0.1%)	1 (<0.1%)		
Small intestinal perforation	小腸穿孔	0	1 (<0.1%)		
Stomatitis	口内炎	1 (<0.1%)	1 (<0.1%)		
Subileus	亜イレウス	1 (<0.1%)	2 (<0.1%)		
Submaxillary gland enlargement	顎下腺腫大	0	1 (<0.1%)	0	1 (<0.1%)
Swollen tongue	舌腫脹	2 (<0.1%)	0		
Tongue disorder	舌障害	1 (<0.1%)	0	1 (<0.1%)	0
Tongue haemorrhage	舌出血	4 (0.2%)	1 (<0.1%)	3 (0.1%)	1 (<0.1%)
Tongue ulceration	舌潰瘍	0	1 (<0.1%)		
Tooth crowding	叢生歯列	1 (<0.1%)	0		
Tooth discolouration	変色歯	2 (<0.1%)	0	1 (<0.1%)	0
Tooth impacted	埋伏歯	1 (<0.1%)	0		
Tooth loss	歯の脱落	2 (<0.1%)	0		
Toothache	歯痛	33 (1.4%)	23 (1.0%)	0	1 (<0.1%)
Umbilical hernia	臍ヘルニア	4 (0.2%)	1 (<0.1%)		
Upper gastrointestinal haemorrhage	上部消化管出血	2 (<0.1%)	3 (0.1%)	2 (<0.1%)	1 (<0.1%)
Varices oesophageal	食道静脈瘤	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Vomiting	嘔吐	57 (2.4%)	78 (3.2%)	4 (0.2%)	2 (<0.1%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	531 (22.0%)	515 (21.4%)	45 (1.9%)	40 (1.7%)
Adverse drug reaction	医薬品副作用	0	1 (<0.1%)		
Application site erythema	適用部位紅斑	0	1 (<0.1%)	0	1 (<0.1%)
Application site rash	適用部位発疹	1 (<0.1%)	1 (<0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Asthenia	無力症	51 (2.1%)	55 (2.3%)	1 (<0.1%)	1 (<0.1%)
Axillary pain	腋窩痛	2 (<0.1%)	1 (<0.1%)		
Catheter site haemorrhage	カテーテル留置部位出血	3 (0.1%)	4 (0.2%)	2 (<0.1%)	0
Catheter site inflammation	カテーテル留置部位炎症	0	1 (<0.1%)		
Catheter site pain	カテーテル留置部位疼痛	0	1 (<0.1%)		
Catheter site phlebitis	カテーテル留置部位静脈炎	2 (<0.1%)	0		
Catheter site swelling	カテーテル留置部位腫脹	0	1 (<0.1%)		
Chest discomfort	胸部不快感	22 (0.9%)	18 (0.7%)	0	1 (<0.1%)
Chest pain	胸痛	196 (8.1%)	196 (8.1%)	8 (0.3%)	6 (0.2%)
Chills	悪寒	7 (0.3%)	4 (0.2%)	1 (<0.1%)	1 (<0.1%)
Cyst	嚢胞	3 (0.1%)	2 (<0.1%)		
Death	死亡	4 (0.2%)	2 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Device breakage	医療機器破損	0	1 (<0.1%)		
Device deposit issue	医療機器沈着物の問題	0	1 (<0.1%)		
Discomfort	不快感	1 (<0.1%)	0		
Drug intolerance	薬物不耐性	0	1 (<0.1%)	0	1 (<0.1%)
Drug withdrawal syndrome	薬剤離脱症候群	0	2 (<0.1%)		
Exercise tolerance decreased	運動耐性低下	2 (<0.1%)	1 (<0.1%)		
Face oedema	顔面浮腫	1 (<0.1%)	0		
Facial pain	顔面痛	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Fatigue	疲労	71 (2.9%)	55 (2.3%)	14 (0.6%)	3 (0.1%)
Feeling cold	冷感	6 (0.2%)	2 (<0.1%)	2 (<0.1%)	0
Feeling hot	熱感	3 (0.1%)	0	1 (<0.1%)	0
Feeling of body temperature change	体温変動感	2 (<0.1%)	0		
Gait disturbance	歩行障害	2 (<0.1%)	2 (<0.1%)		
General physical health deterioration	全身健康状態低下	4 (0.2%)	5 (0.2%)		
Generalised oedema	全身性浮腫	0	1 (<0.1%)		
Granuloma	肉芽腫	0	1 (<0.1%)		
Gravitational oedema	重力性浮腫	1 (<0.1%)	1 (<0.1%)		
Haemorrhagic cyst	出血性嚢胞	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Hyperthermia	高熱	5 (0.2%)	3 (0.1%)		
Hypothermia	低体温	1 (<0.1%)	0		
Impaired healing	治癒不良	1 (<0.1%)	1 (<0.1%)		
Implant site thrombosis	埋込み部位血栓	0	1 (<0.1%)		
Inflammation	炎症	5 (0.2%)	0		
Influenza like illness	インフルエンザ様疾患	18 (0.7%)	20 (0.8%)	1 (<0.1%)	0
Infusion site extravasation	注入部位血管外漏出	1 (<0.1%)	0		
Infusion site inflammation	注入部位炎症	1 (<0.1%)	0		
Injection site discomfort	注射部位不快感	0	1 (<0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Injection site eczema	注射部位湿疹	1 (<0.1%)	0		
Injection site erythema	注射部位紅斑	0	1 (<0.1%)	0	1 (<0.1%)
Injection site extravasation	注射部位血管外漏出	0	1 (<0.1%)	0	1 (<0.1%)
Injection site haematoma	注射部位血腫	5 (0.2%)	16 (0.7%)	3 (0.1%)	13 (0.5%)
Injection site haemorrhage	注射部位出血	1 (<0.1%)	3 (0.1%)	0	2 (<0.1%)
Injection site pain	注射部位疼痛	0	1 (<0.1%)	0	1 (<0.1%)
Injection site rash	注射部位発疹	0	1 (<0.1%)		
Injection site reaction	注射部位反応	0	1 (<0.1%)	0	1 (<0.1%)
Local swelling	局所腫脹	0	1 (<0.1%)		
Localised oedema	限局性浮腫	2 (<0.1%)	1 (<0.1%)		
Malaise	倦怠感	13 (0.5%)	9 (0.4%)	2 (<0.1%)	0
Mass	腫瘤	2 (<0.1%)	0		
Medical device complication	医療機器合併症	1 (<0.1%)	2 (<0.1%)		
Medical device discomfort	医療機器不快感	0	1 (<0.1%)		
Mucosal inflammation	粘膜の炎症	1 (<0.1%)	0		
Multi-organ failure	多臓器不全	1 (<0.1%)	0		
Non-cardiac chest pain	非心臓性胸痛	12 (0.5%)	9 (0.4%)		
Oedema	浮腫	21 (0.9%)	28 (1.2%)	3 (0.1%)	1 (<0.1%)
Oedema peripheral	末梢性浮腫	93 (3.9%)	103 (4.3%)	4 (0.2%)	6 (0.2%)
Pain	疼痛	16 (0.7%)	11 (0.5%)		
Pelvic mass	骨盤腔内腫瘤	1 (<0.1%)	1 (<0.1%)		
Polyp	ポリープ	2 (<0.1%)	1 (<0.1%)		
Puncture site haemorrhage	穿刺部位出血	1 (<0.1%)	0		
Pyrexia	発熱	78 (3.2%)	80 (3.3%)		
Sensation of foreign body	異物感	1 (<0.1%)	0		
Sensation of pressure	圧迫感	0	1 (<0.1%)		
Stent malfunction	ステント機能不良	1 (<0.1%)	0		
Sudden death	突然死	3 (0.1%)	1 (<0.1%)	2 (<0.1%)	0
Tenderness	圧痛	0	2 (<0.1%)		
Thirst	口渇	2 (<0.1%)	0	1 (<0.1%)	0
Thrombosis in device	医療機器内血栓	1 (<0.1%)	0		
Vessel puncture site haematoma	血管穿刺部位血腫	0	3 (0.1%)	0	2 (<0.1%)
Vessel puncture site haemorrhage	血管穿刺部位出血	4 (0.2%)	2 (<0.1%)	3 (0.1%)	2 (<0.1%)
Hepatobiliary disorders	肝胆道系障害	93 (3.9%)	107 (4.4%)	11 (0.5%)	10 (0.4%)
Bile duct stone	胆管結石	1 (<0.1%)	1 (<0.1%)		
Biliary cirrhosis primary	原発性胆汁性肝硬変	0	1 (<0.1%)		
Biliary colic	胆道仙痛	1 (<0.1%)	1 (<0.1%)		
Biliary dilatation	胆管拡張	0	1 (<0.1%)		
Cholangitis	胆管炎	2 (<0.1%)	2 (<0.1%)		
Cholangitis sclerosing	硬化性胆管炎	1 (<0.1%)	0	1 (<0.1%)	0
Cholecystitis	胆嚢炎	2 (<0.1%)	4 (0.2%)	1 (<0.1%)	0
Cholecystitis acute	急性胆嚢炎	0	3 (0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Cholecystitis chronic	慢性胆嚢炎	1 (<0.1%)	1 (<0.1%)		
Cholelithiasis	胆石症	20 (0.8%)	27 (1.1%)		
Cholestasis	胆汁うっ滞	2 (<0.1%)	0	1 (<0.1%)	0
Cytolytic hepatitis	肝細胞融解性肝炎	3 (0.1%)	0	2 (<0.1%)	0
Gallbladder polyp	胆嚢ポリープ	3 (0.1%)	0		
Haemorrhagic hepatic cyst	出血性肝嚢胞	1 (<0.1%)	0		
Hepatic cirrhosis	肝硬変	1 (<0.1%)	2 (<0.1%)		
Hepatic congestion	肝臓うっ血	1 (<0.1%)	0		
Hepatic cyst	肝嚢胞	8 (0.3%)	9 (0.4%)		
Hepatic failure	肝不全	1 (<0.1%)	2 (<0.1%)		
Hepatic function abnormal	肝機能異常	6 (0.2%)	12 (0.5%)	4 (0.2%)	8 (0.3%)
Hepatic mass	肝腫瘤	0	1 (<0.1%)		
Hepatic pain	肝臓痛	1 (<0.1%)	0		
Hepatic steatosis	脂肪肝	41 (1.7%)	45 (1.9%)		
Hepatic vein dilatation	肝静脈拡張	0	1 (<0.1%)		
Hepatitis	肝炎	1 (<0.1%)	2 (<0.1%)	0	1 (<0.1%)
Hepatitis acute	急性肝炎	1 (<0.1%)	0	1 (<0.1%)	0
Hepatitis chronic active	慢性活動性肝炎	1 (<0.1%)	0	1 (<0.1%)	0
Hepatomegaly	肝腫大	7 (0.3%)	8 (0.3%)		
Hyperbilirubinaemia	高ビリルビン血症	0	2 (<0.1%)	0	1 (<0.1%)
Hypertransaminasaemia	高トランスアミナーゼ血症	0	1 (<0.1%)		
Ischaemic hepatitis	虚血性肝炎	1 (<0.1%)	0		
Jaundice	黄疸	1 (<0.1%)	1 (<0.1%)		
Liver disorder	肝障害	0	2 (<0.1%)		
Liver injury	肝損傷	1 (<0.1%)	1 (<0.1%)		
Portal hypertension	門脈圧亢進症	0	1 (<0.1%)		
Portal vein thrombosis	門脈血栓症	0	1 (<0.1%)		
Immune system disorders	免疫系障害	39 (1.6%)	26 (1.1%)	0	3 (0.1%)
Allergy to arthropod sting	節足動物刺傷アレルギー	1 (<0.1%)	0		
Allergy to chemicals	化学物質アレルギー	0	1 (<0.1%)		
Antiphospholipid syndrome	抗リン脂質抗体症候群	4 (0.2%)	2 (<0.1%)		
Contrast media allergy	造影剤アレルギー	0	1 (<0.1%)		
Drug hypersensitivity	薬物過敏症	8 (0.3%)	8 (0.3%)	0	3 (0.1%)
Food allergy	食物アレルギー	1 (<0.1%)	0		
Hypersensitivity	過敏症	6 (0.2%)	2 (<0.1%)		
Latex allergy	ラテックスアレルギー	1 (<0.1%)	0		
Sarcoidosis	サルコイドーシス	2 (<0.1%)	0		
Seasonal allergy	季節性アレルギー	16 (0.7%)	12 (0.5%)		
Infections and infestations	感染症および寄生虫症	789 (32.7%)	773 (32.1%)	12 (0.5%)	7 (0.3%)
Abdominal abscess	腹部膿瘍	1 (<0.1%)	0		
Abdominal infection	腹部感染	0	1 (<0.1%)		
Abdominal wall abscess	腹壁膿瘍	1 (<0.1%)	0		
Abscess jaw	顎膿瘍	1 (<0.1%)	0		
Abscess limb	四肢膿瘍	0	2 (<0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Abscess neck	頚部膿瘍	0	1 (<0.1%)		
Abscess oral	口腔膿瘍	1 (<0.1%)	0		
Abscess soft tissue	軟部組織膿瘍	1 (<0.1%)	1 (<0.1%)		
Acarodermatitis	ダニ皮膚炎	2 (<0.1%)	1 (<0.1%)		
Acute sinusitis	急性副鼻腔炎	1 (<0.1%)	0		
Acute tonsillitis	急性扁桃炎	3 (0.1%)	4 (0.2%)		
Anal abscess	肛門膿瘍	1 (<0.1%)	0		
Appendiceal abscess	虫垂膿瘍	0	1 (<0.1%)		
Appendicitis	虫垂炎	0	2 (<0.1%)		
Arthritis infective	感染性関節炎	0	1 (<0.1%)		
Bacteraemia	菌血症	2 (<0.1%)	1 (<0.1%)		
Bacterial infection	細菌感染	1 (<0.1%)	1 (<0.1%)		
Bacteriuria	細菌尿	0	1 (<0.1%)		
Biliary sepsis	胆道性敗血症	0	1 (<0.1%)		
Biliary tract infection bacterial	細菌性胆道感染	1 (<0.1%)	0		
Blastocystis infection	ブラストシスティス感染	0	1 (<0.1%)		
Bone abscess	骨膿瘍	1 (<0.1%)	0		
Borrelia infection	ボレリア感染	1 (<0.1%)	0		
Bronchitis	気管支炎	111 (4.6%)	93 (3.9%)	2 (<0.1%)	1 (<0.1%)
Bronchitis viral	ウイルス性気管支炎	1 (<0.1%)	1 (<0.1%)		
Bronchopneumonia	気管支肺炎	6 (0.2%)	7 (0.3%)		
Bronchopulmonary aspergillosis	気管支肺アスペルギルス症	2 (<0.1%)	0		
Burn infection	熱傷部感染	0	1 (<0.1%)		
Campylobacter infection	カンピロバクター感染	1 (<0.1%)	1 (<0.1%)		
Candidiasis	カンジダ症	6 (0.2%)	4 (0.2%)		
Catheter site infection	カテーテル留置部位感染	1 (<0.1%)	0		
Cellulitis	蜂巣炎	11 (0.5%)	21 (0.9%)	0	1 (<0.1%)
Cervicitis	子宮頚管炎	1 (<0.1%)	0		
Chlamydial infection	クラミジア感染	0	1 (<0.1%)		
Cholecystitis infective	感染性胆嚢炎	1 (<0.1%)	0		
Chronic sinusitis	慢性副鼻腔炎	1 (<0.1%)	1 (<0.1%)		
Clostridial infection	クロストリジウム感染	0	1 (<0.1%)		
Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	1 (<0.1%)	0		
Conjunctivitis infective	感染性結膜炎	0	1 (<0.1%)		
Conjunctivitis viral	ウイルス性結膜炎	2 (<0.1%)	0		
Cystitis	膀胱炎	17 (0.7%)	31 (1.3%)		
Cytomegalovirus infection	サイトメガロウイルス感染	1 (<0.1%)	0		
Dacryocanaliculitis	涙小管炎	0	1 (<0.1%)		
Dental gangrene	歯組織の壊疽	1 (<0.1%)	0		
Device related infection	医療機器関連感染	2 (<0.1%)	0		
Diarrhoea infectious	感染性下痢	1 (<0.1%)	0		
Diverticulitis	憩室炎	3 (0.1%)	2 (<0.1%)		
Dysentery	赤痢	0	1 (<0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Ear infection	耳感染	9 (0.4%)	4 (0.2%)		
Endocarditis	心内膜炎	1 (<0.1%)	0		
Endocarditis bacterial	細菌性心内膜炎	1 (<0.1%)	0		
Enterocolitis infectious	感染性小腸結腸炎	0	1 (<0.1%)		
Erysipelas	丹毒	4 (0.2%)	8 (0.3%)		
Eye infection	眼感染	2 (<0.1%)	5 (0.2%)		
Folliculitis	毛包炎	8 (0.3%)	2 (<0.1%)	1 (<0.1%)	0
Fungal infection	真菌感染	1 (<0.1%)	1 (<0.1%)		
Fungal oesophagitis	真菌性食道炎	0	1 (<0.1%)		
Fungal skin infection	皮膚真菌感染	4 (0.2%)	3 (0.1%)	1 (<0.1%)	0
Furuncle	せつ	3 (0.1%)	1 (<0.1%)		
Gastroenteritis	胃腸炎	33 (1.4%)	40 (1.7%)	1 (<0.1%)	0
Gastroenteritis norovirus	ノロウイルス性胃腸炎	1 (<0.1%)	2 (<0.1%)		
Gastroenteritis salmonella	サルモネラ菌性胃腸炎	1 (<0.1%)	0		
Gastroenteritis viral	ウイルス性胃腸炎	3 (0.1%)	4 (0.2%)		
Gastrointestinal infection	消化管感染	3 (0.1%)	2 (<0.1%)		
Genital candidiasis	性器カンジダ症	0	1 (<0.1%)		
Genital herpes	陰部ヘルペス	1 (<0.1%)	0		
Genital infection fungal	真菌性性器感染	1 (<0.1%)	2 (<0.1%)		
Genitourinary tract infection	泌尿生殖器感染	1 (<0.1%)	0		
Giardiasis	ジアルジア症	0	2 (<0.1%)		
Gingival abscess	歯肉膿瘍	1 (<0.1%)	0		
Gingival infection	歯肉感染	0	2 (<0.1%)		
Groin abscess	鼠径部膿瘍	0	2 (<0.1%)		
Groin infection	鼠径部感染	0	1 (<0.1%)		
H1N1 influenza	Ｈ１Ｎ１インフルエンザ	0	2 (<0.1%)		
Haematoma infection	血腫感染	1 (<0.1%)	0		
Helicobacter gastritis	ヘリコバクター性胃炎	4 (0.2%)	2 (<0.1%)		
Helicobacter infection	ヘリコバクター感染	3 (0.1%)	3 (0.1%)		
Hepatitis A	Ａ型肝炎	0	1 (<0.1%)		
Hepatitis C	Ｃ型肝炎	1 (<0.1%)	0		
Herpes dermatitis	ヘルペス性皮膚炎	1 (<0.1%)	1 (<0.1%)		
Herpes simplex	単純ヘルペス	2 (<0.1%)	1 (<0.1%)		
Herpes virus infection	ヘルペスウイルス感染	1 (<0.1%)	2 (<0.1%)		
Herpes zoster	帯状疱疹	8 (0.3%)	13 (0.5%)		
Hordeolum	麦粒腫	1 (<0.1%)	3 (0.1%)		
Impetigo	膿痂疹	3 (0.1%)	0		
Infected bites	咬傷感染	1 (<0.1%)	0		
Infected dermal cyst	感染性皮膚嚢腫	1 (<0.1%)	1 (<0.1%)		
Infected skin ulcer	感染性皮膚潰瘍	1 (<0.1%)	2 (<0.1%)		
Infection	感染	3 (0.1%)	4 (0.2%)		
Infectious mononucleosis	伝染性単核症	1 (<0.1%)	0		
Infectious peritonitis	感染性腹膜炎	4 (0.2%)	0		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪	2 (<0.1%)	4 (0.2%)	0	1 (<0.1%)
Infective glossitis	感染性舌炎	1 (<0.1%)	0		
Influenza	インフルエンザ	64 (2.7%)	55 (2.3%)	1 (<0.1%)	0
Injection site infection	注射部位感染	1 (<0.1%)	0		
Intervertebral discitis	椎間板炎	2 (<0.1%)	0		
Intraspinal abscess	脊髄内膿瘍	1 (<0.1%)	0		
Joint abscess	関節膿瘍	1 (<0.1%)	0		
Kidney infection	腎感染	3 (0.1%)	0	1 (<0.1%)	0
Laryngitis	喉頭炎	9 (0.4%)	7 (0.3%)		
Laryngitis viral	ウイルス性喉頭炎	0	1 (<0.1%)		
Listeriosis	リステリア症	1 (<0.1%)	0		
Liver abscess	肝膿瘍	0	1 (<0.1%)		
Lobar pneumonia	大葉性肺炎	4 (0.2%)	2 (<0.1%)		
Localised infection	限局性感染	13 (0.5%)	6 (0.2%)		
Lower respiratory tract infection	下気道感染	21 (0.9%)	33 (1.4%)		
Lung abscess	肺膿瘍	1 (<0.1%)	1 (<0.1%)		
Lung infection	肺感染	22 (0.9%)	19 (0.8%)		
Lyme disease	ライム病	0	1 (<0.1%)		
Mastitis	乳腺炎	1 (<0.1%)	0		
Nasopharyngitis	鼻咽頭炎	188 (7.8%)	196 (8.1%)	5 (0.2%)	1 (<0.1%)
Neutropenic sepsis	好中球減少性敗血症	1 (<0.1%)	0		
Oesophageal candidiasis	食道カンジダ症	4 (0.2%)	1 (<0.1%)		
Onychomycosis	爪真菌症	1 (<0.1%)	1 (<0.1%)		
Oral candidiasis	口腔カンジダ症	7 (0.3%)	9 (0.4%)		
Oral fungal infection	口腔真菌感染	5 (0.2%)	4 (0.2%)		
Oral herpes	口腔ヘルペス	6 (0.2%)	6 (0.2%)		
Oropharyngeal candidiasis	中咽頭カンジダ症	1 (<0.1%)	0		
Oropharyngitis fungal	真菌性口腔咽頭炎	1 (<0.1%)	1 (<0.1%)		
Osteomyelitis	骨髄炎	0	2 (<0.1%)		
Otitis externa	外耳炎	2 (<0.1%)	3 (0.1%)		
Otitis media	中耳炎	4 (0.2%)	5 (0.2%)		
Paronychia	爪囲炎	3 (0.1%)	1 (<0.1%)		
Pericoronitis	歯冠周囲炎	0	1 (<0.1%)		
Pertussis	百日咳	0	1 (<0.1%)		
Pharyngitis	咽頭炎	14 (0.6%)	13 (0.5%)		
Pharyngitis streptococcal	レンサ球菌性咽頭炎	2 (<0.1%)	1 (<0.1%)		
Pilonidal cyst	毛巣嚢胞	1 (<0.1%)	1 (<0.1%)		
Pneumonia	肺炎	40 (1.7%)	49 (2.0%)	0	1 (<0.1%)
Pneumonia bacterial	細菌性肺炎	1 (<0.1%)	0		
Pneumonia mycoplasmal	マイコプラズマ性肺炎	0	1 (<0.1%)		
Pneumonia necrotising	壊死性肺炎	1 (<0.1%)	0		
Pneumonia primary atypical	原発性異型肺炎	0	1 (<0.1%)		
Post procedural infection	処置後感染	2 (<0.1%)	0		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Postoperative wound infection	術後創感染	1 (<0.1%)	3 (0.1%)		
Prostate infection	前立腺感染	0	1 (<0.1%)		
Pseudofolliculitis barbae	偽須毛包炎	0	1 (<0.1%)		
Pseudomembranous colitis	偽膜性大腸炎	1 (<0.1%)	0		
Pulmonary mycosis	肺真菌症	0	2 (<0.1%)		
Pulpitis dental	歯髄炎	0	1 (<0.1%)		
Pyelonephritis	腎盂腎炎	5 (0.2%)	5 (0.2%)		
Pyelonephritis acute	急性腎盂腎炎	0	1 (<0.1%)		
Respiratory tract infection	気道感染	25 (1.0%)	25 (1.0%)		
Respiratory tract infection viral	ウイルス性気道感染	2 (<0.1%)	1 (<0.1%)		
Rhinitis	鼻炎	19 (0.8%)	22 (0.9%)	0	1 (<0.1%)
Rhinolaryngitis	鼻喉頭炎	0	1 (<0.1%)		
Salpingitis	卵管炎	0	1 (<0.1%)		
Salpingo-oophoritis	卵管卵巣炎	1 (<0.1%)	0		
Scrotal abscess	陰嚢膿瘍	0	1 (<0.1%)		
Scrotal infection	陰嚢感染	1 (<0.1%)	0		
Sepsis	敗血症	15 (0.6%)	4 (0.2%)		
Sepsis syndrome	敗血症症候群	1 (<0.1%)	0		
Septic shock	敗血症性ショック	0	1 (<0.1%)		
Sinobronchitis	副鼻腔気管支炎	0	1 (<0.1%)		
Sinusitis	副鼻腔炎	37 (1.5%)	32 (1.3%)	1 (<0.1%)	1 (<0.1%)
Skin bacterial infection	皮膚細菌感染	1 (<0.1%)	2 (<0.1%)		
Skin candida	皮膚カンジダ	0	1 (<0.1%)		
Skin graft infection	植皮感染	1 (<0.1%)	0		
Skin infection	皮膚感染	4 (0.2%)	4 (0.2%)	0	1 (<0.1%)
Soft tissue infection	軟部組織感染	2 (<0.1%)	0		
Staphylococcal infection	ブドウ球菌感染	1 (<0.1%)	2 (<0.1%)		
Stenotrophomonas infection	ステノトロフォモナス感染	0	1 (<0.1%)		
Strongyloidiasis	糞線虫症	0	1 (<0.1%)		
Subcutaneous abscess	皮下組織膿瘍	2 (<0.1%)	0		
Subdiaphragmatic abscess	横隔膜下膿瘍	1 (<0.1%)	0		
Syphilis	梅毒	0	1 (<0.1%)		
Tinea infection	白癬感染	0	1 (<0.1%)		
Tinea manuum	手白癬	0	1 (<0.1%)		
Tinea pedis	足部白癬	3 (0.1%)	2 (<0.1%)		
Tinea versicolour	癜風	1 (<0.1%)	1 (<0.1%)		
Tonsillitis	扁桃炎	3 (0.1%)	9 (0.4%)		
Tooth abscess	歯膿瘍	12 (0.5%)	10 (0.4%)		
Tooth infection	歯感染	11 (0.5%)	8 (0.3%)		
Tracheitis	気管炎	8 (0.3%)	2 (<0.1%)		
Tracheobronchitis	気管気管支炎	2 (<0.1%)	3 (0.1%)		
Tuberculosis	結核	1 (<0.1%)	1 (<0.1%)		
Upper respiratory tract infection	上気道感染	50 (2.1%)	45 (1.9%)	0	1 (<0.1%)
Urethritis	尿道炎	1 (<0.1%)	1 (<0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Urinary tract infection	尿路感染	100 (4.1%)	104 (4.3%)		
Urinary tract infection fungal	真菌性尿路感染	0	1 (<0.1%)		
Urosepsis	尿路性敗血症	2 (<0.1%)	2 (<0.1%)		
Vaginal abscess	膣膿瘍	1 (<0.1%)	0		
Vaginal infection	膣感染	7 (0.3%)	2 (<0.1%)		
Vestibular neuronitis	前庭神経炎	0	2 (<0.1%)		
Viraemia	ウイルス血症	1 (<0.1%)	2 (<0.1%)		
Viral corneal ulcer	ウイルス性角膜潰瘍	1 (<0.1%)	0		
Viral diarrhoea	ウイルス性下痢	1 (<0.1%)	0		
Viral infection	ウイルス感染	9 (0.4%)	2 (<0.1%)		
Viral myocarditis	ウイルス性心筋炎	0	1 (<0.1%)		
Viral rash	ウイルス性発疹	0	1 (<0.1%)		
Viral rhinitis	ウイルス性鼻炎	1 (<0.1%)	0		
Viral tracheitis	ウイルス性気管炎	1 (<0.1%)	0		
Viral upper respiratory tract infection	ウイルス性上気道感染	3 (0.1%)	1 (<0.1%)		
Vulvitis	外陰部炎	1 (<0.1%)	1 (<0.1%)		
Vulvovaginal candidiasis	外陰部膣カンジダ症	1 (<0.1%)	1 (<0.1%)		
Vulvovaginal mycotic infection	外陰膣真菌感染	10 (0.4%)	4 (0.2%)		
Wound infection	創傷感染	9 (0.4%)	3 (0.1%)		
Wound infection bacterial	細菌性創感染	1 (<0.1%)	0	1 (<0.1%)	0
Wound infection staphylococcal	ブドウ球菌性創感染	1 (<0.1%)	0		
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	318 (13.2%)	376 (15.6%)	112 (4.6%)	170 (7.1%)
Accidental overdose	偶発的過量投与	0	1 (<0.1%)		
Alcohol poisoning	アルコール中毒	1 (<0.1%)	1 (<0.1%)		
Anaemia postoperative	術後貧血	0	2 (<0.1%)		
Animal bite	動物咬傷	0	3 (0.1%)		
Ankle fracture	足関節部骨折	3 (0.1%)	1 (<0.1%)	0	1 (<0.1%)
Arthropod bite	節足動物咬傷	6 (0.2%)	2 (<0.1%)		
Arthropod sting	節足動物刺傷	1 (<0.1%)	0		
Back injury	背部損傷	1 (<0.1%)	0		
Bladder injury	膀胱損傷	0	1 (<0.1%)		
Brain contusion	脳挫傷	0	1 (<0.1%)		
Burn oesophageal	食道熱傷	1 (<0.1%)	0		
Cardiac valve replacement complication	心臓弁置換合併症	0	1 (<0.1%)		
Cartilage injury	軟骨損傷	1 (<0.1%)	0		
Cerebral haemorrhage traumatic	外傷性脳出血	1 (<0.1%)	0	1 (<0.1%)	0
Cervical vertebral fracture	頚椎骨折	0	2 (<0.1%)		
Chest injury	胸部損傷	1 (<0.1%)	1 (<0.1%)		
Complications of transplant surgery	移植手術における合併症	0	1 (<0.1%)		
Compression fracture	圧迫骨折	1 (<0.1%)	0		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Concussion	脳振盪	1 (<0.1%)	3 (0.1%)		
Contusion	挫傷	96 (4.0%)	133 (5.5%)	55 (2.3%)	88 (3.7%)
Corneal abrasion	角膜擦過傷	1 (<0.1%)	0		
Craniocerebral injury	頭蓋脳損傷	0	1 (<0.1%)		
Epicondylitis	上顆炎	2 (<0.1%)	2 (<0.1%)		
Eschar	焼痂	0	1 (<0.1%)		
Excoriation	擦過傷	4 (0.2%)	3 (0.1%)		
Exposure during breast feeding	母乳保育時の曝露	1 (<0.1%)	0	1 (<0.1%)	0
Facial bones fracture	顔面骨骨折	2 (<0.1%)	2 (<0.1%)		
Fall	転倒	20 (0.8%)	21 (0.9%)		
Femoral neck fracture	大腿骨頚部骨折	1 (<0.1%)	0		
Femur fracture	大腿骨骨折	1 (<0.1%)	0		
Fibula fracture	腓骨骨折	1 (<0.1%)	1 (<0.1%)		
Foot fracture	足骨折	3 (0.1%)	4 (0.2%)		
Foreign body in eye	眼内異物	0	1 (<0.1%)		
Fracture	骨折	1 (<0.1%)	0		
Graft haemorrhage	移植部位出血	1 (<0.1%)	0	1 (<0.1%)	0
Haematuria traumatic	外傷性血尿	1 (<0.1%)	0	1 (<0.1%)	0
Hand fracture	手骨折	2 (<0.1%)	1 (<0.1%)		
Head injury	頭部損傷	5 (0.2%)	2 (<0.1%)	1 (<0.1%)	0
Hip fracture	股関節部骨折	1 (<0.1%)	0		
Humerus fracture	上腕骨骨折	1 (<0.1%)	3 (0.1%)		
Incision site haemorrhage	切開部位出血	1 (<0.1%)	5 (0.2%)	1 (<0.1%)	3 (0.1%)
Inflammation of wound	創部炎症	0	1 (<0.1%)		
Injury	損傷	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Joint dislocation	関節脱臼	4 (0.2%)	1 (<0.1%)		
Joint injury	関節損傷	7 (0.3%)	9 (0.4%)		
Kidney rupture	腎臓破裂	0	1 (<0.1%)	0	1 (<0.1%)
Laceration	裂傷	8 (0.3%)	8 (0.3%)	1 (<0.1%)	0
Ligament injury	靭帯損傷	1 (<0.1%)	0		
Ligament rupture	靭帯断裂	4 (0.2%)	1 (<0.1%)		
Ligament sprain	靭帯捻挫	13 (0.5%)	11 (0.5%)		
Limb crushing injury	四肢圧挫損傷	1 (<0.1%)	0		
Limb injury	四肢損傷	6 (0.2%)	10 (0.4%)		
Lip injury	口唇損傷	1 (<0.1%)	0		
Lower limb fracture	下肢骨折	1 (<0.1%)	0		
Lumbar vertebral fracture	腰椎骨折	1 (<0.1%)	0		
Maternal exposure during pregnancy	妊娠時の母体の曝露	0	1 (<0.1%)		
Meniscus lesion	半月板障害	2 (<0.1%)	3 (0.1%)		
Multiple injuries	多発性外傷	0	1 (<0.1%)		
Muscle rupture	筋断裂	1 (<0.1%)	1 (<0.1%)		
Muscle strain	肉離れ	5 (0.2%)	10 (0.4%)		
Operative haemorrhage	術中出血	4 (0.2%)	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Overdose	過量投与	7 (0.3%)	13 (0.5%)	0	13 (0.5%)
Pelvic fracture	骨盤骨折	0	1 (<0.1%)		
Periorbital haematoma	眼窩周囲血腫	2 (<0.1%)	3 (0.1%)	1 (<0.1%)	2 (<0.1%)
Perirenal haematoma	腎周囲血腫	0	1 (<0.1%)	0	1 (<0.1%)
Post gastric surgery syndrome	胃手術後症候群	1 (<0.1%)	0		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Post procedural haematoma	処置後血腫	2 (<0.1%)	3 (0.1%)	0	2 (<0.1%)
Post procedural haemorrhage	処置後出血	12 (0.5%)	12 (0.5%)	7 (0.3%)	6 (0.2%)
Post-traumatic neck syndrome	外傷後頚部症候群	0	1 (<0.1%)		
Post-traumatic pain	外傷後疼痛	1 (<0.1%)	2 (<0.1%)		
Postoperative ileus	術後イレウス	1 (<0.1%)	0		
Procedural complication	処置合併症	0	1 (<0.1%)		
Procedural hypertension	処置による高血圧	1 (<0.1%)	1 (<0.1%)		
Procedural nausea	処置による悪心	0	1 (<0.1%)		
Procedural pain	処置による疼痛	5 (0.2%)	9 (0.4%)		
Radiation skin injury	放射線皮膚損傷	1 (<0.1%)	0		
Radius fracture	橈骨骨折	2 (<0.1%)	1 (<0.1%)		
Repetitive strain injury	反復性挫傷	0	1 (<0.1%)		
Rib fracture	肋骨骨折	8 (0.3%)	6 (0.2%)		
Road traffic accident	交通事故	2 (<0.1%)	2 (<0.1%)		
Scratch	引っかき傷	1 (<0.1%)	2 (<0.1%)	0	1 (<0.1%)
Scrotal haematoma	陰嚢血腫	0	1 (<0.1%)		
Skeletal injury	骨格損傷	5 (0.2%)	3 (0.1%)	1 (<0.1%)	0
Skin injury	皮膚損傷	1 (<0.1%)	0		
Soft tissue injury	軟部組織損傷	2 (<0.1%)	3 (0.1%)		
Spinal compression fracture	脊椎圧迫骨折	2 (<0.1%)	2 (<0.1%)		
Spinal fracture	脊椎骨折	0	1 (<0.1%)		
Splenic haematoma	脾血腫	0	1 (<0.1%)	0	1 (<0.1%)
Sternal fracture	胸骨骨折	0	1 (<0.1%)		
Stress fracture	ストレス骨折	1 (<0.1%)	0		
Subcutaneous haematoma	皮下血腫	34 (1.4%)	44 (1.8%)	21 (0.9%)	33 (1.4%)
Subdural haematoma	硬膜下血腫	1 (<0.1%)	3 (0.1%)	1 (<0.1%)	2 (<0.1%)
Subdural haemorrhage	硬膜下出血	0	3 (0.1%)	0	1 (<0.1%)
Sunburn	サンバーン	2 (<0.1%)	0		
Tendon injury	腱損傷	2 (<0.1%)	1 (<0.1%)		
Tendon rupture	腱断裂	3 (0.1%)	1 (<0.1%)		
Thermal burn	熱傷	1 (<0.1%)	1 (<0.1%)		
Thoracic vertebral fracture	胸椎骨折	0	2 (<0.1%)		
Tibia fracture	脛骨骨折	1 (<0.1%)	0		
Tobacco poisoning	タバコ中毒	0	1 (<0.1%)		
Tooth avulsion	歯の完全脱臼	1 (<0.1%)	0		
Tooth fracture	歯牙破折	1 (<0.1%)	4 (0.2%)	0	1 (<0.1%)
Tooth injury	歯牙損傷	3 (0.1%)	0		
Toxicity to various agents	各種物質毒性	1 (<0.1%)	1 (<0.1%)		
Transfusion-related immunomodulation reaction	輸血に伴う免疫修飾反応	0	1 (<0.1%)		
Traumatic fracture	外傷性骨折	2 (<0.1%)	0		
Traumatic haematoma	外傷性血腫	7 (0.3%)	12 (0.5%)	4 (0.2%)	8 (0.3%)
Traumatic haemorrhage	外傷性出血	10 (0.4%)	8 (0.3%)	7 (0.3%)	1 (<0.1%)
Ulna fracture	尺骨骨折	0	1 (<0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Upper limb fracture	上肢骨折	1 (<0.1%)	5 (0.2%)		
Vascular graft complication	移植血管合併症	0	1 (<0.1%)		
Vascular pseudoaneurysm	血管偽動脈瘤	0	2 (<0.1%)	0	1 (<0.1%)
Venous injury	静脈損傷	0	1 (<0.1%)		
Wound	創傷	7 (0.3%)	4 (0.2%)		
Wound complication	創合併症	1 (<0.1%)	1 (<0.1%)		
Wound dehiscence	創し開	0	1 (<0.1%)		
Wound haematoma	創傷血腫	0	1 (<0.1%)	0	1 (<0.1%)
Wound haemorrhage	創傷出血	41 (1.7%)	48 (2.0%)	16 (0.7%)	18 (0.7%)
Wound secretion	創部分泌	0	1 (<0.1%)		
Wrist fracture	手首関節骨折	0	2 (<0.1%)		
Investigations	臨床検査	248 (10.3%)	334 (13.9%)	78 (3.2%)	164 (6.8%)
Activated partial thromboplastin time prolonged	活性化部分トロンボプラスチン時間延長	3 (0.1%)	0	3 (0.1%)	0
Activated partial thromboplastin time shortened	活性化部分トロンボプラスチン時間短縮	0	1 (<0.1%)	0	1 (<0.1%)
Alanine aminotransferase abnormal	アラニン・アミノトランスフェラーゼ異常	1 (<0.1%)	0		
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	56 (2.3%)	78 (3.2%)	27 (1.1%)	33 (1.4%)
Angiotensin converting enzyme increased	アンギオテンシン変換酵素増加	1 (<0.1%)	0		
Anti-thyroid antibody positive	抗甲状腺抗体陽性	0	1 (<0.1%)		
Anticonvulsant drug level decreased	抗痙攣剤濃度減少	0	1 (<0.1%)		
Antinuclear antibody positive	抗核抗体陽性	1 (<0.1%)	0		
Antiphospholipid antibodies positive	抗リン脂質抗体陽性	8 (0.3%)	1 (<0.1%)	1 (<0.1%)	0
Arthroscopy	関節鏡検査	1 (<0.1%)	0		
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	24 (1.0%)	26 (1.1%)	12 (0.5%)	11 (0.5%)
Aspergillus test positive	アスペルギルス検査陽性	1 (<0.1%)	0		
Bacterial test positive	細菌検査陽性	2 (<0.1%)	0		
Bilirubin conjugated increased	抱合ビリルビン増加	6 (0.2%)	1 (<0.1%)	4 (0.2%)	0
Biopsy liver	肝生検	0	1 (<0.1%)		
Biopsy lung	肺生検	0	1 (<0.1%)		
Biopsy prostate	前立腺生検	1 (<0.1%)	0		
Blood alkaline phosphatase decreased	血中アルカリホスファターゼ減少	1 (<0.1%)	0		
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	10 (0.4%)	12 (0.5%)	4 (0.2%)	4 (0.2%)

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Blood amylase increased	血中アミラーゼ増加	8 (0.3%)	5 (0.2%)	2 (<0.1%)	1 (<0.1%)
Blood bilirubin increased	血中ビリルビン増加	11 (0.5%)	4 (0.2%)	6 (0.2%)	0
Blood cholesterol increased	血中コレステロール増加	3 (0.1%)	4 (0.2%)		
Blood chromogranin A increased	血中クロモグラニンA増加	1 (<0.1%)	0		
Blood creatinine increased	血中クレアチニン増加	1 (<0.1%)	7 (0.3%)	0	1 (<0.1%)
Blood follicle stimulating hormone increased	血中卵胞刺激ホルモン増加	0	1 (<0.1%)		
Blood gastrin increased	血中ガストリン増加	1 (<0.1%)	0		
Blood glucose decreased	血中ブドウ糖減少	0	1 (<0.1%)		
Blood glucose increased	血中ブドウ糖増加	9 (0.4%)	1 (<0.1%)		
Blood homocysteine increased	血中ホモシステイン増加	1 (<0.1%)	3 (0.1%)		
Blood immunoglobulin M increased	血中免疫グロブリンM増加	0	1 (<0.1%)		
Blood iron decreased	血中鉄減少	4 (0.2%)	1 (<0.1%)		
Blood iron increased	血中鉄増加	1 (<0.1%)	0		
Blood magnesium decreased	血中マグネシウム減少	1 (<0.1%)	1 (<0.1%)		
Blood phosphorus decreased	血中リン減少	0	1 (<0.1%)		
Blood potassium decreased	血中カリウム減少	5 (0.2%)	4 (0.2%)	0	1 (<0.1%)
Blood potassium increased	血中カリウム増加	1 (<0.1%)	0		
Blood pressure decreased	血圧低下	1 (<0.1%)	0		
Blood pressure increased	血圧上昇	6 (0.2%)	2 (<0.1%)	1 (<0.1%)	0
Blood pressure systolic increased	収縮期血圧上昇	0	1 (<0.1%)		
Blood sodium decreased	血中ナトリウム減少	0	1 (<0.1%)		
Blood thyroid stimulating hormone increased	血中甲状腺刺激ホルモン増加	0	2 (<0.1%)		
Blood triglycerides increased	血中トリグリセリド増加	0	1 (<0.1%)		
Blood urea increased	血中尿素増加	0	2 (<0.1%)	0	1 (<0.1%)
Blood urine present	尿中血陽性	2 (<0.1%)	3 (0.1%)		
Body temperature increased	体温上昇	2 (<0.1%)	0		
Brain scan abnormal	脳スキャン異常	0	1 (<0.1%)		
Breath sounds abnormal	呼吸音異常	0	1 (<0.1%)		
Brucella test positive	ブルセラ検査陽性	1 (<0.1%)	0		
C-reactive protein increased	Ｃ－反応性蛋白増加	3 (0.1%)	3 (0.1%)	1 (<0.1%)	0

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
C-telopeptide increased	Ｃ－テロペプチド増加	1 (<0.1%)	0		
Carbohydrate antigen 125 increased	糖鎖抗原１２５増加	1 (<0.1%)	1 (<0.1%)		
Carbohydrate antigen 19-9 increased	糖鎖抗原１９－９増加	2 (<0.1%)	0		
Carbon dioxide increased	二酸化炭素増加	1 (<0.1%)	0		
Cardiac murmur	心雑音	0	1 (<0.1%)		
Cardiolipin antibody positive	カルジオリピン抗体陽性	2 (<0.1%)	0		
Coagulation factor V level decreased	凝固第Ｖ因子量減少	1 (<0.1%)	0	1 (<0.1%)	0
Coagulation factor VIII level increased	凝固第ＶＩＩＩ因子量増加	0	1 (<0.1%)		
Coagulation factor X level decreased	凝固第Ｘ因子量減少	1 (<0.1%)	0	1 (<0.1%)	0
Coagulation time prolonged	凝固時間延長	0	4 (0.2%)	0	4 (0.2%)
Coagulation time shortened	凝固時間短縮	0	1 (<0.1%)		
Colonoscopy	結腸内視鏡検査	0	2 (<0.1%)		
Creatinine renal clearance decreased	腎クレアチニン・クリアランス減少	1 (<0.1%)	0		
Cytomegalovirus test positive	サイトメガロウイルス検査陽性	2 (<0.1%)	1 (<0.1%)		
Ejection fraction decreased	駆出率減少	0	2 (<0.1%)		
Electrocardiogram	心電図	1 (<0.1%)	0		
Electrocardiogram ST-T segment abnormal	心電図ＳＴ－Ｔ部分異常	1 (<0.1%)	0		
Electrocardiogram T wave amplitude decreased	心電図Ｔ波振幅減少	1 (<0.1%)	0		
Electrophoresis protein abnormal	蛋白電気泳動異常	1 (<0.1%)	0		
Endoscopy upper gastrointestinal tract	上部消化管内視鏡検査	1 (<0.1%)	0		
Epidermal growth factor receptor decreased	上皮増殖因子受容体減少	0	1 (<0.1%)		
Epidermal growth factor receptor increased	上皮増殖因子受容体増加	0	1 (<0.1%)	0	1 (<0.1%)
Epstein-Barr virus test positive	エプスタイン・バーウイルス検査陽性	1 (<0.1%)	0		
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	5 (0.2%)	5 (0.2%)	1 (<0.1%)	0
Gastric pH decreased	胃内ｐＨ低下	0	1 (<0.1%)		
Grip strength decreased	握力低下	1 (<0.1%)	0		
HIV test positive	ＨＩＶ検査陽性	1 (<0.1%)	1 (<0.1%)		
Haemoglobin decreased	ヘモグロビン減少	8 (0.3%)	5 (0.2%)	1 (<0.1%)	1 (<0.1%)

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Haemoglobin increased	ヘモグロビン増加	1 (<0.1%)	1 (<0.1%)		
Heart rate increased	心拍数増加	0	1 (<0.1%)		
Heart rate irregular	心拍数不整	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Hepatic enzyme increased	肝酵素上昇	12 (0.5%)	8 (0.3%)	7 (0.3%)	7 (0.3%)
Hepatitis A virus test positive	A型肝炎ウイルス検査陽性	1 (<0.1%)	0		
Herpes simplex serology positive	単純ヘルペス血清学的検査陽性	0	1 (<0.1%)		
International normalised ratio abnormal	ＩＮＲ異常	0	2 (<0.1%)	0	2 (<0.1%)
International normalised ratio decreased	ＩＮＲ減少	0	23 (1.0%)	0	16 (0.7%)
International normalised ratio fluctuation	ＩＮＲ変動	0	1 (<0.1%)	0	1 (<0.1%)
International normalised ratio increased	ＩＮＲ増加	9 (0.4%)	85 (3.5%)	4 (0.2%)	79 (3.3%)
Lipids abnormal	脂質異常	0	1 (<0.1%)		
Lipids increased	脂質増加	0	2 (<0.1%)		
Liver function test abnormal	肝機能検査異常	25 (1.0%)	39 (1.6%)	13 (0.5%)	17 (0.7%)
Low density lipoprotein increased	低比重リポ蛋白増加	0	1 (<0.1%)		
Lumbar puncture	腰椎穿刺	0	1 (<0.1%)		
Medical observation	医学的観察	1 (<0.1%)	0		
Moraxella test positive	モラクセラ検査陽性	1 (<0.1%)	0		
Neutrophil count decreased	好中球数減少	0	1 (<0.1%)		
Occult blood positive	便潜血陽性	11 (0.5%)	5 (0.2%)	6 (0.2%)	1 (<0.1%)
Platelet count decreased	血小板数減少	3 (0.1%)	1 (<0.1%)		
Platelet count increased	血小板数増加	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Prostatic specific antigen increased	前立腺特異性抗原増加	7 (0.3%)	4 (0.2%)		
Proteus test positive	プロテウス検査陽性	1 (<0.1%)	0		
Prothrombin level decreased	プロトロンビン量減少	2 (<0.1%)	0	1 (<0.1%)	0
Prothrombin time prolonged	プロトロンビン時間延長	0	1 (<0.1%)	0	1 (<0.1%)
Prothrombin time ratio decreased	プロトロンビン時間比減少	1 (<0.1%)	0	1 (<0.1%)	0
Prothrombin time shortened	プロトロンビン時間短縮	1 (<0.1%)	0	1 (<0.1%)	0
Pulmonary arterial pressure increased	肺動脈圧上昇	1 (<0.1%)	0		
Serum ferritin decreased	血清フェリチン減少	4 (0.2%)	3 (0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Thyroid gland scan abnormal	甲状腺スキャン異常	0	1 (<0.1%)		
Thyroxine free increased	遊離サイロキシン増加	0	1 (<0.1%)		
Transaminases increased	トランスアミナーゼ上昇	6 (0.2%)	10 (0.4%)	3 (0.1%)	5 (0.2%)
Transferrin saturation decreased	トランスフェリン飽和度低下	2 (<0.1%)	1 (<0.1%)		
Troponin increased	トロポニン増加	0	2 (<0.1%)		
Ultrasound kidney abnormal	腎超音波検査異常	2 (<0.1%)	0		
Ultrasound liver abnormal	肝超音波検査異常	1 (<0.1%)	0	1 (<0.1%)	0
Urinary sediment present	尿沈渣陽性	0	1 (<0.1%)		
Urine analysis abnormal	尿検査異常	0	1 (<0.1%)		
Urine output decreased	尿量減少	1 (<0.1%)	0		
Vitamin D decreased	ビタミンD減少	0	2 (<0.1%)		
Walking distance test abnormal	歩行距離テスト異常	1 (<0.1%)	0		
Weight decreased	体重減少	6 (0.2%)	14 (0.6%)		
Weight increased	体重増加	16 (0.7%)	7 (0.3%)	2 (<0.1%)	1 (<0.1%)
White blood cell count decreased	白血球数減少	1 (<0.1%)	0		
White blood cell count increased	白血球数増加	1 (<0.1%)	1 (<0.1%)		
White blood cells urine positive	尿中白血球陽性	1 (<0.1%)	0		
Metabolism and nutrition disorders	代謝および栄養障害	217 (9.0%)	233 (9.7%)	8 (0.3%)	8 (0.3%)
Acidosis	アシドーシス	2 (<0.1%)	0		
Appetite disorder	食欲障害	0	1 (<0.1%)		
Cachexia	悪液質	1 (<0.1%)	0		
Calcium deficiency	カルシウム欠乏	1 (<0.1%)	0		
Combined hyperlipidaemia	複合型高脂血症	0	1 (<0.1%)		
Decreased appetite	食欲減退	17 (0.7%)	20 (0.8%)	2 (<0.1%)	2 (<0.1%)
Dehydration	脱水	9 (0.4%)	9 (0.4%)		
Diabetes mellitus	糖尿病	19 (0.8%)	11 (0.5%)		
Diabetes mellitus inadequate control	コントロール不良の糖尿病	3 (0.1%)	0		
Dyslipidaemia	脂質異常症	5 (0.2%)	9 (0.4%)		
Failure to thrive	成長障害	0	1 (<0.1%)		
Fluid overload	水分過負荷	1 (<0.1%)	1 (<0.1%)		
Fluid retention	体液貯留	3 (0.1%)	2 (<0.1%)		
Folate deficiency	葉酸欠乏	3 (0.1%)	2 (<0.1%)		
Food craving	食物渇望	0	1 (<0.1%)		
Food intolerance	食物不耐性	0	1 (<0.1%)		
Glucose tolerance impaired	耐糖能障害	1 (<0.1%)	1 (<0.1%)		
Gout	痛風	17 (0.7%)	23 (1.0%)	2 (<0.1%)	2 (<0.1%)
Hyperamylasaemia	高アミラーゼ血症	1 (<0.1%)	0		
Hypercalcaemia	高カルシウム血症	2 (<0.1%)	1 (<0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Hypercholesterolaemia	高コレステロール血症	23 (1.0%)	31 (1.3%)		
Hyperglycaemia	高血糖	9 (0.4%)	9 (0.4%)		
Hyperhomocysteinaemia	高ホモシステイン血症	9 (0.4%)	7 (0.3%)		
Hyperkalaemia	高カリウム血症	2 (<0.1%)	9 (0.4%)		
Hyperlipidaemia	高脂血症	12 (0.5%)	14 (0.6%)	0	1 (<0.1%)
Hypertriglyceridaemia	高トリグリセリド血症	4 (0.2%)	3 (0.1%)		
Hyperuricaemia	高尿酸血症	6 (0.2%)	6 (0.2%)		
Hypoalbuminaemia	低アルブミン血症	0	4 (0.2%)		
Hypocalcaemia	低カルシウム血症	2 (<0.1%)	5 (0.2%)		
Hypochloraemia	低クロール血症	0	1 (<0.1%)		
Hypoglycaemia	低血糖症	5 (0.2%)	1 (<0.1%)		
Hypokalaemia	低カリウム血症	42 (1.7%)	48 (2.0%)	0	1 (<0.1%)
Hypomagnesaemia	低マグネシウム血症	3 (0.1%)	2 (<0.1%)		
Hyponatraemia	低ナトリウム血症	4 (0.2%)	6 (0.2%)		
Hypophosphataemia	低リン酸血症	0	6 (0.2%)		
Hypoproteinaemia	低蛋白血症	2 (<0.1%)	0		
Hypovolaemia	血液量減少症	1 (<0.1%)	2 (<0.1%)	0	1 (<0.1%)
Increased appetite	食欲亢進	0	1 (<0.1%)		
Iron deficiency	鉄欠乏	12 (0.5%)	5 (0.2%)	2 (<0.1%)	1 (<0.1%)
Ketoacidosis	ケトアシドーシス	0	1 (<0.1%)		
Lactic acidosis	乳酸アシドーシス	0	1 (<0.1%)		
Latent tetany	潜伏テタニー	1 (<0.1%)	0		
Lipid metabolism disorder	脂質代謝障害	0	1 (<0.1%)		
Magnesium deficiency	マグネシウム欠乏	1 (<0.1%)	0		
Malnutrition	栄養障害	0	2 (<0.1%)		
Metabolic acidosis	代謝性アシドーシス	0	1 (<0.1%)		
Metabolic disorder	代謝障害	0	1 (<0.1%)		
Methylenetetrahydrofolate reductase polymorphism	メチレンテトラヒドロ葉酸還元酵素多型	11 (0.5%)	9 (0.4%)		
Obesity	肥満	0	2 (<0.1%)		
Plasminogen activator inhibitor polymorphism	プラスミノーゲン活性化因子インヒビター多型	4 (0.2%)	3 (0.1%)		
Polydipsia	多飲症	1 (<0.1%)	2 (<0.1%)		
Shock hypoglycaemic	低血糖ショック	1 (<0.1%)	0		
Type 2 diabetes mellitus	２型糖尿病	12 (0.5%)	4 (0.2%)		
Vitamin B12 deficiency	ビタミンＢ１２欠乏	5 (0.2%)	5 (0.2%)		
Vitamin D deficiency	ビタミンＤ欠乏	6 (0.2%)	7 (0.3%)	1 (<0.1%)	0
Weight loss poor	体重減少不良	1 (<0.1%)	0	1 (<0.1%)	0
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	559 (23.2%)	572 (23.8%)	34 (1.4%)	31 (1.3%)
Ankylosing spondylitis	強直性脊椎炎	0	1 (<0.1%)		
Arthralgia	関節痛	89 (3.7%)	82 (3.4%)	7 (0.3%)	2 (<0.1%)
Arthritis	関節炎	10 (0.4%)	10 (0.4%)	1 (<0.1%)	0
Articular calcification	関節石灰化	1 (<0.1%)	0		
Back pain	背部痛	92 (3.8%)	139 (5.8%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Bone cyst	骨嚢腫	0	1 (<0.1%)		
Bone pain	骨痛	9 (0.4%)	7 (0.3%)		
Bunion	バニオン	1 (<0.1%)	0		
Bursa disorder	滑液包障害	0	1 (<0.1%)		
Bursitis	滑液包炎	4 (0.2%)	5 (0.2%)		
Cervical spinal stenosis	頚部脊柱管狭窄症	1 (<0.1%)	1 (<0.1%)		
Coccydynia	尾骨痛	0	1 (<0.1%)		
Costochondritis	肋軟骨炎	2 (<0.1%)	3 (0.1%)		
Exostosis	外骨腫	2 (<0.1%)	1 (<0.1%)		
Flank pain	側腹部痛	6 (0.2%)	14 (0.6%)	0	1 (<0.1%)
Foot deformity	足変形	2 (<0.1%)	0		
Gouty arthritis	痛風性関節炎	2 (<0.1%)	1 (<0.1%)		
Groin pain	鼠径部痛	6 (0.2%)	6 (0.2%)		
Haemarthrosis	出血性関節症	5 (0.2%)	3 (0.1%)	4 (0.2%)	3 (0.1%)
Intervertebral disc compression	椎間板圧迫	0	1 (<0.1%)		
Intervertebral disc degeneration	椎間板変性症	1 (<0.1%)	1 (<0.1%)		
Intervertebral disc disorder	椎間板障害	1 (<0.1%)	2 (<0.1%)		
Intervertebral disc protrusion	椎間板突出	5 (0.2%)	4 (0.2%)		
Jaw cyst	顎骨嚢胞	0	1 (<0.1%)		
Joint contracture	関節拘縮	1 (<0.1%)	0		
Joint effusion	関節滲出液	8 (0.3%)	2 (<0.1%)		
Joint stiffness	関節硬直	3 (0.1%)	3 (0.1%)		
Joint swelling	関節腫脹	16 (0.7%)	14 (0.6%)		
Kyphosis	脊柱後弯症	1 (<0.1%)	0		
Ligament calcification	靭帯石灰化	0	1 (<0.1%)		
Limb discomfort	四肢不快感	4 (0.2%)	5 (0.2%)		
Lordosis	脊柱前弯症	1 (<0.1%)	0		
Lower extremity mass	下肢腫瘤	2 (<0.1%)	4 (0.2%)		
Mobility decreased	運動性低下	1 (<0.1%)	1 (<0.1%)		
Monarthritis	単関節炎	0	2 (<0.1%)		
Muscle contracture	筋拘縮	3 (0.1%)	1 (<0.1%)		
Muscle fatigue	筋肉疲労	3 (0.1%)	1 (<0.1%)		
Muscle haemorrhage	筋肉内出血	3 (0.1%)	11 (0.5%)	1 (<0.1%)	11 (0.5%)
Muscle rigidity	筋固縮	1 (<0.1%)	0		
Muscle spasms	筋痙縮	50 (2.1%)	57 (2.4%)	5 (0.2%)	6 (0.2%)
Muscle tightness	筋緊張	2 (<0.1%)	2 (<0.1%)		
Muscle twitching	筋攣縮	2 (<0.1%)	2 (<0.1%)	1 (<0.1%)	0
Muscular weakness	筋力低下	10 (0.4%)	7 (0.3%)		
Musculoskeletal chest pain	筋骨格系胸痛	31 (1.3%)	25 (1.0%)	0	1 (<0.1%)
Musculoskeletal discomfort	筋骨格不快感	1 (<0.1%)	4 (0.2%)		
Musculoskeletal pain	筋骨格痛	41 (1.7%)	40 (1.7%)	2 (<0.1%)	0
Musculoskeletal stiffness	筋骨格硬直	6 (0.2%)	2 (<0.1%)		
Myalgia	筋肉痛	38 (1.6%)	34 (1.4%)	5 (0.2%)	2 (<0.1%)
Myalgia intercostal	肋間筋肉痛	0	1 (<0.1%)		

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Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Myofascial pain syndrome	筋膜疼痛症候群	0	1 (<0.1%)		
Neck mass	頚部腫瘤	1 (<0.1%)	0		
Neck pain	頚部痛	16 (0.7%)	23 (1.0%)		
Osteitis	骨炎	1 (<0.1%)	1 (<0.1%)		
Osteitis deformans	変形性骨炎	1 (<0.1%)	0		
Osteoarthritis	変形性関節症	28 (1.2%)	20 (0.8%)	1 (<0.1%)	0
Osteochondritis	骨軟骨炎	1 (<0.1%)	0		
Osteolysis	骨溶解	2 (<0.1%)	0		
Osteonecrosis	骨壊死	2 (<0.1%)	1 (<0.1%)		
Osteopenia	骨減少症	1 (<0.1%)	0		
Osteoporosis	骨粗鬆症	5 (0.2%)	4 (0.2%)		
Osteorrhagia	骨出血	0	1 (<0.1%)	0	1 (<0.1%)
Pain in extremity	四肢痛	176 (7.3%)	163 (6.8%)	12 (0.5%)	5 (0.2%)
Pain in jaw	顎痛	1 (<0.1%)	2 (<0.1%)		
Pathological fracture	病的骨折	1 (<0.1%)	0		
Periarthritis	関節周囲炎	4 (0.2%)	3 (0.1%)		
Plantar fasciitis	足底筋膜炎	1 (<0.1%)	0		
Polyarthritis	多発性関節炎	2 (<0.1%)	1 (<0.1%)		
Polymyalgia rheumatica	リウマチ性多発筋痛	1 (<0.1%)	0		
Pseudarthrosis	偽関節	0	1 (<0.1%)		
Pubic pain	恥骨痛	1 (<0.1%)	0		
Rhabdomyolysis	横紋筋融解症	1 (<0.1%)	1 (<0.1%)		
Rheumatoid arthritis	関節リウマチ	2 (<0.1%)	4 (0.2%)		
Rickets	くる病	0	1 (<0.1%)		
Rotator cuff syndrome	肩回旋筋腱板症候群	5 (0.2%)	3 (0.1%)		
Sacroiliitis	仙腸骨炎	1 (<0.1%)	0		
Scleroderma	強皮症	0	1 (<0.1%)		
Scoliosis	側弯症	2 (<0.1%)	1 (<0.1%)		
Sensation of heaviness	重感	3 (0.1%)	7 (0.3%)		
Soft tissue haemorrhage	軟部組織出血	0	1 (<0.1%)	0	1 (<0.1%)
Soft tissue mass	軟部組織腫瘤	1 (<0.1%)	0		
Spinal column stenosis	脊柱管狭窄症	0	2 (<0.1%)		
Spinal disorder	脊椎障害	2 (<0.1%)	0		
Spinal osteoarthritis	変形性脊椎症	10 (0.4%)	9 (0.4%)		
Spondylitis	脊椎炎	0	2 (<0.1%)		
Sympathetic posterior cervical syndrome	交感神経性後頚部症候群	1 (<0.1%)	0		
Synovial cyst	滑液嚢腫	3 (0.1%)	7 (0.3%)		
Synovial disorder	滑膜障害	1 (<0.1%)	0		
Systemic lupus erythematosus	全身性エリテマトーデス	1 (<0.1%)	3 (0.1%)		
Temporomandibular joint syndrome	顎関節症候群	0	2 (<0.1%)		
Tendon disorder	腱障害	3 (0.1%)	2 (<0.1%)		
Tendon pain	腱痛	0	2 (<0.1%)		
Tendonitis	腱炎	14 (0.6%)	5 (0.2%)		
Tenosynovitis	腱鞘炎	2 (<0.1%)	2 (<0.1%)		
Torticollis	斜頚	2 (<0.1%)	0		
Vertebral column mass	脊柱腫瘤	1 (<0.1%)	0		
Vertebral foraminal stenosis	椎間孔狭窄	1 (<0.1%)	0		

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		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	123 (5.1%)	115 (4.8%)	0	2 (<0.1%)
Acute lymphocytic leukaemia	急性リンパ性白血病	0	1 (<0.1%)		
Acute promyelocytic leukaemia	急性前骨髄球性白血病	1 (<0.1%)	0		
Adenocarcinoma	腺癌	1 (<0.1%)	0		
Adrenal adenoma	副腎腺腫	2 (<0.1%)	1 (<0.1%)		
Adrenal neoplasm	副腎新生物	0	1 (<0.1%)		
Angiolipoma	血管脂肪腫	1 (<0.1%)	0		
Angiomyolipoma	血管筋脂肪腫	0	1 (<0.1%)		
Anogenital warts	肛門性器疣贅	0	1 (<0.1%)		
B-cell lymphoma	Ｂ細胞性リンパ腫	1 (<0.1%)	1 (<0.1%)		
Basal cell carcinoma	基底細胞癌	7 (0.3%)	7 (0.3%)		
Benign bone neoplasm	骨の良性新生物	1 (<0.1%)	0		
Benign breast neoplasm	乳房の良性新生物	1 (<0.1%)	1 (<0.1%)		
Benign hepatic neoplasm	肝の良性新生物	2 (<0.1%)	0		
Benign neoplasm	良性新生物	0	1 (<0.1%)		
Benign oesophageal neoplasm	食道の良性新生物	1 (<0.1%)	0		
Benign ovarian tumour	卵巣良性腫瘍	1 (<0.1%)	0		
Benign renal neoplasm	腎臓の良性新生物	1 (<0.1%)	1 (<0.1%)		
Bile duct cancer non-resectable	切除不能な胆管癌	0	1 (<0.1%)		
Bladder cancer	膀胱癌	1 (<0.1%)	2 (<0.1%)		
Bladder neoplasm	膀胱新生物	0	2 (<0.1%)		
Bowen's disease	ボーエン病	1 (<0.1%)	0		
Brain neoplasm	脳新生物	2 (<0.1%)	0		
Breast cancer	乳癌	2 (<0.1%)	1 (<0.1%)		
Breast cancer metastatic	転移性乳癌	1 (<0.1%)	0		
Breast cancer recurrent	再発乳癌	1 (<0.1%)	1 (<0.1%)		
Breast neoplasm	乳房新生物	1 (<0.1%)	0		
Bronchial carcinoma	気管支癌	0	1 (<0.1%)		
Cerebellar tumour	小脳腫瘍	1 (<0.1%)	0		
Cervix carcinoma	子宮頚部癌	0	1 (<0.1%)		
Chronic myeloid leukaemia	慢性骨髄性白血病	0	1 (<0.1%)		
Colon adenoma	大腸腺腫	0	2 (<0.1%)		
Colon cancer	結腸癌	8 (0.3%)	1 (<0.1%)		
Colon cancer metastatic	転移性結腸癌	0	1 (<0.1%)		
Colon cancer recurrent	再発結腸癌	0	1 (<0.1%)		
Colon neoplasm	結腸新生物	2 (<0.1%)	0		
Colorectal cancer	結腸直腸癌	2 (<0.1%)	0		
Endometrial cancer	子宮内膜癌	0	2 (<0.1%)		
Essential thrombocythaemia	本態性血小板血症	1 (<0.1%)	0		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Extranodal marginal zone B-cell lymphoma (MALT type)	節外周辺帯Ｂ細胞リンパ腫（ＭＡＬＴ型）	1 (<0.1%)	0		
Fibroadenoma of breast	乳腺線維腺腫	1 (<0.1%)	0		
Fibroma	線維腫	1 (<0.1%)	0		
Focal nodular hyperplasia	限局性結節性過形成	1 (<0.1%)	0		
Gallbladder cancer	胆嚢癌	1 (<0.1%)	0		
Gastric cancer	胃癌	4 (0.2%)	0		
Gastric neoplasm	胃新生物	0	1 (<0.1%)		
Gastrointestinal stromal tumour	消化管間質性腫瘍	0	1 (<0.1%)		
Gastrointestinal tract adenoma	胃腸管腺腫	0	1 (<0.1%)		
Glioblastoma multiforme	多形性神経膠芽細胞腫	0	1 (<0.1%)		
Haemangioma of liver	肝臓血管腫	3 (0.1%)	7 (0.3%)		
Haemangioma of skin	皮膚血管腫	0	1 (<0.1%)		
Haemangioma of spleen	脾血管腫	0	1 (<0.1%)		
Hepatic neoplasm	肝新生物	1 (<0.1%)	0		
Histiocytosis haematophagic	貪食細胞性組織球症	1 (<0.1%)	1 (<0.1%)		
Inflammatory pseudotumour	炎症性偽腫瘍	1 (<0.1%)	0		
Lipoma	脂肪腫	4 (0.2%)	0		
Liposarcoma	脂肪肉腫	2 (<0.1%)	0		
Lung adenocarcinoma	肺腺癌	3 (0.1%)	4 (0.2%)		
Lung cancer metastatic	転移性肺癌	1 (<0.1%)	2 (<0.1%)		
Lung carcinoma cell type unspecified recurrent	再発肺癌、細胞タイプ不明	1 (<0.1%)	1 (<0.1%)		
Lung neoplasm	肺新生物	4 (0.2%)	5 (0.2%)	0	1 (<0.1%)
Lung neoplasm malignant	肺の悪性新生物	5 (0.2%)	4 (0.2%)		
Lung squamous cell carcinoma stage unspecified	肺扁平上皮癌、病期不明	1 (<0.1%)	1 (<0.1%)		
Lymphoma	リンパ腫	0	2 (<0.1%)		
Malignant ascites	悪性腹水	1 (<0.1%)	1 (<0.1%)		
Malignant melanoma	悪性黒色腫	1 (<0.1%)	0		
Malignant pleural effusion	悪性胸水	0	1 (<0.1%)		
Mantle cell lymphoma	マントル細胞リンパ腫	0	1 (<0.1%)		
Melanocytic naevus	メラノサイト性母斑	1 (<0.1%)	1 (<0.1%)		
Meningioma	髄膜腫	1 (<0.1%)	1 (<0.1%)		
Mesothelioma malignant	悪性中皮腫	0	1 (<0.1%)		
Mesothelioma malignant advanced	進行した悪性中皮腫	0	1 (<0.1%)		
Metastases to bone	骨転移	0	1 (<0.1%)		
Metastases to central nervous system	中枢神経系転移	0	2 (<0.1%)		
Metastases to liver	肝転移	2 (<0.1%)	4 (0.2%)		
Metastases to lung	肺転移	0	3 (0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Metastases to lymph nodes	リンパ節転移	0	1 (<0.1%)		
Metastases to peritoneum	腹膜転移	1 (<0.1%)	0		
Metastases to pleura	胸膜転移	0	2 (<0.1%)		
Metastases to spine	脊椎転移	1 (<0.1%)	0		
Metastasis	転移	0	2 (<0.1%)		
Metastatic gastric cancer	転移性胃癌	0	1 (<0.1%)		
Metastatic neoplasm	転移性新生物	1 (<0.1%)	2 (<0.1%)		
Morton's neuroma	モートン神経腫	1 (<0.1%)	0		
Multiple myeloma	多発性骨髄腫	2 (<0.1%)	1 (<0.1%)		
Myelodysplastic syndrome	骨髄異形成症候群	0	1 (<0.1%)		
Myelofibrosis	骨髄線維症	1 (<0.1%)	0		
Neoplasm	新生物	1 (<0.1%)	0		
Neoplasm malignant	悪性新生物	0	2 (<0.1%)		
Neoplasm prostate	前立腺新生物	1 (<0.1%)	0		
Non-small cell lung cancer	非小細胞肺癌	2 (<0.1%)	0		
Ovarian cancer	卵巣癌	1 (<0.1%)	0		
Ovarian epithelial cancer	卵巣上皮癌	2 (<0.1%)	0		
Ovarian germ cell teratoma benign	卵巣胚細胞良性奇形腫	1 (<0.1%)	0		
Pancreatic carcinoma	膵癌	1 (<0.1%)	0		
Pancreatic carcinoma metastatic	転移性膵癌	1 (<0.1%)	0		
Papilloma	乳頭腫	1 (<0.1%)	0		
Parathyroid tumour benign	良性副甲状腺腫瘍	0	2 (<0.1%)		
Pelvic neoplasm	骨盤新生物	0	1 (<0.1%)		
Pituitary tumour	下垂体腫瘍	1 (<0.1%)	0		
Polycythaemia vera	真性多血症	0	2 (<0.1%)		
Prostate cancer	前立腺癌	3 (0.1%)	9 (0.4%)		
Prostate cancer recurrent	再発前立腺癌	0	1 (<0.1%)		
Prostatic adenoma	前立腺腺腫	3 (0.1%)	2 (<0.1%)		
Rectal cancer	直腸癌	2 (<0.1%)	1 (<0.1%)		
Rectal cancer metastatic	転移性直腸癌	0	1 (<0.1%)		
Rectal neoplasm	直腸新生物	1 (<0.1%)	1 (<0.1%)		
Renal cancer	腎癌	1 (<0.1%)	3 (0.1%)		
Renal cell carcinoma	腎細胞癌	1 (<0.1%)	0		
Renal neoplasm	腎新生物	1 (<0.1%)	1 (<0.1%)		
Sarcoma	肉腫	1 (<0.1%)	0		
Seborrhoeic keratosis	脂漏性角化症	3 (0.1%)	0		
Skin cancer	皮膚癌	1 (<0.1%)	0		
Skin papilloma	皮膚乳頭腫	1 (<0.1%)	0		
Small cell lung cancer stage unspecified	小細胞肺癌、病期不明	1 (<0.1%)	0		
Squamous cell carcinoma	扁平上皮癌	0	1 (<0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0	3 (0.1%)		
T-cell lymphoma	Ｔ細胞性リンパ腫	1 (<0.1%)	0		
Thyroid cancer	甲状腺癌	0	3 (0.1%)		
Thyroid neoplasm	甲状腺新生物	7 (0.3%)	4 (0.2%)		
Tumour haemorrhage	腫瘍出血	3 (0.1%)	2 (<0.1%)	0	1 (<0.1%)
Tumour pain	腫瘍疼痛	1 (<0.1%)	0		
Uterine leiomyoma	子宮平滑筋腫	7 (0.3%)	4 (0.2%)		
Nervous system disorders	神経系障害	430 (17.8%)	421 (17.5%)	61 (2.5%)	26 (1.1%)
Ageusia	味覚消失	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Altered state of consciousness	意識変容状態	1 (<0.1%)	0		
Amnesia	健忘	3 (0.1%)	1 (<0.1%)		
Amyotrophic lateral sclerosis	筋萎縮性側索硬化症	1 (<0.1%)	1 (<0.1%)		
Anosmia	無嗅覚	1 (<0.1%)	0		
Aphasia	失語症	1 (<0.1%)	0		
Ataxia	運動失調	3 (0.1%)	1 (<0.1%)		
Autonomic nervous system imbalance	自律神経失調	0	1 (<0.1%)		
Axonal neuropathy	軸索型ニューロパチー	1 (<0.1%)	0		
Balance disorder	平衡障害	4 (0.2%)	3 (0.1%)		
Burning sensation	灼熱感	7 (0.3%)	3 (0.1%)	1 (<0.1%)	0
Carotid arteriosclerosis	頚動脈硬化症	0	5 (0.2%)		
Carotid artery stenosis	頚動脈狭窄	0	2 (<0.1%)		
Carpal tunnel syndrome	手根管症候群	1 (<0.1%)	4 (0.2%)		
Cauda equina syndrome	馬尾症候群	1 (<0.1%)	0		
Central nervous system lesion	中枢神経系病変	1 (<0.1%)	0		
Cerebellar haemorrhage	小脳出血	1 (<0.1%)	0	1 (<0.1%)	0
Cerebral arteriosclerosis	脳動脈硬化症	1 (<0.1%)	1 (<0.1%)		
Cerebral artery stenosis	大脳動脈狭窄	1 (<0.1%)	0		
Cerebral atrophy	大脳萎縮	1 (<0.1%)	1 (<0.1%)		
Cerebral haemorrhage	脳出血	0	4 (0.2%)	0	3 (0.1%)
Cerebral infarction	脳梗塞	0	2 (<0.1%)		
Cerebral ischaemia	脳虚血	1 (<0.1%)	2 (<0.1%)		
Cerebrovascular accident	脳血管発作	1 (<0.1%)	0	1 (<0.1%)	0
Cerebrovascular insufficiency	脳血管不全	1 (<0.1%)	0		
Cervical root pain	頚髄神経根痛	1 (<0.1%)	0		
Cervicobrachial syndrome	頚腕症候群	2 (<0.1%)	1 (<0.1%)		
Clumsiness	不器用	1 (<0.1%)	0	1 (<0.1%)	0
Cognitive disorder	認知障害	1 (<0.1%)	0		
Coma	昏睡	1 (<0.1%)	0		
Complex regional pain syndrome	複合性局所疼痛症候群	0	3 (0.1%)		
Convulsion	痙攣	4 (0.2%)	4 (0.2%)	1 (<0.1%)	0

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Decreased vibratory sense	振動覚低下	1 (<0.1%)	0		
Dementia	認知症	1 (<0.1%)	0		
Dementia Alzheimer's type	アルツハイマー型認知症	2 (<0.1%)	1 (<0.1%)		
Depressed level of consciousness	意識レベルの低下	1 (<0.1%)	0		
Diabetic neuropathy	糖尿病性ニューロパチー	1 (<0.1%)	0		
Disturbance in attention	注意力障害	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Dizziness	浮動性めまい	68 (2.8%)	97 (4.0%)	9 (0.4%)	3 (0.1%)
Dizziness exertional	労作性めまい	0	1 (<0.1%)		
Dizziness postural	体位性めまい	2 (<0.1%)	4 (0.2%)		
Dysaesthesia	異常感覚	2 (<0.1%)	2 (<0.1%)	1 (<0.1%)	0
Dysarthria	構語障害	1 (<0.1%)	1 (<0.1%)		
Dysgeusia	味覚異常	5 (0.2%)	3 (0.1%)	3 (0.1%)	1 (<0.1%)
Dystonia	ジストニー	0	1 (<0.1%)		
Encephalomalacia	脳軟化	1 (<0.1%)	0		
Encephalopathy	脳症	0	1 (<0.1%)		
Epilepsy	てんかん	2 (<0.1%)	2 (<0.1%)		
Essential tremor	本態性振戦	1 (<0.1%)	0		
Facial neuralgia	顔面部神経痛	0	1 (<0.1%)		
Guillain-Barre syndrome	ギラン・バレー症候群	1 (<0.1%)	0		
Haemorrhage intracranial	頭蓋内出血	1 (<0.1%)	2 (<0.1%)	0	2 (<0.1%)
Haemorrhagic transformation stroke	卒中の出血性変化	1 (<0.1%)	0		
Headache	頭痛	200 (8.3%)	183 (7.6%)	35 (1.5%)	11 (0.5%)
Hemiparesis	不全片麻痺	2 (<0.1%)	1 (<0.1%)		
Hepatic encephalopathy	肝性脳症	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Hyperaesthesia	知覚過敏	1 (<0.1%)	0		
Hypersomnia	過眠症	0	1 (<0.1%)		
Hypoaesthesia	感覚鈍麻	13 (0.5%)	18 (0.7%)	2 (<0.1%)	0
Intercostal neuralgia	肋間神経痛	1 (<0.1%)	0		
Intracranial pressure increased	頭蓋内圧上昇	1 (<0.1%)	0		
Ischaemic stroke	虚血性脳卒中	13 (0.5%)	7 (0.3%)	0	1 (<0.1%)
Lacunar infarction	ラクナ梗塞	2 (<0.1%)	1 (<0.1%)		
Lethargy	嗜眠	11 (0.5%)	6 (0.2%)	1 (<0.1%)	0
Leukoencephalopathy	白質脳症	1 (<0.1%)	0		
Loss of consciousness	意識消失	1 (<0.1%)	2 (<0.1%)	0	1 (<0.1%)
Memory impairment	記憶障害	4 (0.2%)	3 (0.1%)		
Migraine	片頭痛	10 (0.4%)	7 (0.3%)	2 (<0.1%)	0
Migraine with aura	前兆を伴う片頭痛	1 (<0.1%)	0		
Muscle contractions involuntary	不随意性筋収縮	0	1 (<0.1%)		
Nerve compression	神経圧迫	2 (<0.1%)	2 (<0.1%)		
Nervous system disorder	神経系障害	1 (<0.1%)	0		
Neuralgia	神経痛	3 (0.1%)	5 (0.2%)		
Neuropathy peripheral	末梢性ニューロパチー	6 (0.2%)	3 (0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Orthostatic intolerance	起立不耐性	0	1 (<0.1%)		
Paraesthesia	錯感覚	31 (1.3%)	25 (1.0%)	4 (0.2%)	2 (<0.1%)
Paraparesis	不全対麻痺	1 (<0.1%)	0		
Parkinson's disease	パーキンソン病	2 (<0.1%)	2 (<0.1%)		
Parkinsonism	パーキンソニズム	1 (<0.1%)	1 (<0.1%)		
Partial seizures	部分発作	0	1 (<0.1%)		
Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1 (<0.1%)	0		
Peroneal nerve palsy	腓骨神経麻痺	1 (<0.1%)	0		
Polyneuropathy	多発ニューロパチー	0	2 (<0.1%)		
Poor quality sleep	睡眠の質低下	0	2 (<0.1%)		
Post herpetic neuralgia	ヘルペス後神経痛	0	1 (<0.1%)		
Presyncope	失神寸前の状態	12 (0.5%)	11 (0.5%)		
Pseudoradicular syndrome	偽性根症候群	0	1 (<0.1%)		
Radicular pain	神経根痛	1 (<0.1%)	0		
Radiculitis	神経根炎	0	1 (<0.1%)		
Restless legs syndrome	下肢静止不能症候群	4 (0.2%)	5 (0.2%)	2 (<0.1%)	0
Sciatica	坐骨神経痛	18 (0.7%)	18 (0.7%)	0	1 (<0.1%)
Sedation	鎮静	0	1 (<0.1%)		
Sensory disturbance	感覚障害	1 (<0.1%)	2 (<0.1%)		
Sinus headache	副鼻腔炎に伴う頭痛	1 (<0.1%)	2 (<0.1%)		
Somnolence	傾眠	4 (0.2%)	6 (0.2%)		
Spinal cord compression	脊髄圧迫	0	1 (<0.1%)		
Subacute combined cord degeneration	亜急性脊髄連合変性症	1 (<0.1%)	0		
Subarachnoid haemorrhage	くも膜下出血	0	1 (<0.1%)	0	1 (<0.1%)
Syncope	失神	25 (1.0%)	23 (1.0%)	1 (<0.1%)	0
Tension headache	緊張性頭痛	1 (<0.1%)	4 (0.2%)	0	2 (<0.1%)
Thermohyperaesthesia	温度覚過敏	0	1 (<0.1%)		
Transient ischaemic attack	一過性脳虚血発作	4 (0.2%)	4 (0.2%)		
Tremor	振戦	15 (0.6%)	10 (0.4%)	3 (0.1%)	0
Trigeminal neuralgia	三叉神経痛	0	1 (<0.1%)		
VIIth nerve paralysis	第７脳神経麻痺	1 (<0.1%)	2 (<0.1%)		
Vascular headache	血管性頭痛	0	1 (<0.1%)		
Pregnancy, puerperium and perinatal conditions	妊娠、産褥および周産期の状態	3 (0.1%)	7 (0.3%)		
Perineal haematoma	会陰血腫	0	1 (<0.1%)		
Post abortion haemorrhage	流産後の出血	0	1 (<0.1%)		
Pregnancy	妊娠	3 (0.1%)	6 (0.2%)		
Psychiatric disorders	精神障害	225 (9.3%)	227 (9.4%)	10 (0.4%)	5 (0.2%)
Abnormal dreams	異常な夢	0	1 (<0.1%)		
Acute stress disorder	急性ストレス反応	0	1 (<0.1%)		
Affective disorder	感情障害	2 (<0.1%)	0	1 (<0.1%)	0
Agitation	激越	4 (0.2%)	2 (<0.1%)		
Agoraphobia	広場恐怖症	0	1 (<0.1%)		
Alcohol abuse	アルコール乱用	1 (<0.1%)	2 (<0.1%)		

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Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Alcohol withdrawal syndrome	アルコール離脱症候群	0	2 (<0.1%)		
Alcoholic hangover	アルコールによる宿酔	0	1 (<0.1%)		
Alcoholism	アルコール症	0	1 (<0.1%)		
Anxiety	不安	85 (3.5%)	79 (3.3%)	2 (<0.1%)	0
Anxiety disorder	不安障害	0	1 (<0.1%)		
Apathy	無感情	1 (<0.1%)	0		
Attention deficit/hyperactivity disorder	注意欠陥多動性障害	1 (<0.1%)	0		
Bipolar I disorder	双極１型障害	2 (<0.1%)	1 (<0.1%)		
Confusional state	錯乱状態	9 (0.4%)	7 (0.3%)	1 (<0.1%)	0
Delirium	譫妄	1 (<0.1%)	2 (<0.1%)		
Delusion	妄想	1 (<0.1%)	0		
Depressed mood	抑うつ気分	3 (0.1%)	1 (<0.1%)		
Depression	うつ病	41 (1.7%)	44 (1.8%)	2 (<0.1%)	1 (<0.1%)
Depressive symptom	抑うつ症状	1 (<0.1%)	0		
Disorientation	失見当識	1 (<0.1%)	1 (<0.1%)		
Emotional distress	感情的苦悩	1 (<0.1%)	0		
Initial insomnia	初期不眠症	0	2 (<0.1%)		
Insomnia	不眠症	69 (2.9%)	79 (3.3%)	3 (0.1%)	1 (<0.1%)
Libido increased	リビドー亢進	1 (<0.1%)	0		
Loss of libido	リビド消失	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Mania	躁病	1 (<0.1%)	0		
Mental disorder	精神障害	0	1 (<0.1%)		
Mental disorder due to a general medical condition	身体疾患による精神障害	0	1 (<0.1%)		
Mental status changes	精神状態変化	1 (<0.1%)	1 (<0.1%)		
Mood swings	気分動揺	2 (<0.1%)	0		
Nervousness	神経過敏	7 (0.3%)	2 (<0.1%)	1 (<0.1%)	0
Neurosis	神経症	3 (0.1%)	1 (<0.1%)		
Nightmare	悪夢	1 (<0.1%)	0		
Orgasm abnormal	オルガズム異常	0	1 (<0.1%)	0	1 (<0.1%)
Panic attack	パニック発作	6 (0.2%)	4 (0.2%)		
Panic disorder	パニック障害	2 (<0.1%)	1 (<0.1%)		
Panic reaction	パニック反応	0	1 (<0.1%)		
Persecutory delusion	被害妄想	1 (<0.1%)	0		
Post-traumatic stress disorder	外傷後ストレス障害	0	1 (<0.1%)		
Psychotic disorder	精神病性障害	1 (<0.1%)	0		
Restlessness	落ち着きのなさ	3 (0.1%)	0		
Sleep disorder	睡眠障害	6 (0.2%)	12 (0.5%)	0	1 (<0.1%)
Somatoform disorder	身体表現性障害	2 (<0.1%)	0		
Stress	ストレス	2 (<0.1%)	2 (<0.1%)		
Suicide attempt	自殺企図	1 (<0.1%)	2 (<0.1%)		
Thinking abnormal	思考異常	1 (<0.1%)	0		
Renal and urinary disorders	腎および尿路障害	163 (6.8%)	173 (7.2%)	53 (2.2%)	55 (2.3%)
Acute prerenal failure	急性腎前性腎不全	2 (<0.1%)	0		
Anuria	無尿	0	2 (<0.1%)		
Bilirubinuria	ビリルビン尿	0	1 (<0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Bladder dilatation	膀胱拡大	0	1 (<0.1%)		
Bladder mass	膀胱腫瘤	1 (<0.1%)	0		
Bladder pain	膀胱痛	0	1 (<0.1%)		
Bladder prolapse	膀胱脱	1 (<0.1%)	1 (<0.1%)		
Bladder spasm	膀胱痙縮	1 (<0.1%)	1 (<0.1%)		
Calculus bladder	膀胱結石	1 (<0.1%)	1 (<0.1%)		
Calculus ureteric	尿管結石	0	1 (<0.1%)	0	1 (<0.1%)
Calculus urinary	尿路結石	0	1 (<0.1%)		
Cystitis haemorrhagic	出血性膀胱炎	1 (<0.1%)	2 (<0.1%)	0	1 (<0.1%)
Dysuria	排尿困難	13 (0.5%)	9 (0.4%)	1 (<0.1%)	0
Enuresis	遺尿	0	1 (<0.1%)		
Glomerulonephritis membranous	膜性糸球体腎炎	1 (<0.1%)	0		
Haematuria	血尿	76 (3.2%)	76 (3.2%)	50 (2.1%)	53 (2.2%)
Hydronephrosis	水腎症	2 (<0.1%)	0		
Hypertonic bladder	緊張性膀胱	1 (<0.1%)	0		
Incontinence	失禁	1 (<0.1%)	0		
Kidney enlargement	腎腫大	1 (<0.1%)	1 (<0.1%)		
Microalbuminuria	ミクロアルブミン尿	0	2 (<0.1%)		
Micturition disorder	排尿異常	1 (<0.1%)	1 (<0.1%)		
Micturition urgency	尿意切迫	1 (<0.1%)	0		
Nephritis	腎炎	1 (<0.1%)	1 (<0.1%)		
Nephroangiosclerosis	腎血管硬化症	0	1 (<0.1%)		
Nephrocalcinosis	腎石灰沈着症	0	1 (<0.1%)		
Nephrolithiasis	腎結石症	10 (0.4%)	13 (0.5%)		
Nephropathy toxic	中毒性ネフロパシー	0	1 (<0.1%)		
Nephrosclerosis	腎硬化症	1 (<0.1%)	0		
Nephrotic syndrome	ネフローゼ症候群	1 (<0.1%)	0		
Neurogenic bladder	神経因性膀胱	0	1 (<0.1%)		
Nocturia	夜間頻尿	1 (<0.1%)	0		
Oliguria	乏尿	1 (<0.1%)	1 (<0.1%)		
Pollakiuria	頻尿	5 (0.2%)	9 (0.4%)	1 (<0.1%)	0
Polyuria	多尿	3 (0.1%)	2 (<0.1%)		
Proteinuria	蛋白尿	2 (<0.1%)	1 (<0.1%)		
Pyelocaliectasis	腎盂腎杯拡張症	0	1 (<0.1%)		
Pyuria	膿尿	0	1 (<0.1%)		
Renal atrophy	腎萎縮	0	2 (<0.1%)		
Renal colic	腎仙痛	1 (<0.1%)	6 (0.2%)		
Renal cyst	腎嚢胞	20 (0.8%)	26 (1.1%)		
Renal failure	腎不全	4 (0.2%)	3 (0.1%)	0	1 (<0.1%)
Renal failure acute	急性腎不全	4 (0.2%)	6 (0.2%)	0	1 (<0.1%)
Renal haemorrhage	腎出血	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Renal impairment	腎機能障害	4 (0.2%)	3 (0.1%)		
Renal mass	腎腫瘤	2 (<0.1%)	3 (0.1%)		
Renal pain	腎臓痛	3 (0.1%)	3 (0.1%)		
Renal tubular necrosis	腎尿細管壊死	0	1 (<0.1%)		
Stress urinary incontinence	腹圧性尿失禁	0	1 (<0.1%)		
Ureteric perforation	尿管穿孔	1 (<0.1%)	0		
Urethral disorder	尿道障害	0	1 (<0.1%)		
Urethral stenosis	尿道狭窄	0	3 (0.1%)		
Urge incontinence	切迫性尿失禁	1 (<0.1%)	1 (<0.1%)		
Urinary bladder polyp	膀胱ポリープ	1 (<0.1%)	1 (<0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Urinary incontinence	尿失禁	4 (0.2%)	4 (0.2%)		
Urinary retention	尿閉	9 (0.4%)	5 (0.2%)	1 (<0.1%)	0
Urinary tract disorder	尿路障害	1 (<0.1%)	0		
Urinary tract obstruction	尿路閉塞	2 (<0.1%)	0		
Reproductive system and breast disorders	生殖系および乳房障害	189 (7.8%)	142 (5.9%)	98 (4.1%)	61 (2.5%)
Amenorrhoea	無月経	2 (<0.1%)	4 (0.2%)	0	1 (<0.1%)
Atrophic vulvovaginitis	萎縮性外陰腟炎	4 (0.2%)	0		
Balanitis	亀頭炎	1 (<0.1%)	0		
Balanoposthitis	亀頭包皮炎	1 (<0.1%)	0		
Bartholin's cyst	バルトリン嚢腫	1 (<0.1%)	0		
Benign prostatic hyperplasia	良性前立腺肥大症	13 (0.5%)	7 (0.3%)		
Breast calcifications	乳房石灰化	0	1 (<0.1%)		
Breast cyst	乳房嚢胞	1 (<0.1%)	0		
Breast discharge	乳房分泌	0	1 (<0.1%)		
Breast disorder	乳房障害	1 (<0.1%)	0		
Breast haematoma	乳房血腫	1 (<0.1%)	0	1 (<0.1%)	0
Breast induration	乳房硬結	1 (<0.1%)	0		
Breast mass	乳房腫瘤	4 (0.2%)	1 (<0.1%)	0	1 (<0.1%)
Breast necrosis	乳房壊死	0	1 (<0.1%)		
Breast pain	乳房痛	1 (<0.1%)	4 (0.2%)		
Breast swelling	乳房腫脹	1 (<0.1%)	0		
Breast tenderness	乳房圧痛	1 (<0.1%)	0		
Cervical cyst	子宮頚部嚢胞	2 (<0.1%)	0		
Cervical dysplasia	子宮頚部上皮異形成	0	1 (<0.1%)		
Cervical polyp	子宮頚管ポリープ	1 (<0.1%)	3 (0.1%)		
Cervix disorder	子宮頚部障害	1 (<0.1%)	0		
Coital bleeding	性交出血	3 (0.1%)	2 (<0.1%)	2 (<0.1%)	0
Cystocele	膀胱瘤	1 (<0.1%)	0		
Dysfunctional uterine bleeding	機能障害性子宮出血	1 (<0.1%)	0	1 (<0.1%)	0
Dysmenorrhoea	月経困難症	8 (0.3%)	9 (0.4%)	2 (<0.1%)	0
Dyspareunia	性交困難	1 (<0.1%)	0		
Endometrial hyperplasia	子宮内膜増殖症	0	1 (<0.1%)		
Endometrial hypertrophy	子宮内膜肥厚	0	1 (<0.1%)		
Epididymitis	精巣上体炎	1 (<0.1%)	2 (<0.1%)		
Erectile dysfunction	勃起不全	3 (0.1%)	0	1 (<0.1%)	0
Fibrocystic breast disease	線維嚢胞性乳腺疾患	0	1 (<0.1%)		
Genital discomfort	性器不快感	0	1 (<0.1%)		
Genital erythema	性器紅斑	1 (<0.1%)	0		
Genital haemorrhage	性器出血	1 (<0.1%)	2 (<0.1%)		
Genital lesion	生殖器病変	1 (<0.1%)	0		
Genital pain	生殖器痛	0	1 (<0.1%)		
Genital ulceration	性器潰瘍形成	2 (<0.1%)	0		
Gynaecomastia	女性化乳房	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Haematospermia	血精液症	1 (<0.1%)	3 (0.1%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Haemorrhagic ovarian cyst	出血性卵巣嚢胞	0	2 (<0.1%)	0	1 (<0.1%)
Hypomenorrhoea	過少月経	0	1 (<0.1%)		
Menometrorrhagia	機能性子宮出血	0	3 (0.1%)	0	2 (<0.1%)
Menopausal symptoms	閉経期症状	0	2 (<0.1%)		
Menorrhagia	月経過多	75 (3.1%)	47 (2.0%)	62 (2.6%)	35 (1.5%)
Menstruation delayed	月経遅延	1 (<0.1%)	0		
Menstruation irregular	不規則月経	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Metrorrhagia	不正子宮出血	13 (0.5%)	17 (0.7%)	10 (0.4%)	15 (0.6%)
Nipple exudate bloody	血性乳頭滲出液	1 (<0.1%)	0		
Nipple pain	乳頭痛	0	1 (<0.1%)		
Ovarian cyst	卵巣嚢胞	7 (0.3%)	5 (0.2%)		
Ovarian enlargement	卵巣腫大	0	1 (<0.1%)		
Pelvic pain	骨盤痛	4 (0.2%)	3 (0.1%)		
Penile haematoma	陰茎血腫	0	1 (<0.1%)	0	1 (<0.1%)
Penile oedema	陰茎浮腫	0	1 (<0.1%)		
Polycystic ovaries	多嚢胞性卵巣	1 (<0.1%)	1 (<0.1%)		
Priapism	持続勃起症	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Prostatic calcification	前立腺石灰化	0	2 (<0.1%)		
Prostatic dysplasia	前立腺異形成	1 (<0.1%)	0		
Prostatic mass	前立腺腫瘤	0	1 (<0.1%)		
Prostatism	前立腺症	3 (0.1%)	0		
Prostatitis	前立腺炎	4 (0.2%)	7 (0.3%)		
Prostatomegaly	前立腺腫大	1 (<0.1%)	4 (0.2%)		
Scrotal haematocoele	陰嚢血瘤	1 (<0.1%)	0	1 (<0.1%)	0
Scrotal oedema	陰嚢浮腫	1 (<0.1%)	0		
Scrotal swelling	陰嚢腫脹	0	1 (<0.1%)		
Testicular cyst	精巣嚢胞	0	1 (<0.1%)		
Uterine atrophy	子宮萎縮	2 (<0.1%)	0		
Uterine cervical erosion	子宮頚部びらん	0	1 (<0.1%)		
Uterine cervix atrophy	子宮頚部萎縮	2 (<0.1%)	0		
Uterine cyst	子宮嚢胞	0	1 (<0.1%)		
Uterine enlargement	子宮肥大	2 (<0.1%)	0		
Uterine polyp	子宮ポリープ	2 (<0.1%)	3 (0.1%)		
Uterine prolapse	子宮脱	1 (<0.1%)	0		
Uterine spasm	子宮痙攣	1 (<0.1%)	0		
Vaginal discharge	膣分泌物	0	1 (<0.1%)		
Vaginal haemorrhage	膣出血	29 (1.2%)	13 (0.5%)	19 (0.8%)	9 (0.4%)
Vaginal inflammation	膣の炎症	0	1 (<0.1%)		
Vulval disorder	外陰部障害	1 (<0.1%)	0		
Vulvovaginal discomfort	外陰膣不快感	1 (<0.1%)	0		
Vulvovaginal dryness	外陰膣乾燥	1 (<0.1%)	1 (<0.1%)		
Vulvovaginal pruritus	外陰膣そう痒症	2 (<0.1%)	0		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	688 (28.5%)	677 (28.1%)	248 (10.3%)	210 (8.7%)
Acute pulmonary oedema	急性肺水腫	1 (<0.1%)	0		
Acute respiratory distress syndrome	急性呼吸窮迫症候群	2 (<0.1%)	1 (<0.1%)		
Acute respiratory failure	急性呼吸不全	1 (<0.1%)	4 (0.2%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Allergic cough	アレルギー性咳嗽	0	3 (0.1%)		
Allergic sinusitis	アレルギー性副鼻腔炎	1 (<0.1%)	0		
Alveolar proteinosis	肺胞蛋白症	1 (<0.1%)	0		
Alveolitis	胞隔炎	1 (<0.1%)	0		
Alveolitis allergic	アレルギー性胞隔炎	0	1 (<0.1%)		
Asthma	喘息	15 (0.6%)	18 (0.7%)	1 (<0.1%)	0
Asthma exercise induced	運動誘発喘息	0	1 (<0.1%)		
Atelectasis	無気肺	5 (0.2%)	0		
Bronchial disorder	気管支障害	1 (<0.1%)	0		
Bronchial haemorrhage	気管支出血	1 (<0.1%)	0		
Bronchial hyperreactivity	気管支反応性亢進	2 (<0.1%)	0		
Bronchial irritation	気管支刺激	1 (<0.1%)	0	1 (<0.1%)	0
Bronchial obstruction	気管支閉塞	0	1 (<0.1%)		
Bronchiectasis	気管支拡張症	1 (<0.1%)	2 (<0.1%)		
Bronchitis chronic	慢性気管支炎	3 (0.1%)	4 (0.2%)		
Bronchopneumopathy	気管支肺症	1 (<0.1%)	1 (<0.1%)		
Bronchospasm	気管支痙攣	5 (0.2%)	5 (0.2%)		
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	19 (0.8%)	13 (0.5%)	1 (<0.1%)	0
Cough	咳嗽	161 (6.7%)	179 (7.4%)	7 (0.3%)	2 (<0.1%)
Diaphragmalgia	横隔膜痛	0	1 (<0.1%)		
Diaphragmatic disorder	横隔膜障害	0	1 (<0.1%)		
Diaphragmatic hernia	横隔膜ヘルニア	0	1 (<0.1%)		
Dry throat	咽喉乾燥	1 (<0.1%)	1 (<0.1%)		
Dysphonia	発声障害	4 (0.2%)	6 (0.2%)		
Dyspnoea	呼吸困難	168 (7.0%)	154 (6.4%)	4 (0.2%)	6 (0.2%)
Dyspnoea at rest	安静時呼吸困難	0	1 (<0.1%)	0	1 (<0.1%)
Dyspnoea exertional	労作性呼吸困難	19 (0.8%)	22 (0.9%)	2 (<0.1%)	0
Dyspnoea paroxysmal nocturnal	発作性夜間呼吸困難	1 (<0.1%)	0		
Emphysema	肺気腫	3 (0.1%)	2 (<0.1%)		
Epistaxis	鼻出血	230 (9.5%)	207 (8.6%)	175 (7.3%)	167 (6.9%)
Haemoptysis	喀血	82 (3.4%)	82 (3.4%)	62 (2.6%)	46 (1.9%)
Haemothorax	血胸	2 (<0.1%)	3 (0.1%)	2 (<0.1%)	1 (<0.1%)
Hiccups	しゃっくり	0	2 (<0.1%)		
Hypercapnia	高炭酸ガス血症	0	1 (<0.1%)		
Hyperventilation	過換気	4 (0.2%)	2 (<0.1%)		
Hypoxia	低酸素症	2 (<0.1%)	1 (<0.1%)		
Increased upper airway secretion	上気道分泌増加	0	1 (<0.1%)		
Interstitial lung disease	間質性肺疾患	1 (<0.1%)	0		
Laryngeal haemorrhage	喉頭出血	0	1 (<0.1%)		
Laryngeal hypertrophy	喉頭肥大	0	1 (<0.1%)		
Laryngeal inflammation	喉頭の炎症	1 (<0.1%)	0		
Laryngeal oedema	喉頭浮腫	1 (<0.1%)	0		
Lower respiratory tract inflammation	下気道の炎症	1 (<0.1%)	0		
Lung cyst	肺嚢胞	0	1 (<0.1%)		
Lung disorder	肺障害	7 (0.3%)	5 (0.2%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Lung infiltration	肺浸潤	1 (<0.1%)	1 (<0.1%)		
Mediastinal haemorrhage	縦隔出血	0	1 (<0.1%)		
Nasal congestion	鼻閉	6 (0.2%)	8 (0.3%)		
Nasal dryness	鼻乾燥	3 (0.1%)	0		
Nasal obstruction	鼻閉塞	0	3 (0.1%)		
Nasal polyps	鼻茸	1 (<0.1%)	0		
Nasal septum deviation	鼻中隔弯曲	2 (<0.1%)	0		
Nocturnal dyspnoea	夜間呼吸困難	0	2 (<0.1%)		
Obstructive airways disorder	閉塞性気道障害	0	2 (<0.1%)		
Oropharyngeal blistering	口腔咽頭水疱形成	0	1 (<0.1%)	0	1 (<0.1%)
Oropharyngeal discomfort	口腔咽頭不快感	1 (<0.1%)	0		
Oropharyngeal pain	口腔咽頭痛	28 (1.2%)	31 (1.3%)		
Orthopnoea	起坐呼吸	3 (0.1%)	2 (<0.1%)		
Paranasal cyst	副鼻腔嚢胞	0	1 (<0.1%)		
Paranasal sinus haematoma	副鼻腔血腫	0	1 (<0.1%)	0	1 (<0.1%)
Paranasal sinus hypersecretion	副鼻腔分泌過多	0	1 (<0.1%)		
Paranasal sinus mucosal hypertrophy	副鼻腔粘膜肥厚	0	1 (<0.1%)		
Pharyngeal cyst	咽頭嚢腫	0	1 (<0.1%)		
Pharyngeal haemorrhage	咽頭出血	1 (<0.1%)	0		
Pharyngeal hypertrophy	咽頭肥大	0	1 (<0.1%)		
Pharyngeal inflammation	咽頭の炎症	1 (<0.1%)	0		
Pleural adhesion	胸膜癒着	3 (0.1%)	4 (0.2%)		
Pleural effusion	胸水	22 (0.9%)	30 (1.2%)	0	1 (<0.1%)
Pleural fibrosis	胸膜線維症	3 (0.1%)	0		
Pleural haemorrhage	胸腔内出血	2 (<0.1%)	0	1 (<0.1%)	0
Pleurisy	胸膜炎	6 (0.2%)	11 (0.5%)		
Pleuritic pain	胸膜痛	22 (0.9%)	21 (0.9%)		
Pneumonia aspiration	誤嚥性肺炎	1 (<0.1%)	0		
Pneumothorax	気胸	2 (<0.1%)	4 (0.2%)		
Productive cough	湿性咳嗽	12 (0.5%)	10 (0.4%)	2 (<0.1%)	0
Pulmonary arterial hypertension	肺動脈高血圧症	1 (<0.1%)	2 (<0.1%)		
Pulmonary congestion	肺うっ血	4 (0.2%)	2 (<0.1%)	0	1 (<0.1%)
Pulmonary embolism	肺塞栓症	6 (0.2%)	1 (<0.1%)	1 (<0.1%)	0
Pulmonary fibrosis	肺線維症	1 (<0.1%)	3 (0.1%)		
Pulmonary haemorrhage	肺出血	2 (<0.1%)	0	1 (<0.1%)	0
Pulmonary hypertension	肺高血圧症	10 (0.4%)	13 (0.5%)		
Pulmonary infarction	肺梗塞	5 (0.2%)	3 (0.1%)	1 (<0.1%)	0
Pulmonary oedema	肺水腫	1 (<0.1%)	3 (0.1%)		
Pulmonary sarcoidosis	肺サルコイドーシス	1 (<0.1%)	0		
Pulmonary venous thrombosis	肺静脈血栓症	1 (<0.1%)	0	1 (<0.1%)	0
Rales	ラ音	1 (<0.1%)	2 (<0.1%)		
Reflux laryngitis	逆流性喉頭炎	1 (<0.1%)	0		
Respiratory arrest	呼吸停止	1 (<0.1%)	1 (<0.1%)		
Respiratory distress	呼吸窮迫	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Respiratory failure	呼吸不全	6 (0.2%)	5 (0.2%)	2 (<0.1%)	0
Respiratory tract congestion	気道うっ血	3 (0.1%)	2 (<0.1%)		
Respiratory tract haemorrhage	気道出血	0	1 (<0.1%)		
Respiratory tract inflammation	気道の炎症	0	1 (<0.1%)		
Rhinitis allergic	アレルギー性鼻炎	9 (0.4%)	6 (0.2%)		
Rhinitis seasonal	季節性鼻炎	1 (<0.1%)	2 (<0.1%)		
Rhinorrhoea	鼻漏	7 (0.3%)	7 (0.3%)	1 (<0.1%)	0
Sinus congestion	副鼻腔うっ血	8 (0.3%)	5 (0.2%)		
Sinus polyp	副鼻腔ポリープ	1 (<0.1%)	0		
Sleep apnoea syndrome	睡眠時無呼吸症候群	4 (0.2%)	8 (0.3%)		
Sneezing	くしゃみ	0	1 (<0.1%)		
Snoring	いびき	0	1 (<0.1%)		
Sputum discoloured	変色痰	0	2 (<0.1%)		
Tachypnoea	頻呼吸	12 (0.5%)	7 (0.3%)		
Throat irritation	咽喉刺激感	1 (<0.1%)	4 (0.2%)		
Throat tightness	咽喉絞扼感	1 (<0.1%)	1 (<0.1%)		
Tracheal inflammation	気管の炎症	1 (<0.1%)	0		
Upper-airway cough syndrome	上気道咳症候群	2 (<0.1%)	2 (<0.1%)		
Wheezing	喘鳴	2 (<0.1%)	3 (0.1%)		
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	319 (13.2%)	275 (11.4%)	105 (4.4%)	79 (3.3%)
Acne	ざ瘡	8 (0.3%)	6 (0.2%)	2 (<0.1%)	0
Actinic keratosis	日光性角化症	1 (<0.1%)	2 (<0.1%)		
Alopecia	脱毛症	23 (1.0%)	29 (1.2%)	10 (0.4%)	21 (0.9%)
Alopecia areata	円形脱毛症	0	1 (<0.1%)	0	1 (<0.1%)
Angioedema	血管浮腫	3 (0.1%)	2 (<0.1%)	1 (<0.1%)	0
Blister	水疱	2 (<0.1%)	4 (0.2%)	1 (<0.1%)	1 (<0.1%)
Blood blister	血性水疱	2 (<0.1%)	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Chloasma	肝斑	0	1 (<0.1%)		
Cold sweat	冷汗	0	1 (<0.1%)		
Cutaneous lupus erythematosus	皮膚エリテマトーデス	1 (<0.1%)	0		
Cutaneous vasculitis	皮膚血管炎	1 (<0.1%)	0	1 (<0.1%)	0
Decubitus ulcer	褥瘡性潰瘍	2 (<0.1%)	2 (<0.1%)		
Dermal cyst	皮膚嚢腫	2 (<0.1%)	1 (<0.1%)		
Dermatitis	皮膚炎	6 (0.2%)	5 (0.2%)		
Dermatitis acneiform	ざ瘡様皮膚炎	1 (<0.1%)	0		
Dermatitis allergic	アレルギー性皮膚炎	10 (0.4%)	7 (0.3%)	4 (0.2%)	1 (<0.1%)
Dermatitis atopic	アトピー性皮膚炎	2 (<0.1%)	0		
Dermatitis contact	接触性皮膚炎	5 (0.2%)	4 (0.2%)		
Dermatitis exfoliative	剥脱性皮膚炎	1 (<0.1%)	0		
Dermatomyositis	皮膚筋炎	1 (<0.1%)	0		
Diabetic ulcer	糖尿病性潰瘍	0	1 (<0.1%)		
Drug eruption	薬疹	4 (0.2%)	4 (0.2%)		
Dry skin	皮膚乾燥	6 (0.2%)	4 (0.2%)	3 (0.1%)	0
Dyshidrosis	発汗障害	1 (<0.1%)	1 (<0.1%)		
Ecchymosis	斑状出血	17 (0.7%)	20 (0.8%)	11 (0.5%)	15 (0.6%)
Eczema	湿疹	12 (0.5%)	9 (0.4%)	1 (<0.1%)	0
Erythema	紅斑	12 (0.5%)	9 (0.4%)	2 (<0.1%)	2 (<0.1%)

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Erythema nodosum	結節性紅斑	0	1 (<0.1%)		
Haemorrhage subcutaneous	皮下出血	1 (<0.1%)	4 (0.2%)	1 (<0.1%)	3 (0.1%)
Hair texture abnormal	毛質異常	2 (<0.1%)	0	2 (<0.1%)	0
Heat rash	紅色汗疹	0	2 (<0.1%)		
Hirsutism	男性型多毛症	0	1 (<0.1%)	0	1 (<0.1%)
Hyperhidrosis	多汗症	13 (0.5%)	7 (0.3%)	5 (0.2%)	0
Hyperkeratosis	過角化	3 (0.1%)	1 (<0.1%)	1 (<0.1%)	0
Increased tendency to bruise	内出血発生の増加傾向	4 (0.2%)	1 (<0.1%)	3 (0.1%)	1 (<0.1%)
Ingrowing nail	嵌入爪	0	2 (<0.1%)		
Intertrigo	間擦疹	3 (0.1%)	0		
Itching scar	瘢痕そう痒感	0	1 (<0.1%)		
Keratosis pilaris	毛孔性角化症	1 (<0.1%)	0		
Koilonychia	さじ状爪	1 (<0.1%)	0		
Lentigo	黒子	1 (<0.1%)	0		
Lichen planus	扁平苔癬	1 (<0.1%)	0		
Lichenoid keratosis	苔癬様角化症	0	1 (<0.1%)		
Macule	斑	1 (<0.1%)	0		
Nail bed bleeding	爪床出血	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Nail bed inflammation	爪床の炎症	0	1 (<0.1%)		
Nail disorder	爪の障害	0	1 (<0.1%)		
Nail pigmentation	爪色素沈着	1 (<0.1%)	0		
Night sweats	寝汗	5 (0.2%)	8 (0.3%)	1 (<0.1%)	1 (<0.1%)
Onychalgia	爪痛	0	1 (<0.1%)		
Onychoclasis	爪破損	1 (<0.1%)	0		
Onychomadesis	爪甲脱落症	0	1 (<0.1%)		
Onychomalacia	爪軟化症	1 (<0.1%)	0	1 (<0.1%)	0
Pain of skin	皮膚疼痛	1 (<0.1%)	0		
Palmar-plantar erythrodysaesthesia syndrome	手掌・足底発赤知覚不全症候群	1 (<0.1%)	0		
Petechiae	点状出血	3 (0.1%)	5 (0.2%)	2 (<0.1%)	3 (0.1%)
Photosensitivity allergic reaction	アレルギー性光線過敏性反応	1 (<0.1%)	0	1 (<0.1%)	0
Pityriasis	粃糠疹	0	1 (<0.1%)		
Pityriasis rosea	ばら色粃糠疹	0	1 (<0.1%)		
Precancerous skin lesion	前癌性皮膚病変	1 (<0.1%)	0		
Prurigo	痒疹	1 (<0.1%)	1 (<0.1%)		
Pruritus	そう痒症	55 (2.3%)	30 (1.2%)	21 (0.9%)	8 (0.3%)
Pruritus generalised	全身性そう痒症	4 (0.2%)	3 (0.1%)	0	1 (<0.1%)
Psoriasis	乾癬	5 (0.2%)	3 (0.1%)	2 (<0.1%)	0
Purpura	紫斑	6 (0.2%)	1 (<0.1%)	2 (<0.1%)	1 (<0.1%)
Rash	発疹	76 (3.2%)	64 (2.7%)	30 (1.2%)	10 (0.4%)
Rash erythematous	紅斑性皮疹	2 (<0.1%)	4 (0.2%)	1 (<0.1%)	1 (<0.1%)
Rash generalised	全身性皮疹	3 (0.1%)	1 (<0.1%)	2 (<0.1%)	0
Rash macular	斑状皮疹	3 (0.1%)	3 (0.1%)	0	1 (<0.1%)
Rash maculo-papular	斑状丘疹状皮疹	0	1 (<0.1%)	0	1 (<0.1%)
Rash morbilliform	麻疹様発疹	1 (<0.1%)	0	1 (<0.1%)	0
Rash papular	丘疹性皮疹	2 (<0.1%)	2 (<0.1%)	2 (<0.1%)	1 (<0.1%)
Rash pruritic	そう痒性皮疹	2 (<0.1%)	2 (<0.1%)	0	2 (<0.1%)
Rash vesicular	小水疱性皮疹	1 (<0.1%)	0		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Rosacea	酒さ	2 (<0.1%)	0		
Scar	瘢痕	1 (<0.1%)	0		
Scar pain	瘢痕痛	0	1 (<0.1%)		
Seborrhoeic dermatitis	脂漏性皮膚炎	1 (<0.1%)	1 (<0.1%)		
Skin discolouration	皮膚変色	1 (<0.1%)	2 (<0.1%)		
Skin disorder	皮膚障害	1 (<0.1%)	2 (<0.1%)	1 (<0.1%)	0
Skin exfoliation	皮膚剥脱	2 (<0.1%)	0		
Skin fissures	皮膚亀裂	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Skin haemorrhage	皮膚出血	13 (0.5%)	8 (0.3%)	5 (0.2%)	5 (0.2%)
Skin irritation	皮膚刺激	1 (<0.1%)	3 (0.1%)		
Skin lesion	皮膚病変	8 (0.3%)	4 (0.2%)		
Skin mass	皮膚腫瘤	0	2 (<0.1%)		
Skin necrosis	皮膚壊死	0	1 (<0.1%)	0	1 (<0.1%)
Skin ulcer	皮膚潰瘍	7 (0.3%)	5 (0.2%)	1 (<0.1%)	0
Skin ulcer haemorrhage	出血性皮膚潰瘍	0	1 (<0.1%)		
Skin warm	皮膚熱感	1 (<0.1%)	0	1 (<0.1%)	0
Stasis dermatitis	うっ滞性皮膚炎	1 (<0.1%)	2 (<0.1%)		
Swelling face	顔面腫脹	0	1 (<0.1%)	0	1 (<0.1%)
Telangiectasia	毛細血管拡張症	0	3 (0.1%)	0	1 (<0.1%)
Transient acantholytic dermatosis	一過性棘融解性皮膚症	1 (<0.1%)	0		
Urticaria	蕁麻疹	11 (0.5%)	7 (0.3%)	2 (<0.1%)	1 (<0.1%)
Xanthoma	黄色腫	0	1 (<0.1%)		
Xeroderma	乾皮症	0	1 (<0.1%)		
Social circumstances	社会環境	4 (0.2%)	3 (0.1%)	1 (<0.1%)	0
Alcohol use	アルコール摂取	1 (<0.1%)	1 (<0.1%)		
Exposure to communicable disease	伝染病曝露	1 (<0.1%)	0		
Menopause	閉経	1 (<0.1%)	1 (<0.1%)		
Miscarriage of partner	パートナーの自然流産	1 (<0.1%)	0	1 (<0.1%)	0
Stress at work	職場でのストレス	0	1 (<0.1%)		
Surgical and medical procedures	外科および内科処置	6 (0.2%)	5 (0.2%)		
Abortion induced	人工流産	2 (<0.1%)	3 (0.1%)		
Medical device removal	医療機器除去	1 (<0.1%)	1 (<0.1%)		
Radical neck dissection	根治的頚部郭清術	1 (<0.1%)	0		
Spinal laminectomy	脊椎椎弓切除	1 (<0.1%)	0		
Tooth extraction	抜歯	1 (<0.1%)	1 (<0.1%)		
Vascular disorders	血管障害	279 (11.6%)	310 (12.9%)	51 (2.1%)	81 (3.4%)
Aortic aneurysm	大動脈瘤	2 (<0.1%)	6 (0.2%)		
Aortic aneurysm rupture	大動脈瘤破裂	0	2 (<0.1%)		
Aortic arteriosclerosis	大動脈硬化症	2 (<0.1%)	2 (<0.1%)		
Aortic calcification	大動脈石灰化	1 (<0.1%)	3 (0.1%)		
Aortic dilatation	大動脈拡張	2 (<0.1%)	4 (0.2%)		
Aortic dissection	大動脈解離	2 (<0.1%)	0		
Aortic thrombosis	大動脈血栓症	1 (<0.1%)	1 (<0.1%)		
Arterial disorder	動脈障害	1 (<0.1%)	0		
Arterial haemorrhage	動脈出血	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Arterial stenosis	動脈狭窄	1 (<0.1%)	0		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Arteriosclerosis	動脈硬化症	1 (<0.1%)	1 (<0.1%)		
Circulatory collapse	循環虚脱	1 (<0.1%)	2 (<0.1%)		
Collateral circulation	側副血行	6 (0.2%)	7 (0.3%)	1 (<0.1%)	1 (<0.1%)
Deep vein thrombosis	深部静脈血栓症	1 (<0.1%)	0		
Distributive shock	血液分布異常性ショック	0	1 (<0.1%)		
Embolism arterial	動脈塞栓症	0	1 (<0.1%)		
Extremity necrosis	四肢壊死	0	1 (<0.1%)		
Flushing	潮紅	0	4 (0.2%)	0	1 (<0.1%)
Haematoma	血腫	65 (2.7%)	101 (4.2%)	39 (1.6%)	71 (3.0%)
Hot flush	ほてり	8 (0.3%)	12 (0.5%)	2 (<0.1%)	2 (<0.1%)
Hypertension	高血圧	121 (5.0%)	91 (3.8%)	7 (0.3%)	2 (<0.1%)
Hypertensive crisis	高血圧クリーゼ	3 (0.1%)	3 (0.1%)		
Hypotension	低血圧	28 (1.2%)	21 (0.9%)		
Hypovolaemic shock	血液量減少性ショック	0	1 (<0.1%)		
Iliac artery occlusion	腸骨動脈閉塞	0	1 (<0.1%)		
Iliac artery thrombosis	腸骨動脈血栓症	0	1 (<0.1%)		
Inferior vena caval occlusion	下大静脈閉塞	1 (<0.1%)	0		
Intra-abdominal haematoma	腹腔内血腫	0	3 (0.1%)	0	2 (<0.1%)
Intra-abdominal haemorrhage	腹腔内出血	1 (<0.1%)	2 (<0.1%)	1 (<0.1%)	0
Labile blood pressure	不安定血圧	0	1 (<0.1%)		
Labile hypertension	不安定高血圧	1 (<0.1%)	0		
Lymphocele	リンパ嚢腫	1 (<0.1%)	0		
Lymphoedema	リンパ浮腫	1 (<0.1%)	0		
Orthostatic hypotension	起立性低血圧	4 (0.2%)	7 (0.3%)		
Pallor	蒼白	1 (<0.1%)	0		
Paradoxical embolism	奇異性塞栓症	1 (<0.1%)	0		
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	1 (<0.1%)	1 (<0.1%)		
Peripheral coldness	末梢冷感	2 (<0.1%)	2 (<0.1%)	0	1 (<0.1%)
Peripheral ischaemia	末梢性虚血	1 (<0.1%)	0		
Periphlebitis	静脈周囲炎	1 (<0.1%)	0		
Phlebitis	静脈炎	2 (<0.1%)	8 (0.3%)		
Phlebitis superficial	表在性静脈炎	1 (<0.1%)	1 (<0.1%)		
Poor peripheral circulation	末梢循環不良	0	1 (<0.1%)		
Post thrombotic syndrome	血栓後症候群	4 (0.2%)	2 (<0.1%)		
Raynaud's phenomenon	レイノー現象	0	1 (<0.1%)		
Subclavian steal syndrome	鎖骨下動脈スチール症候群	0	1 (<0.1%)		
Superficial vein prominence	表在静脈隆起	0	1 (<0.1%)		
Superior vena cava syndrome	上大静脈症候群	0	1 (<0.1%)		
Systolic hypertension	収縮期高血圧	0	1 (<0.1%)		
Temporal arteritis	側頭動脈炎	0	1 (<0.1%)		
Thrombophlebitis	血栓性静脈炎	4 (0.2%)	5 (0.2%)		

付表 2.7.6.2- 1 すべての有害事象及び治験薬との因果関係が否定できないすべての有害事象の発現頻度（試験 11702-PE、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		All		All study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Thrombophlebitis superficial	表在性血栓性静脈炎	4 (0.2%)	3 (0.1%)		
Thrombosis	血栓症	0	1 (<0.1%)		
Varicophlebitis	静脈瘤性静脈炎	1 (<0.1%)	0		
Varicose ulceration	静脈瘤性潰瘍	0	1 (<0.1%)		
Varicose vein	静脈瘤	4 (0.2%)	14 (0.6%)	1 (<0.1%)	0
Vasculitis	血管炎	0	1 (<0.1%)		
Vasoconstriction	血管収縮	1 (<0.1%)	0	1 (<0.1%)	0
Vasodilatation	血管拡張	2 (<0.1%)	3 (0.1%)		
Vein pain	静脈痛	5 (0.2%)	5 (0.2%)		
Vena cava thrombosis	大静脈血栓症	1 (<0.1%)	1 (<0.1%)		
Venous haemorrhage	静脈出血	1 (<0.1%)	0		
Venous insufficiency	静脈不全	11 (0.5%)	12 (0.5%)		
Venous thrombosis	静脈血栓症	0	1 (<0.1%)		
Venous thrombosis limb	四肢静脈血栓症	0	1 (<0.1%)		

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term of any primary SOC.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-1-2.sas erjli 21MAR2013 10:00
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）

Subject ID: 100013005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100013005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/50/WHITE/GERMANY/YES
Medical history	Diabetes mellitus, Hypertension, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMARYL, BISOPROLOL, COUMADIN, ENOXAPARIN, HCT, METFORMIN, WARFARIN
Adverse Events (AE) Preferred term	1. Dizziness
	2. Oedema peripheral
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES
	2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 11NOV2008 (12) - 13NOV2008 (14)
	2. 10OCT2009 (345) - 30OCT2009 (365)
Duration of AE	1. 3
	2. 21
Dose on AE onset	1.
	2.
Dose status on AE onset	1.
	2.
Action taken	1. NONE
	2. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100013009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100013009/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/59/WHITE/GERMANY/YES
Medical history	Hypertension, Osteoarthritis, Osteoarthritis, Thyroidectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC AKUT, AMLODIPIN, APPROVEL, BECLOMETASON, CLEXANE, DICLOFENAC, ENOXAPARIN, EUTHYROX, FOLAVIT, IBUHEXAL, MILFONIDE, MUCOSOLVAN SAFT, NOVALGIN, SALBUTAMOL, TRAMADOLOR, WARFARIN
Adverse Events (AE) Preferred term	1. Methylenetetrahydrofolate reductase polymorphism 2. Sensation of pressure 3. Chest pain 4. Musculoskeletal pain 5. Vein pain 6. Nasopharyngitis 7. Nasopharyngitis 8. Osteoarthritis 9. Osteoarthritis 10. Concussion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/YES/YES 10. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 20AUG2009 (9) - --------- (.) 2. 21AUG2009 (10) - 25AUG2009 (14) 3. 21AUG2009 (10) - 25AUG2009 (14) 4. 15SEP2009 (35) - 17SEP2009 (37) 5. 01OCT2009 (51) - 17NOV2009 (98) 6. 20DEC2009 (131) - 10JAN2010 (152) 7. 05FEB2010 (178) - 01MAR2010 (202) 8. 01APR2010 (233) - 16APR2010 (248) 9. 16APR2010 (248) - 19APR2010 (251) 10. 13AUG2010 (367) - 26AUG2010 (380)
Duration of AE	1. . 2. 5 3. 5 4. 3 5. 48 6. 22 7. 25

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100013009

Parameter	Value
	8. 16
	9. 4
	10. 14
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. NONE
	2. OTHER
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY,OTHER
	8. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	9. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. WORSENED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100013009

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100013015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100013015/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/36/WHITE/GERMANY/YES
Medical history	Asthma, Seasonal allergy, Iron deficiency anaemia, Obesity, Raynaud's phenomenon
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, DICLOFENAC, ENOXAPARIN, FERRO SANOL, INUVAIR SPRAY, SALBUTAMOL, UNKNOWN ANTIBIOTICS, UNKNOWN CONTRACEPTION PILL, WARFARIN
Adverse Events (AE) Preferred term	1. Headache 2. Cough 3. Arthralgia 4. Arthritis 5. Cyst 6. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 20DEC2010 (47) - 20DEC2010 (47) 2. 20DEC2010 (47) - 30DEC2010 (57) 3. 26JAN2011 (84) - 23FEB2011 (112) 4. 26JAN2011 (84) - 24FEB2011 (113) 5. 14FEB2011 (103) - 24FEB2011 (113) 6. 20APR2011 (168) - 31MAY2011 (209)
Duration of AE	1. 1 2. 11 3. 29 4. 30 5. 11 6. 42
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100013015

Parameter	Value
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100023006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100023006/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/19/WHITE/GERMANY/YES
Medical history	Hypothyroidism, Pleurisy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTAN, IBUPROFEN, NOVALGIN, PANTOZOL, PARACETAMOL, TAVANIC, TRAMAL
Adverse Events (AE) Preferred term	1. Pneumonia
	2. Pneumonia
	3. Pneumonia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
	2. MILD/NO/NO/YES
	3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 23MAR2009 (23) - 28MAR2009 (28)
	2. 28MAR2009 (28) - 03APR2009 (34)
	3. 03APR2009 (34) - 24APR2009 (55)
Duration of AE	1. 6
	2. 7
	3. 22
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. WORSENED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100023008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100023008/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/50/WHITE/GERMANY/YES
Medical history	Thrombocytopenia, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARIXTRA, ENOXAPARIN, METFORMIN, NOVALGIN, TRAMAL, WARFARIN
Adverse Events (AE) Preferred term	1. Pleurisy
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 03NOV2009 (83) - 07NOV2009 (87)
Duration of AE	1. 5
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100023009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100023009/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/69/WHITE/GERMANY/YES
Medical history	Hypertension, Anaemia macrocytic, Skin ulcer, Pneumonia, Venous insufficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMPHO-MORONAL, AUGMENTAN, BIFITERAL, DELIX, DIPIDOLOR, KLACID, TAZOBAC
Adverse Events (AE) Preferred term	1. Constipation
	2. Epistaxis
	3. Multiple myeloma
	4. Thrombocytopenia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. SEVERE/NO/NO/YES
	3. SEVERE/NO/YES/YES
	4. SEVERE/NO/NO/YES
Start/stop date of event with relative date	1. 24OCT2009 (2) - 24OCT2009 (2)
	2. 01APR2010 (161) - 01APR2010 (161)
	3. 01APR2010 (161) - --------- (.)
	4. 01APR2010 (161) - --------- (.)
Duration of AE	1. 1
	2. 1
	3. .
	4. .
Dose on AE onset	1. 15 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED PERMANENTLY
	3. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100023009

Parameter	Value
	4. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100033011/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/64/WHITE/GERMANY/YES
Medical history	Chronic obstructive pulmonary disease, Gastritis, Hypertension, Transient ischaemic attack, Tachyarrhythmia, Renal failure chronic, Hyperlipidaemia, Venous insufficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLSALICYLIC ACID, AMLODIPIN, ENOXAPARIN, RAMIPRIL, RAMIPRIL COMP, SIMVAHEXAL, SYMBICORT, WARFARIN
Adverse Events (AE) Preferred term	1. Headache 2. Dermatitis 3. Skin ulcer
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --JAN2009 (.) - 18FEB2009 (366) 2. 08SEP2008 (203) - 16SEP2008 (211) 3. 08SEP2008 (203) - 16SEP2008 (211)
Duration of AE	1. . 2. 9 3. 9
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. OTHER 3. OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033030

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100033030/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/75/WHITE/GERMANY/YES
Medical history	Back pain, Depression, Gastrooesophageal reflux disease, Hypertension, Myocardial infarction, Prostate cancer, Prostatectomy, Hyperlipidaemia, Cataract operation, Coronary artery disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC, BISOPROLOL, CARMEN, CLEXANE, EBRANTIL, IBUPROFEN, IRENAT, LEXOTANIL, MEBEMERCK, MOVICOL, NOVALGIN, OMEPRAZOL, RAMIPRIL, RAMIPRIL 5 PLUS, SIMVASTATIN, UNACID, UNAZID
Adverse Events (AE) Preferred term	1. Constipation 2. Hypertensive crisis 3. Bile duct stone 4. Osteoarthritis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 07NOV2008 (1) - 13NOV2008 (7) 2. 20NOV2008 (14) - 21NOV2008 (15) 3. 13JUL2009 (249) - 14JUL2009 (250) 4. 27OCT2009 (355) - --------- (.)
Duration of AE	1. 7 2. 2 3. 2 4. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. I 4. .
Action taken	1. REMEDIAL DRUG THERAPY 2. OTHER 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 4. OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033030

Parameter	Value
	4. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033034

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100033034/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/39/WHITE/GERMANY/YES
Medical history	Obesity, Glaucoma surgery, Glaucoma surgery
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, FRAGMIN P FORTE, FRESH FROZEN PLASMA, GRIPPOSTAD [PARACETAMAL, ASCORBIC ACID, CAFFEINE, CHLORPHENAMINMALEAT], MEDINAIT, OMEPRAZOL, PARACETAMOL, VALETTE, VOLTAREN
Adverse Events (AE) Preferred term	1. Menorrhagia 2. Leukopenia 3. Uterine leiomyoma 4. Nasopharyngitis
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 01FEB2009 (20) - 02FEB2009 (21) 2. 02FEB2009 (21) - --------- (.) 3. 25FEB2009 (44) - 06MAR2009 (53) 4. 01SEP2009 (232) - 06SEP2009 (237)
Duration of AE	1. 2 2. . 3. 10 4. 6
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 20 mg
Dose status on AE onset	1. I 2. I 3. I 4. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 2. NONE 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. INSUFFICIENT FOLLOW-UP 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033034

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033035

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100033035/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/69/WHITE/GERMANY/YES
Medical history	Renal cyst, Cystitis, Gastritis, Hiatus hernia, Hypertension, Factor V Leiden mutation, Deep vein thrombosis, Deep vein thrombosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CEFAZOLIN, CLEXANE, GENTAMYCIN, INFECTOTRIMET, MARCUMAR, MONO EMBOLEX, MOVICOL, NEXIUM, RULID, UNACID
Adverse Events (AE) Preferred term	1. Blood alkaline phosphatase decreased 2. Urinary tract disorder 3. Urinary tract disorder
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 12MAY2009 (68) - 10JUN2009 (97) 2. 26AUG2009 (174) - 01SEP2009 (180) 3. 08OCT2009 (217) - 18OCT2009 (227)
Duration of AE	1. 30 2. 7 3. 11
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. I 3. I
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033037

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100033037/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/67/WHITE/GERMANY/YES
Medical history	Diabetes mellitus, Hiatus hernia, Hip arthroplasty, Hypertension, Obesity, Osteoarthritis, Benign prostatic hyperplasia, Varicose vein, Hyperlipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLCYSTEIN, DELIX, DIAZEPAM, ENOXAPARIN, IBUPROFEN, INDOMETACIN, IRENAT, LACTULOSE, NEXIUM, NOVALGIN, PERENTEROL, SORTIS, TARGIN, UNACID, VOLTAREN, WARFARIN
Adverse Events (AE) Preferred term	1. Osteoarthritis 2. Osteoarthritis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 10DEC2009 (274) - 01MAR2010 (355) 2. 02MAR2010 (356) - 15MAR2010 (369)
Duration of AE	1. 82 2. 14
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033044

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100033044/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/72/WHITE/GERMANY/YES
Medical history	Atrioventricular block, Cardiac failure chronic, Cardiomyopathy, Depression, Hypertension, Temporal arteritis, Thrombophlebitis, Venous insufficiency, Heart valve incompetence
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTONE [SPIRONOLACTONE], ANTRA MUPS, ATACAND [CANDESARTAN], CIPRAMIL, CITALOPRAM, CONCOR, COTRIM FORTE, DECORTIN, FOSAMAX, FUROSEMID, GLUCOSE 12%, GLUCOSE 40%, GLUCOSE 5%, INSULIN, ISOPTIN, LASIX, MOVICOL, NATRIUMBICARBONAT, NATRIUMCHLORIDE 0.9%, NEXIUM, NOCTAMID, OXYGENIUM, RESONIUM, TOREM, TRANXILIUM, VITAMINE B1
Adverse Events (AE) Preferred term	1. Tachyarrhythmia 2. Tremor 3. Blood potassium increased 4. Insomnia 5. Dysuria 6. Panic attack
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 17AUG2009 (12) - --------- (.) 2. 30AUG2009 (25) - --------- (.) 3. 05NOV2009 (92) - 11NOV2009 (98) 4. 05NOV2009 (92) - 10NOV2009 (97) 5. 09NOV2009 (96) - 11NOV2009 (98) 6. 30MAR2010 (237) - --------- (.)
Duration of AE	1. . 2. . 3. 7 4. 6 5. 3 6. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033044

Parameter	Value
	5. I
	6. .
Action taken	1. NONE
	2. NONE
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033047

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100033047/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/44/WHITE/GERMANY/YES
Medical history	Appendicectomy, Caesarean section, Carpal tunnel decompression, Cholecystectomy, Hypertension, Nervousness, Thrombosis, Meniscus operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLIN, BALDRIAN, BAYOTENSIN, BISOPROLOL, CODEIN, CONCOR, ENOXAPARIN, MIDAZOLAM, NATRIUMCHLORIDE, NEXIUM, NITROLINGUAL SPRAY, NOCTAMID, NOVALGIN, ORELOX, RULID, TRANXILIUM, UNACID, WARFARIN
Adverse Events (AE) Preferred term	1. Diverticulum 2. Hypertensive crisis 3. Hypertensive crisis 4. Liver function test abnormal 5. Platelet count increased 6. International normalised ratio decreased 7. Pyelonephritis 8. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/YES/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 23OCT2009 (3) - --------- (.) 2. 24OCT2009 (4) - 24OCT2009 (4) 3. 31OCT2009 (11) - 05NOV2009 (16) 4. 31OCT2009 (11) - 04NOV2009 (15) 5. 31OCT2009 (11) - --------- (.) 6. 31OCT2009 (11) - 13NOV2009 (24) 7. 28NOV2009 (39) - 01DEC2009 (42) 8. 22DEC2009 (63) - 23DEC2009 (64)
Duration of AE	1. . 2. 1 3. 6 4. 5 5. . 6. 14 7. 4 8. 2
Dose on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033047

Parameter	Value
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. IMPROVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-100033047[1)]	HYPERTENSIVE CRISIS（PT：高血圧クリーゼ） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、合併症（高血圧）によるものであり、エノキサパリン又はワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033053

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100033053/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/75/WHITE/GERMANY/YES
Medical history	Asthma, Cataract, Cataract, Chronic obstructive pulmonary disease, Hyperlipidaemia, Hypertension, Pneumonia, Polyneuropathy, Prostatic adenoma, Renal cyst, Spinal osteoarthritis, Pain, Varicose vein operation, Spinal operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMITRIPTYLIN, ANTRA, B-KOMPLEX, CIPRAMIL, CLEXANE, COMBACTAM, CONCOR, CRATAEGUTT NOVO, DELIX, IBUPROFEN, KALIUM MAGNESIUM, KELTICAN FORTE, KELTICAN N, KLACID, LOPRESOR MITE, MOVICOL, NEXIUM, NOVALGIN, PANTOZOL, PIPRIL, PLAVIX 75, RAMIPRIL 5, ROXIHEXAL, RULID, SAB SIMPLEX, SEVREDOL, SIMVASTATIN, SPASMEX 30, SPIRIVA, SYMBICORT, TARGIN, TAVANIC
Adverse Events (AE) Preferred term	1. Tinnitus 2. Bronchitis 3. Coronary artery disease 4. Nasopharyngitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JUN2010 (.) - --JUN2010 (.) 2. 25JUN2010 (54) - 28JUN2010 (57) 3. 25NOV2010 (207) - 27NOV2010 (209) 4. 18FEB2011 (292) - 28FEB2011 (302)
Duration of AE	1. . 2. 4 3. 3 4. 11
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. 2. . 3. I 4. .
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033053

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033056

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100033056/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/37/WHITE/GERMANY/YES
Medical history	C-reactive protein increased, Cardiac pacemaker insertion, Gastritis erosive, Hyperkalaemia, Hypertension, Multiple sclerosis, Obesity, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC 600, AVALOX, COMBACTAM, CORTISON, CPS POWDER, DELIX 5, ENOXAPARIN, HEPARIN, IRENAT, MARCUMAR, MUCOSOLVAN, NEXIUM 20, NOVALGIN, OMEP 10, ORELOX 200, PANTOZOL, PERFALGAN, PIPRIL 4, RAMIPRIL, RULID, SULTANOL, TORASEMID, TRANXILIUM, UNACID, WARFARIN
Adverse Events (AE) Preferred term	1. Pneumonia 2. C-reactive protein increased 3. Medical device complication 4. Atrial thrombosis 5. Implant site thrombosis 6. Cardiac failure 7. Pyrexia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 19AUG2010 (45) - 26AUG2010 (52) 2. 26AUG2010 (52) - 27AUG2010 (53) 3. 16DEC2010 (164) - 03FEB2011 (213) 4. 16DEC2010 (164) - 27JAN2011 (206) 5. 24JAN2011 (203) - 07FEB2011 (217) 6. 18MAY2011 (317) - 28JUL2011 (388) 7. 21JUL2011 (381) - 27JUL2011 (387)
Duration of AE	1. 8 2. 2 3. 50 4. 43 5. 15 6. 72 7. 7
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100033056

Parameter	Value
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100053009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100053009/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/29/WHITE/GERMANY/YES
Medical history	Cough
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC AKUT, ALVESCO, CAPVAL, DOLODOBENDAN, GRIPPOSTAD [ASCORBIC ACID, CAFFEINE, CHLORPHENAMINE MALEAT AND PARACETAMOL], GRIPPOSTAD [INGREDIENTS ARE ASCORBIC ACID, CAFFEINE, CHLORPHENAMINE MALEAT AND P, IBUPROFEN, NOVALGIN, PANTOZOL, SILOMAT DMP
Adverse Events (AE) Preferred term	1. Miscarriage of partner 2. Cholestasis 3. Headache 4. Nasopharyngitis 5. Back pain 6. Nasopharyngitis
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MODERATE/YES/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --MAR2009 (.) - 20MAR2009 (142) 2. 01DEC2008 (33) - --------- (.) 3. 11DEC2008 (43) - 11DEC2008 (43) 4. 05JAN2009 (68) - 10JAN2009 (73) 5. 22FEB2009 (116) - 22FEB2009 (116) 6. 23MAR2009 (145) - 27MAR2009 (149)
Duration of AE	1. . 2. . 3. 1 4. 6 5. 1 6. 5
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. . 5. . 6. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100053009

Parameter	Value
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100063007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/69/WHITE/GERMANY/YES
Medical history	Breast cancer, Spinal osteoarthritis, Hyperlipidaemia, Hypertension, Hysterectomy, Lymphoma, Obesity, Cerebrovascular accident, Cholelithiasis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BALDRIAN, CAPVAL, ENOXAPARIN, HCT, INNOHEP, METOHEXAL, NASONEX, RAMIPRIL, TAMOXIFEN, VOLTAREN, WARFARIN
Adverse Events (AE) Preferred term	1. Ovarian cyst 2. Oedema peripheral 3. Pain in extremity 4. Laryngitis 5. Dyspnoea 6. Lymphadenopathy 7. Lymphoma 8. Syncope
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/YES/YES 7. MODERATE/NO/YES/YES 8. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. --JAN2009 (.) - --------- (.) 2. 10JAN2009 (54) - --JUL2009 (.) 3. 23MAR2009 (126) - 20APR2009 (154) 4. 14APR2009 (148) - 04MAY2009 (168) 5. 05JUN2009 (200) - 19JUN2009 (214) 6. 29JUN2009 (224) - 20JUL2009 (245) 7. 22OCT2009 (339) - --------- (.) 8. 04NOV2009 (352) - 04NOV2009 (352)
Duration of AE	1. . 2. . 3. 29 4. 21 5. 15 6. 22 7. . 8. 1
Dose on AE onset	1. 2. 3. 4. 5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063007

Parameter	Value
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. OTHER
	2. OTHER
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	8. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. IMPROVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063018

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100063018/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/85/WHITE/GERMANY/YES
Medical history	Cholelithiasis, Gastric ulcer, Glaucoma, Haematuria, Hepatitis, Hypertension, Polyarthritis, Polymyalgia rheumatica, Renal failure chronic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPISOL, ASS, CLEXANE, COSOPT, HYDROCHLOROTHIAZID, METOPROLOL, PANTOZOL, PLAVIX, PREDNISOLON, RAMIPRIL, SIMVASTATIN, XALATAN
Adverse Events (AE) Preferred term	1. Hyperuricaemia 2. Gout 3. Angina unstable 4. Haematoma 5. Upper gastrointestinal haemorrhage 6. Infected dermal cyst 7. Upper gastrointestinal haemorrhage 8. Renal failure acute 9. Cystitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/YES/YES/YES 4. MODERATE/YES/YES/YES 5. SEVERE/YES/YES/YES 6. MODERATE/NO/NO/YES 7. SEVERE/NO/YES/NO 8. MODERATE/NO/YES/NO 9. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --JAN2010 (.) - --------- (.) 2. 08AUG2009 (23) - 15AUG2009 (30) 3. 05DEC2009 (142) - 17DEC2009 (154) 4. 17DEC2009 (154) - 20DEC2009 (157) 5. 21DEC2009 (158) - 22DEC2009 (159) 6. 23DEC2009 (160) - 23DEC2009 (160) 7. 26DEC2009 (163) - 15JAN2010 (183) 8. 27JAN2010 (195) - 02FEB2010 (201) 9. 27JAN2010 (195) - 02FEB2010 (201)
Duration of AE	1. . 2. 8 3. 13 4. 4 5. 2 6. 1 7. 21 8. 7 9. 7
Dose on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063018

Parameter	Value
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. I
	5. .
	6. F
	7. F
	8. F
	9. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	5. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	6. OTHER
	7. REMEDIAL DRUG THERAPY,OTHER
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-100063018[1),2)]	PEPTIC ULCER DISEASE（PT：消化性潰瘍） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、時間的関連性がなく、また他の併用薬（アスピリン、クロピドグレル、プレドニゾロン)による可能性が高いことから、リバーロキサバンとの因果関係は否定できると考える。 UNSTABLE ANGINA（PT：不安定狭心症） 治験担当医はリバーロキサバンと報告事象との関連性があると判断した。弊社は、合併症（ステント処置を要した冠動脈疾患）によるものであり、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100063020/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/79/WHITE/GERMANY/YES
Medical history	Depression, Hypertension, Macular degeneration, Benign prostatic hyperplasia, Psoriasis, Intervertebral disc protrusion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASS, ATROVENT, AVALOX, CARVEDILOL, CLEXANE, ENOXAPARIN, MIRTAZAPIN, MUCOSOLVAN, SULTANOL, TAMSULOSIN, WARFARIN
Adverse Events (AE) Preferred term	1. Depression 2. Colonic polyp 3. Bronchitis 4. Bronchitis 5. Coronary artery disease 6. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/YES/YES/YES 6. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --APR2010 (.) - --------- (.) 2. 30NOV2009 (6) - --------- (.) 3. 10JAN2010 (47) - 20JAN2010 (57) 4. 20JAN2010 (57) - 23JAN2010 (60) 5. 14APR2010 (141) - 27APR2010 (154) 6. 05JUN2010 (193) - --------- (.)
Duration of AE	1. . 2. . 3. 11 4. 4 5. 14 6. .
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063020

Parameter	Value
	2. NONE 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY 5. OTHER 6. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. UNCHANGED 3. RESOLVED 4. RESOLVED 5. RESOLVED 6. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-100063020[2)]	SUSPICION OF CORONARY ARTERY DISEASE（PT：冠動脈疾患） 治験担当医はワルファリンと報告事象との関連性があると判断した。弊社は、心臓カテーテル検査により冠動脈疾患に罹患していないと判明したため、ワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100063021/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/36/WHITE/GERMANY/YES
Medical history	Hypertension, Hypothyroidism, Bundle branch block right, Cluster headache
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DIOVANE, ENOXAPARIN, IBUPROFEN, L-THYROXIN, METAMIZOL, NASIVIN, NEXIUM, WARFARIN
Adverse Events (AE) Preferred term	1. Haemoptysis 2. Nasopharyngitis 3. Lower gastrointestinal haemorrhage 4. Dyspepsia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 25JAN2010 (6) - 02FEB2010 (14) 2. 18MAR2010 (58) - --MAR2010 (.) 3. 27MAY2010 (128) - 28MAY2010 (129) 4. 28MAY2010 (129) - --------- (.)
Duration of AE	1. 9 2. . 3. 2 4. .
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. NONE 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063021

Parameter	Value
	4. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100063023/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/31/WHITE/GERMANY/YES
Medical history	Neuropathic arthropathy, Depression, Diabetic gastropathy, Diabetic retinopathy, Dyspnoea, Hypertension, Iron deficiency anaemia, Migraine, Type 1 diabetes mellitus, Renal failure chronic, Vitrectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOLODIPIN, ANTITHROMBIN 3, ENOXAPARIN, HAEMOPROTECT, IBUPROFEN, INSULIN, LAMUNA, MCP DROPS, MIRTAZAPIN, NACL 0.9%, NITROGLYCERIN, OMEPRAZOL, RAMIPRIL, UNFRACTIONATED HEPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Benign breast neoplasm 2. Eye pain 3. Menorrhagia 4. Ketoacidosis 5. Menorrhagia 6. Eye pain 7. Metrorrhagia 8. Metrorrhagia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/YES/YES 7. MILD/YES/NO/YES 8. MILD/YES/NO/YES
Start/stop date of event with relative date	1. --MAR2010 (.) - --MAR2010 (.) 2. --MAR2010 (.) - 05JUL2010 (151) 3. 05FEB2010 (1) - 05APR2010 (60) 4. 09FEB2010 (5) - 10FEB2010 (6) 5. 17MAY2010 (102) - 08JUN2010 (124) 6. 06JUL2010 (152) - 08JUL2010 (154) 7. 12JUL2010 (158) - 19JUL2010 (165) 8. 02AUG2010 (179) - --AUG2010 (.)
Duration of AE	1. . 2. . 3. 60 4. 2 5. 23 6. 3 7. 8 8. .
Dose on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063023

Parameter	Value
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. OTHER
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	7. NONE
	8. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063024

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100063024/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/33/WHITE/GERMANY/YES
Medical history	Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, IBUPROFEN, METAMIZOL, NOVALGIN, TRAMAL, WARFARIN, ZOPICLON
Adverse Events (AE) Preferred term	1. Sleep disorder 2. Liver function test abnormal 3. Craniocerebral injury 4. Joint swelling
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 08MAR2010 (4) - 09MAR2010 (5) 2. 18MAR2010 (14) - --------- (.) 3. 04MAY2010 (61) - --------- (.) 4. 27JUN2010 (115) - 28JUN2010 (116)
Duration of AE	1. 2 2. . 3. . 4. 2
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. STUDY DRUG DISCONTINUED AND RESTARTED 4. NONE
Outcome of event	1. RESOLVED 2. IMPROVED 3. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063024

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063025

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100063025/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/36/WHITE/GERMANY/YES
Medical history	Asthma, Haemorrhoids, HIV infection, Obesity, Umbilical hernia, Sleep apnoea syndrome
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ABACAVIR, ASPIRIN, LAMIVUDINE, METOCLOPRAMID, MOMETASONFURAT, NITROGLYCERIN, NOVALGIN, PANTOPROZOL, PRAVASTATIN, PROPOFOL, SIMVASTATIN, SUSTIVA
Adverse Events (AE) Preferred term	1. Hypertensive crisis 2. Somatoform disorder 3. Nausea 4. Dyslipidaemia 5. Tinea pedis 6. Rectal haemorrhage 7. Dyspnoea 8. Pain in extremity 9. Gastrointestinal haemorrhage 10. Oral fungal infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/YES/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/YES/YES/YES 10. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 15MAY2010 (5) - 15MAY2010 (5) 2. 16MAY2010 (6) - --JUN2010 (.) 3. 16MAY2010 (6) - 16MAY2010 (6) 4. 17MAY2010 (7) - --------- (.) 5. 17MAY2010 (7) - 27MAY2010 (17) 6. 07JUN2010 (28) - 07JUN2010 (28) 7. 11JUL2010 (62) - 20JUL2010 (71) 8. 11JUL2010 (62) - 20JUL2010 (71) 9. 20OCT2010 (163) - 26OCT2010 (169) 10. 24NOV2010 (198) - --------- (.)
Duration of AE	1. 1 2. . 3. 1 4. . 5. 11 6. 1 7. 10 8. 10

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063025

Parameter	Value
	9. 7
	10. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY,OTHER
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063025

Parameter	Value
	10. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-100063025[1),3)]	DYSLIPIDEMIA（PT：脂質異常症） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、肥満に起因また併発症であると判断し、リバーロキサバンとの因果関係は否定できると考える。 RECTAL BLEED（PT：直腸出血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、リバーロキサバンの抗凝固作用を考慮し、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063031

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100063031/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/61/WHITE/GERMANY/YES
Medical history	Breast cancer, Bursitis, Carpal tunnel syndrome, Diverticulum, Dermatitis contact, Vomiting, Gastrooesophageal reflux disease, Hypercholesterolaemia, Hyperthyroidism, Rectal prolapse, Syncope, Tachycardia, Vertigo, Postmenopause, Tobacco abuse
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACICLOVIR, AVALOX, BISOPROLOL, CITALOPRAM, CLEXANE, DICLOFENAC, ENOXAPARIN, FEMARA, IBUPROFEN, LACTULOSE, LORMETAZAPAN, MCP, MEPIVACANIN O.5%, MIRTAZAPIN, NOVALGIN, OMEPRAZOL, SIMVASTATIN, TRIAMCIONOLON, VOMEX, WARFARIN
Adverse Events (AE) Preferred term	1. Tenosynovitis 2. Oedema peripheral 3. Dyspnoea 4. Sinusitis 5. Syncope 6. Depressed mood 7. Dizziness 8. Nausea 9. Herpes zoster 10. International normalised ratio decreased 11. Intestinal haemorrhage 12. Intestinal haemorrhage 13. Foot fracture
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/YES/YES 10. MILD/NO/NO/YES 11. MILD/YES/NO/YES 12. MILD/YES/NO/YES 13. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --MAR2011 (.) - --------- (.) 2. --AUG2011 (.) - --------- (.) 3. 16MAR2011 (27) - 16MAR2011 (27) 4. 13MAY2011 (85) - 21MAY2011 (93) 5. 09JUN2011 (112) - 09JUN2011 (112) 6. 09JUN2011 (112) - --------- (.) 7. 09JUN2011 (112) - 16JUN2011 (119) 8. 11JUN2011 (114) - 13JUN2011 (116) 9. 12JUN2011 (115) - 20JUN2011 (123)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063031

Parameter	Value
	10. 18JUN2011 (121) - 18JUN2011 (121)
	11. 03AUG2011 (167) - 03AUG2011 (167)
	12. 15AUG2011 (179) - 15AUG2011 (179)
	13. 17SEP2011 (212) - --------- (.)
Duration of AE	1. .
	2. .
	3. 1
	4. 9
	5. 1
	6. .
	7. 8
	8. 3
	9. 9
	10. 1
	11. 1
	12. 1
	13. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100063031

Parameter	Value
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY,OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. NONE
	13. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100083005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100083005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/58/WHITE/GERMANY/YES
Medical history	Appendicectomy, Depression, Dysarthria, Glaucoma, Hypertension, Cerebrovascular accident, Tonsillectomy, Intervertebral disc protrusion, Intervertebral disc protrusion, Intervertebral disc protrusion, Intervertebral disc protrusion, Pain, Meniscus operation, Hyperlipidaemia, Hemiparesis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPHAGAN AT, ANALGESIC DRUG (TRADE NAME IS UNKNOWN), ASS, ENOXAPAPRIN, ENOXAPARIN, FLUOXETIN, KATADOLON S LONG, LIORESAL, LYRICA, OXYGESIC, SORTIS, TRAMAL, VOTUM, WARFARIN
Adverse Events (AE) Preferred term	1. Hyperventilation 2. Bone pain 3. Bone pain 4. Dyspnoea 5. Chest pain 6. Hypoaesthesia 7. Foot fracture 8. Coagulation factor VIII level increased
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 26JUL2008 (31) - 30JUL2008 (35) 2. 16OCT2008 (113) - --------- (.) 3. 23OCT2008 (120) - 25OCT2008 (122) 4. 09MAR2009 (257) - 10MAR2009 (258) 5. 09MAR2009 (257) - 10MAR2009 (258) 6. 09MAR2009 (257) - 10MAR2009 (258) 7. 15MAR2009 (263) - 15MAR2009 (263) 8. 27MAY2009 (336) - --------- (.)
Duration of AE	1. 5 2. . 3. 3 4. 2 5. 2 6. 2 7. 1 8. .
Dose on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100083005

Parameter	Value
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. OTHER
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. OTHER
	8. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-100083005[1)]	PAIN SYNDROME (SPINE) (PT：脊椎痛) 治験担当医は報告事象との因果関係評価を行っていない。弊社は、慢性疾患と判断し、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1) 治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2) 治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3) 治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4) 治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5) 治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6) 治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100083009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100083009/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/51/WHITE/GERMANY/YES
Medical history	Appendicectomy, Chest pain, Pneumonia, Sterilisation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANTRA, AVALOX, GLUCOSE 5%, MIDAZOLAM, NACL 0.9%, NOVALGIN, NOVAMINSULFON, OMBETA, PANTOPRAZOL, PARACETAMOL, STEROFUNDIN, TRAMAL
Adverse Events (AE) Preferred term	1. Vertigo 2. Diarrhoea haemorrhagic 3. Pyrexia 4. Nausea 5. Menorrhagia 6. Back pain 7. Chest pain 8. Dyspnoea 9. Menorrhagia 10. Menorrhagia 11. Tachycardia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/YES/NO/YES 10. MODERATE/YES/NO/YES 11. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --JAN2010 (.) - --------- (.) 2. 11JAN2009 (4) - 13JAN2009 (6) 3. 11JAN2009 (4) - 13JAN2009 (6) 4. 11JAN2009 (4) - 14JAN2009 (7) 5. 22MAR2009 (74) - 23MAR2009 (75) 6. 05MAY2009 (118) - 14MAY2009 (127) 7. 05MAY2009 (118) - 14MAY2009 (127) 8. 05MAY2009 (118) - 14MAY2009 (127) 9. 05AUG2009 (210) - 07AUG2009 (212) 10. 09SEP2009 (245) - 10SEP2009 (246) 11. 11JAN2010 (369) - 11JAN2010 (369)
Duration of AE	1. . 2. 3 3. 3 4. 4 5. 2

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100083009

Parameter	Value
	6. 10
	7. 10
	8. 10
	9. 3
	10. 2
	11. 1
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. I
	10. .
	11. F
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. STUDY DRUG DISCONTINUED AND RESTARTED
	10. STUDY DRUG DISCONTINUED AND RESTARTED
	11. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100083009

Parameter	Value
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-100083009[4)]	BLOODY DIARRHOEA（PT：血性下痢） 治験担当医は、併発症と考え、否定できると判断した。弊社は、リバーロキサバンの抗凝固作用を考慮し、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100093010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100093010/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/80/WHITE/GERMANY/YES
Medical history	Cardiac failure chronic, Blood creatine phosphokinase increased, Hypertension, Hyperuricaemia, Spinal osteoarthritis, Urinary tract infection, Renal failure chronic, Dyslipidaemia, Cerebrovascular insufficiency, Constipation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, BISACODYL, BRISERIN N (RESERPIN / CLOPAMID), CEFUROXIM, FUROSEMID, KALINOR BRAUSE, KCL, LACTULOSE, LAXANS, NACL, UNACID
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Lumbar vertebral fracture 3. Cholecystitis infective 4. Infectious peritonitis 5. Sepsis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. SEVERE/NO/YES/NO 4. SEVERE/NO/YES/NO 5. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 26JUN2008 (28) - 04JUL2008 (36) 2. 04JUL2008 (36) - 10JUL2008 (42) 3. 14JUL2008 (46) - --------- (.) 4. 15JUL2008 (47) - --------- (.) 5. 17JUL2008 (49) - 13AUG2008 (76)
Duration of AE	1. 9 2. 7 3. . 4. . 5. 28
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. F 3. F 4. F 5. F
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER 3. REMEDIAL DRUG THERAPY,OTHER 4. REMEDIAL DRUG THERAPY 5. NONE
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100093010

Parameter	Value
	2. RESOLVED
	3. UNCHANGED
	4. UNCHANGED
	5. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100093025

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100093025/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/72/WHITE/GERMANY/YES
Medical history	Cardiac failure chronic, Cholecystectomy, Diabetes mellitus, Haemangioma of liver, Hypertension, Iron deficiency, Pulmonary hypertension, Coronary arterial stent insertion, Coronary artery disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BISACODYL, BISOPROLOL, DYTIDE H (TRIAMTEREN/HYDROCHLOROTHIAZID), EISENDRAGEES, ENOXAPARIN, GLIBENCLAMID, ISDN, METOCLOPRAMID, RAMIPRIL, SIMVASTATIN, WARFARIN
Adverse Events (AE) Preferred term	1. Tumour haemorrhage 2. Gastric neoplasm 3. Metastatic gastric cancer 4. Haemorrhoids 5. Colonic polyp
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/YES/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 08JUN2009 (133) - --------- (.) 2. 08JUN2009 (133) - --JUN2009 (.) 3. 08JUN2009 (133) - --------- (.) 4. 08JUN2009 (133) - --------- (.) 5. 08JUN2009 (133) - --------- (.)
Duration of AE	1. . 2. . 3. . 4. . 5. .
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 2. NONE 3. STUDY DRUG DISCONTINUED PERMANENTLY 4. NONE 5. NONE
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. DEATH

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100093025

Parameter	Value
	3. INSUFFICIENT FOLLOW-UP 4. UNCHANGED 5. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-100093025[4)]	GASTRIC TUMOR BLEEDING（PT：腫瘍出血） 治験担当医は、因果関係は否定できると判断した。弊社は、ワルファリンの抗凝固作用を考慮すると、因果関係は否定できない。また、合併症（胃腺癌）によるものとも考えられる。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100093042

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100093042/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/22/WHITE/GERMANY/YES
Medical history	Pneumonia, Rheumatoid arthritis, Back pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBROXOL, ATOSIL, ATROPIN, AVALOX, CALCICARE D3, CEFTRIAXON, CEFUROXIM, CERTOPARIN, ENOXAPARIN, FOLINSÄURE (FOLIC-ACID), IBEROGAST, JONOSTERIL, MCP (METOCLOPRAMID), METHOTREXAT, METOPROLOL, MIDAZOLAM, NOVAMINSULFON, OMEP, PARACETAMOL, PARACODIN, PREDNISOLON, RANITIDIN, RINGER-LACTAT, TRAMAL, VALETTE (ETHIMYLESTRADIOL / DIENOGEST), VOMEX A (DIMENHYDRINAT), WARFARIN, XYLOCAIN [LIDOCAIN ALONE]
Adverse Events (AE) Preferred term	1. Factor II mutation 2. Pneumonia 3. Anxiety disorder 4. Gastritis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 06AUG2009 (6) - --------- (.) 2. 08AUG2009 (8) - 18AUG2009 (18) 3. 20AUG2009 (20) - --------- (.) 4. 15SEP2009 (46) - 18SEP2009 (49)
Duration of AE	1. . 2. 11 3. . 4. 4
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY,OTHER 4. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. RESOLVED 3. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100093042

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100093050

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100093050/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/55/WHITE/GERMANY/YES
Medical history	Haemorrhoids
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Prostate cancer
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 24FEB2010 (51) - 29APR2010 (115)
Duration of AE	1. 65
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100093056

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100093056/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/81/WHITE/GERMANY/YES
Medical history	Gastritis, Cardiac failure chronic, Constipation, Hypertension, Hyperuricaemia, Pneumonia, Pulmonary hypertension, Renal failure, Sleep disorder, Spinal osteoarthritis, Cholelithiasis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, ASPIRIN, BISACODYL, CEFTRIAXON, CHOLSPASMIN FORTE, ENOXAPARIN, FUROSEMID, HYDRCHLOROTHIAZID, JONOSTERIL, LACTULOSE, LANITOP, METOCLOPRAMID, MIDAZOLAM, NOVAMINSULFON, OMEPRAZOL, RAMIPRIL, RANITIDIN, RINGER LACTAT, VERAPAMIL, WARFARIN, ZOPICLON
Adverse Events (AE) Preferred term	1. Gastritis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 17AUG2010 (23) - 20AUG2010 (26)
Duration of AE	1. 4
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100103003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100103003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/55/WHITE/GERMANY/YES
Medical history	Bursa removal, Dupuytren's contracture, Dupuytren's contracture, Epilepsy, Intervertebral disc protrusion, Intervertebral disc operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BRONCHIPRET, CLARITHROMYCIN, ENOXAPARIN, MONO-EMBOLEX, NOVALGIN, PANTOZOL, VOLAREN RESINAT, VOLTAREN, VOLTAREN RESINAT, WARFARIN, ZENTROPIL
Adverse Events (AE) Preferred term	1. Headache 2. Bronchitis 3. Nasopharyngitis 4. Traumatic haematoma 5. Traumatic haematoma 6. Rectal polyp
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/YES/NO/YES 5. MODERATE/YES/YES/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 07OCT2008 (8) - 20OCT2008 (21) 2. 20OCT2008 (21) - 29OCT2008 (30) 3. 20OCT2008 (21) - 29OCT2008 (30) 4. 05DEC2008 (67) - 07DEC2008 (69) 5. 07DEC2008 (69) - 19DEC2008 (81) 6. 30MAR2009 (182) - 30MAR2009 (182)
Duration of AE	1. 14 2. 10 3. 10 4. 3 5. 13 6. 1
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100103003

Parameter	Value
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. WORSENED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100103005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100103005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/24/WHITE/GERMANY/YES
Medical history	Asthma, Appendicectomy, Attention deficit/hyperactivity disorder, Horner's syndrome, Pneumonia, Gastrooesophageal reflux disease, Venous thrombosis limb, Syncope, Syncope, Syncope
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ALT-INSULIN, ATROVENT, AVALOX, BRICANYL, BRONCHOSPASMIN, COMBACTAM, DECORTIN H, DIMENHYDRINAT, DIPIPERON, ENOXAPARIN, EPINEPHRIN, ESKETAMINE, FORADIL, FUROSEMID, HEPARIN, IBUPROFEN, KCL, KETANEST, LAXOBERAL, LORAZEPAM EXPIDET, LYSTHERON, MCP, MCP PASPERTIN, MIDAZOLAM, MORPHIN, MOXIFLOXACIN, NACL, NATRIUMBICARBONAT, NATRIUMCHLORID, NORADRENALIN, NOVALGIN, PANCOURONIUM, PANTOPRAZOL, PANTOZOL, PANTOZOL 20, PANTOZOL 40, PARACEFAN, PARACETAMOL, PERFALGAN, PIPERACILLIN, PREDNISOLON, PROPOFOL, RANITIC, RANITIDIN, RINGER INFUSION, ROXITHROMYCIN, SALBUTAMOL ON DEMAND, SOLODECORTIN H, SOLU-DECORTIN H, SPIRIVA, SUFENTA, SULTANOL, TAVOR EXPEDIT, TAVOR [LORAZEPAM], TAZOBAC, TRAMAL, VALORON, VIANI 50/250, VOLTAREN RESINAT, ZANTIC
Adverse Events (AE) Preferred term	1. Pneumonia 2. Hyperglycaemia 3. Bronchospasm 4. Hyperkalaemia 5. Labile blood pressure 6. Oedema 7. Constipation 8. Nasopharyngitis 9. Gastrooesophageal reflux disease
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 08FEB2009 (35) - 20FEB2009 (47) 2. 08FEB2009 (35) - 12FEB2009 (39) 3. 08FEB2009 (35) - 20FEB2009 (47) 4. 08FEB2009 (35) - 10FEB2009 (37) 5. 08FEB2009 (35) - 10FEB2009 (37) 6. 10FEB2009 (37) - 10FEB2009 (37) 7. 11FEB2009 (38) - 11FEB2009 (38) 8. 13APR2009 (99) - 22APR2009 (108) 9. 14AUG2009 (222) - --------- (.)
Duration of AE	1. 13 2. 5

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100103005

Parameter	Value
	3. 13
	4. 3
	5. 3
	6. 1
	7. 1
	8. 10
	9. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100103005

Parameter	Value
	9. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100103012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100103012/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/54/WHITE/GERMANY/YES
Medical history	Hypertension, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CONCOR, DUPHASTON, LAMUNA, NORVASC, TARDYFERON
Adverse Events (AE) Preferred term	1. Vaginal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 14JUL2010 (125) - 28JUL2010 (139)
Duration of AE	1. 15
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100103020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100103020/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/35/WHITE/GERMANY/YES
Medical history	Drug dependence, Hepatitis C, Sleep disorder, Thrombosis, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACOIN, AMOCILLIN, BAYOTENSIN, BISOPROLOL, CLEXANE, CLINDA- HEXAL, DORMICUM, DOXEPIN, DOXIPIN, IBUPROFEN, LIDOCAIN, MAGNESIUM, MARCUMAR, NOVALGIN, OMEPRAZOL, PANTOZOL, POLAMIDON, PROPOFOL, PROPRANOLOL, SAB SIMPLEX, SUCRALFAT, UNACID PD
Adverse Events (AE) Preferred term	1. Headache 2. Toothache 3. Dyspnoea 4. Hypertension 5. Chest pain 6. Haemoptysis 7. Haemoptysis 8. Chest pain 9. Gastrooesophageal reflux disease 10. Pain in extremity 11. Lower respiratory tract inflammation 12. Petechiae 13. Poor dental condition 14. Polyp 15. Portal hypertensive gastropathy 16. Varices oesophageal 17. Helicobacter gastritis 18. Headache
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. SEVERE/NO/NO/YES 6. MILD/YES/NO/YES 7. MILD/YES/YES/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/YES/NO/YES 13. SEVERE/NO/NO/YES 14. MILD/NO/NO/YES 15. MILD/YES/NO/YES 16. MILD/YES/NO/YES 17. MILD/NO/NO/YES 18. MILD/NO/NO/NO

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100103020

Parameter	Value
Start/stop date of event with relative date	1. 23FEB2011 (1) - 23FEB2011 (1) 2. 20MAR2011 (26) - 25MAR2011 (31) 3. 09APR2011 (46) - 12APR2011 (49) 4. 12APR2011 (49) - 12APR2011 (49) 5. 11JUL2011 (139) - 05AUG2011 (164) 6. 25JUL2011 (153) - 05AUG2011 (164) 7. 19AUG2011 (178) - 07SEP2011 (197) 8. 19AUG2011 (178) - --AUG2011 (.) 9. 21AUG2011 (180) - --------- (.) 10. 22AUG2011 (181) - 22AUG2011 (181) 11. 25AUG2011 (184) - --------- (.) 12. 26AUG2011 (185) - --------- (.) 13. 26AUG2011 (185) - --------- (.) 14. 26AUG2011 (185) - --------- (.) 15. 29AUG2011 (188) - --------- (.) 16. 29AUG2011 (188) - --------- (.) 17. 29AUG2011 (188) - --------- (.) 18. 04SEP2011 (194) - 04SEP2011 (194)
Duration of AE	1. 1 2. 6 3. 4 4. 1 5. 26 6. 12 7. 20 8. . 9. . 10. 1 11. . 12. . 13. . 14. . 15. . 16. . 17. . 18. 1
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg 8. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100103020

Parameter	Value
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. I
	16. I
	17. I
	18. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY,OTHER
	3. OTHER
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. OTHER
	8. NONE
	9. REMEDIAL DRUG THERAPY,OTHER
	10. NONE
	11. NONE
	12. NONE
	13. NONE
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100103020

Parameter	Value
	17. NONE
	18. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. INSUFFICIENT FOLLOW-UP
	10. RESOLVED
	11. INSUFFICIENT FOLLOW-UP
	12. INSUFFICIENT FOLLOW-UP
	13. INSUFFICIENT FOLLOW-UP
	14. INSUFFICIENT FOLLOW-UP
	15. INSUFFICIENT FOLLOW-UP
	16. INSUFFICIENT FOLLOW-UP
	17. INSUFFICIENT FOLLOW-UP
	18. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100223005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100223005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/85/WHITE/GERMANY/YES
Medical history	Anaemia, Chronic obstructive pulmonary disease, Chronic obstructive pulmonary disease, Hypertension, Hyperthyroidism, Hyperuricaemia, Pneumonia, Renal failure chronic, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, AVALOX, BERODUAL, BIFITERAL, DIGITOXIN, ENOXAPARIN, FURESE, FURORESE, IRENAT, KALINOR BT, PANTOZOL, PREDNISOLON, SPIRIVA, TAVOR [LORAZEPAM], TAZOBAC, URBASON, VERAHEXAL
Adverse Events (AE) Preferred term	1. Tachyarrhythmia 2. Pulmonary oedema 3. Chronic obstructive pulmonary disease 4. Pneumonia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 15JAN2009 (1) - 15JAN2009 (1) 2. 16JAN2009 (2) - --------- (.) 3. 16JAN2009 (2) - 16JAN2009 (2) 4. 17JAN2009 (3) - 19JAN2009 (5)
Duration of AE	1. 1 2. . 3. 1 4. 3
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. NONE
Outcome of event	1. RESOLVED 2. IMPROVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100223005

Parameter	Value
	4. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100223031

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100223031/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/GERMANY/YES
Medical history	Renal failure acute, Cerebrovascular accident, Basal cell carcinoma, Colitis, Depression, Drug abuse, Hypertension, Hyperthyroidism, Obesity, Spinal osteoarthritis, Thyroid neoplasm, Postmenopause, Bone pain, Varicophlebitis, Restless legs syndrome, Hyperlipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPIN, ASS 100, FENTANYL, GABAPENTIN, IRENAT, METOHEXAL, MOXOBETA, PALLADON RETARD, PANTOZOL, RAMIPRIL PLUS, REMERGIL
Adverse Events (AE) Preferred term	1. Gastritis 2. Cholelithiasis 3. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 26MAY2009 (8) - --------- (.) 2. 27MAY2009 (9) - --------- (.) 3. 03JUN2009 (16) - 05JUN2009 (18)
Duration of AE	1. . 2. . 3. 3
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. NONE 2. NONE 3. OTHER
Outcome of event	1. UNCHANGED 2. UNCHANGED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100223046

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100223046/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/64/WHITE/GERMANY/YES
Medical history	Atrial fibrillation, Hypertension, Renal cyst, Renal cyst, Tinnitus, Varicose vein
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATACAND [CANDESARTAN CILEXETIL ALONE], CONCOR, CORDAREX, ENOXAPARIN, TRENTAL 600, WARFARIN
Adverse Events (AE) Preferred term	1. Atrial fibrillation
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 26FEB2010 (221) - 02MAR2010 (225)
Duration of AE	1. 5
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100223055

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100223055/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/67/WHITE/GERMANY/YES
Medical history	Anal cancer, Diverticulum intestinal, Hypercholesterolaemia, Metastases to lymph nodes, Sleep disorder, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	5-FOLIN ACID, ENOXAPARIN, LENDORMIN, MITOMYCIN, SIMVASTATIN, WARFARIN
Adverse Events (AE) Preferred term	1. Rectal haemorrhage 2. Pancytopenia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/NO/NO 2. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 02OCT2009 (32) - --------- (.) 2. 02OCT2009 (32) - --------- (.)
Duration of AE	1. . 2. .
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. NONE 2. NONE
Outcome of event	1. UNCHANGED 2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100223056

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100223056/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/86/WHITE/GERMANY/YES
Medical history	Osteoarthritis, Arteriosclerosis, Cough, Hypertension, Bundle branch block left, Osteoporosis, Pain in extremity, Cataract, Type 2 diabetes mellitus, Micturition urgency, Postmenopause, Hyperlipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTONEL, ARCOXIA, ASS, ATACAND [CANDESARTAN CILEXETIL], BELOC ZOK MITE, CALCILAC KT, CLONT, DELIX, DRIDASE, ENOXAPARIN, JURNISTA, NOVALGIN, PREDNISOLON, TOREM, TRYASOL, WARFARIN
Adverse Events (AE) Preferred term	1. Anaemia 2. Appendicitis 3. Impaired healing 4. Small intestinal perforation 5. Acute myocardial infarction
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. SEVERE/NO/YES/NO 4. SEVERE/NO/YES/NO 5. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 12OCT2009 (4) - --------- (.) 2. 23FEB2010 (138) - 24FEB2010 (139) 3. 25FEB2010 (140) - 07MAR2010 (150) 4. 14MAR2010 (157) - 22MAR2010 (165) 5. 15MAR2010 (158) - 07MAY2010 (211)
Duration of AE	1. . 2. 2 3. 11 4. 9 5. 54
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER 3. REMEDIAL DRUG THERAPY,OTHER 4. OTHER 5. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100223056

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100223057

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100223057/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/76/WHITE/GERMANY/YES
Medical history	Ascites, Mammoplasty, Hypertension, Macular degeneration, Night sweats, Constipation, Splenomegaly, Hepatic steatosis, Uterine leiomyoma, Pancreas lipomatosis, Postmenopause, Cataract operation, Myomectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACULAR, BELOCZOK MITE, BIFITERAL, CALCILAC, CARBOPLATIN MONO, CARMEN, CLEXANE, ENALAPRIL, NEUPOGEN, PANTOZOL, TOREM
Adverse Events (AE) Preferred term	1. Ovarian epithelial cancer 2. Type 2 diabetes mellitus
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 14JAN2010 (84) - --------- (.) 2. 19JAN2010 (89) - --------- (.)
Duration of AE	1. . 2. .
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. NONE
Outcome of event	1. UNCHANGED 2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100223074

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100223074/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/73/WHITE/GERMANY/YES
Medical history	Appendicectomy, Bronchospasm, Chronic obstructive pulmonary disease, Dyspnoea, Kyphosis, Nasal septum disorder, Oedema peripheral, Onychomycosis, Hip arthroplasty, Hernia repair, Obesity, Glucose tolerance impaired, Sleep apnoea syndrome, Adhesiolysis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BERODUAL, EUPHYLONG, FRAXIPARIN, FUROSEMID, MORPHIUM, PREDNISOLON, SALBUTAMOL, SALBUTAMOL N, TAVOR [LORAZEPAM], TORASEMID
Adverse Events (AE) Preferred term	1. Chronic obstructive pulmonary disease
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 25JUL2010 (10) - 30JUL2010 (15)
Duration of AE	1. 6
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100223076

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100223076/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/57/WHITE/GERMANY/YES
Medical history	Hyperlipidaemia, Hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DELIX, PANTOZOL, PREPACOL, RAMILICH, SIMVAHEXAL, SIMVASTATIN
Adverse Events (AE) Preferred term	1. Gastritis 2. Hydrocele
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 07SEP2010 (5) - --------- (.) 2. 18MAR2011 (197) - 24MAR2011 (203)
Duration of AE	1. . 2. 7
Dose on AE onset	1. 15 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. UNCHANGED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100223090

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100223090/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/82/WHITE/GERMANY/YES
Medical history	Aortic aneurysm, Cardiac failure, Chronic obstructive pulmonary disease, Hypertension, Pneumonia, Prostate cancer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BICALUTAMID, DELIX, UNACID
Adverse Events (AE) Preferred term	1. Prostate cancer
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 23MAR2011 (24) - --------- (.)
Duration of AE	1. .
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. I
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100293001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100293001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/GERMANY/YES
Medical history	Gastrooesophageal reflux disease, Hypertension, Hyperuricaemia, Nephrectomy, Pulmonary hypertension, Postmenopause, Dyspnoea exertional, Type 1 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, ALT INSULIN, CARMEN, CARVEDILOL, DELIX, ENOXAPARIN, PANTOZOL, PENTALONG, TAVEGIL, TORASEMID, UNACID, WARFARIN
Adverse Events (AE) Preferred term	1. Drug eruption 2. Headache 3. Vertigo 4. Thoracic vertebral fracture 5. Subcutaneous haematoma 6. Bone pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/YES/NO/YES 6. MILD/NO/YES/YES
Start/stop date of event with relative date	1. -----2008 (.) - --------- (.) 2. --SEP2008 (.) - --------- (.) 3. --SEP2008 (.) - --------- (.) 4. 25OCT2008 (94) - --------- (.) 5. 25OCT2008 (94) - 27OCT2008 (96) 6. 25OCT2008 (94) - --------- (.)
Duration of AE	1. . 2. . 3. . 4. . 5. 3 6. .
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100293001

Parameter	Value
	2. NONE
	3. NONE
	4. STUDY DRUG DISCONTINUED PERMANENTLY
	5. STUDY DRUG DISCONTINUED PERMANENTLY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. IMPROVED
	5. RESOLVED
	6. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100303005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100303005/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/67/WHITE/GERMANY/YES
Medical history	Anaemia, Depression, Hypertension, Hysterectomy, Renal impairment, Spinal osteoarthritis, Spinal osteoarthritis, Pneumonia, Back pain, Hyperlipidaemia, Meniscal degeneration
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPIN, AUGMENTAN, BIFITERAL, BISOPROLOL, CEFTRIAXON, CIPROBAY, DIAZEPAM, DICLOFENAC, FENTANYL, HCT, HEPARIN, LISINOPRIL, MCP RATIOPHARM, METAMIZOL, MST MUNDIPHARMA, NUTRIFLEX LIPID PERI, NYSTATIN, PANTOPRAZOL, PANTOZOL, PARACETAMOL, PERFALGAN, SAROTEN, SIMVASTATIN
Adverse Events (AE) Preferred term	1. Nausea 2. Pneumonia 3. Constipation 4. Vomiting 5. Diarrhoea 6. Pyrexia 7. Thrombophlebitis 8. Depression 9. Pain in extremity 10. Chest pain 11. Chest pain 12. Cough 13. Bronchopneumonia 14. Bronchopneumonia 15. Goitre 16. Sleep disorder 17. Constipation
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MILD/NO/NO/YES 13. MODERATE/NO/NO/NO 14. MODERATE/NO/YES/NO 15. MILD/NO/NO/NO 16. MILD/NO/NO/NO 17. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --FEB2010 (.) - 22FEB2010 (5)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100303005

Parameter	Value
	2. --FEB2010 (.) - 03MAR2010 (14)
	3. 18FEB2010 (1) - 18FEB2010 (1)
	4. 20FEB2010 (3) - 21FEB2010 (4)
	5. 21FEB2010 (4) - 21FEB2010 (4)
	6. 21FEB2010 (4) - 23FEB2010 (6)
	7. 21FEB2010 (4) - 25FEB2010 (8)
	8. 25FEB2010 (8) - 02MAR2010 (13)
	9. 03MAR2010 (14) - 10MAR2010 (21)
	10. 31MAR2010 (42) - 05MAY2010 (77)
	11. 05MAY2010 (77) - --MAY2010 (.)
	12. 16MAY2010 (88) - 21MAY2010 (93)
	13. 07JUN2010 (110) - 09JUN2010 (112)
	14. 09JUN2010 (112) - 18JUN2010 (121)
	15. 09JUN2010 (112) - --------- (.)
	16. 10JUN2010 (113) - 17JUN2010 (120)
	17. 10JUN2010 (113) - 10JUN2010 (113)
Duration of AE	1. .
	2. .
	3. 1
	4. 2
	5. 1
	6. 3
	7. 5
	8. 6
	9. 8
	10. 36
	11. .
	12. 6
	13. 3
	14. 10
	15. .
	16. 8
	17. 1
Dose on AE onset	1.
	2.
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 20 mg
	11. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100303005

Parameter	Value
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. F
	14. F
	15. F
	16. F
	17. F
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. NONE
	12. NONE
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. NONE
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100303005

Parameter	Value
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. WORSENED
	11. RESOLVED
	12. RESOLVED
	13. WORSENED
	14. RESOLVED
	15. UNCHANGED
	16. RESOLVED
	17. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100323001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100323001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/62/WHITE/GERMANY/YES
Medical history	Hypercalcaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, OXAZEPAM, TAMSULOSIN, WARFARIN
Adverse Events (AE) Preferred term	1. Sleep disorder 2. Psoriasis 3. Parathyroid tumour benign 4. Benign prostatic hyperplasia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 03OCT2008 (1) - 05OCT2008 (3) 2. 06OCT2008 (4) - --------- (.) 3. 09OCT2008 (7) - 18OCT2008 (16) 4. 09OCT2008 (7) - --------- (.)
Duration of AE	1. 3 2. . 3. 10 4. .
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. UNCHANGED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100323001

Parameter	Value
	4. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100323002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100323002/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/56/WHITE/GERMANY/YES
Medical history	Hypercholesterolaemia, Hypertension, Hypothyroidism, Lymphoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DIOVAN, GREVILON, JOD THYROX, PANTOZOL, TOREM
Adverse Events (AE) Preferred term	1. B-cell lymphoma
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 25MAR2009 (135) - --------- (.)
Duration of AE	1. .
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100343008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100343008/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/66/WHITE/GERMANY/YES
Medical history	Atrial fibrillation, Failure to anastomose, Haemorrhoids, Hip arthroplasty, Hypertension, Inguinal hernia, Nephrolithiasis, Rectal cancer, Vertigo, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASS 100, BELOC ZOK, BIFITERAL, CELLIDRIN, EMSER SALZ, HCT 25, OXALIPLATIN, PANTOZOL, SPIRONOLACTONE, XELODA
Adverse Events (AE) Preferred term	1. Metastases to peritoneum 2. Skin haemorrhage 3. Malignant ascites
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. --APR2010 (.) - --------- (.) 2. 07FEB2010 (12) - 08FEB2010 (13) 3. 01APR2010 (65) - --------- (.)
Duration of AE	1. . 2. 2 3. .
Dose on AE onset	1. 2. 15 mg 3. 20 mg
Dose status on AE onset	1. 2. . 3. .
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. RESOLVED 3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100343009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100343009/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/52/WHITE/GERMANY/YES
Medical history	Arthralgia, Gout, Joint effusion, Osteoarthritis, Procedural pain, Meniscus lesion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, BEPANTHEN NASENSALBE, DECORTIN, ENOXAPARIN, IBOPRUFEN, IMBUN, LACTULOSE, NOVALGIN, PANTOZOEL, PANTOZOL, TAVANIC, TRAMAL, WARFARIN
Adverse Events (AE) Preferred term	1. Gout 2. Chest pain 3. Gastritis erosive 4. Hepatic steatosis 5. Post procedural haemorrhage 6. Osteoarthritis 7. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MODERATE/NO/YES/YES 7. MILD/YES/NO/YES
Start/stop date of event with relative date	1. --MAR2010 (.) - 12APR2010 (60) 2. 15FEB2010 (4) - 16FEB2010 (5) 3. 16FEB2010 (5) - 25FEB2010 (14) 4. 16FEB2010 (5) - --------- (.) 5. 17FEB2010 (6) - 14MAY2010 (92) 6. 24MAR2010 (41) - 30MAR2010 (47) 7. 14APR2010 (62) - 14APR2010 (62)
Duration of AE	1. . 2. 2 3. 10 4. . 5. 87 6. 7 7. 1
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100343009

Parameter	Value
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY
	2. OTHER
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. DOSE OF STUDY DRUG REDUCED,STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100343014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100343014/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/72/WHITE/GERMANY/YES
Medical history	Hiatus hernia, Pneumonia, Scoliosis, Torticollis, Tricuspid valve incompetence, Cholelithiasis, Spinal operation, Carcinoid tumour of the gastrointestinal tract
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTAN, EMSER SALZ, ENOXAPARIN, MOVICOL, PANTOZOL, WARFARIN
Adverse Events (AE) Preferred term	1. Vertigo 2. Muscle haemorrhage 3. Oedema peripheral
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/YES/YES/YES 3. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 29SEP2010 (12) - 29SEP2010 (12) 2. 14DEC2010 (88) - 14JAN2011 (119) 3. 02FEB2011 (138) - 02FEB2011 (138)
Duration of AE	1. 1 2. 32 3. 1
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER 3. OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100343017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100343017/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/61/WHITE/GERMANY/YES
Medical history	Night sweats, Pneumonia, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTAN, CIPROBAY, ENOXAPARIN, IMBUN, INSIDON, KALINOR, MUCOSOLVAN, PANTOZOL, PREDNISOLON, UNACID
Adverse Events (AE) Preferred term	1. Metastases to liver 2. Gastroenteritis norovirus 3. Lung adenocarcinoma 4. Metastases to pleura 5. Cerebral infarction
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 07DEC2010 (1) - --------- (.) 2. 08DEC2010 (2) - 17DEC2010 (11) 3. 15DEC2010 (9) - 10JAN2011 (35) 4. 15DEC2010 (9) - --------- (.) 5. 15DEC2010 (9) - 23DEC2010 (17)
Duration of AE	1. . 2. 10 3. 27 4. . 5. 9
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. NONE 2. OTHER 3. NONE 4. NONE 5. NONE
Outcome of event	1. UNCHANGED 2. RESOLVED 3. DEATH

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100343017

Parameter	Value
	4. UNCHANGED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100343018

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100343018/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/89/WHITE/GERMANY/YES
Medical history	Cardiac pacemaker insertion, Diabetes mellitus, Hemiparesis, Hypercalcaemia, Hypertension, Neurodermatitis, Osteoporosis, Pneumonia, Polyarthritis, Cerebrovascular accident, Cervicobrachial syndrome
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPIN, AUGMENTAN, CALICIGEN D, DELIX 5 PLUS, ENOXAPARIN, IBOHEXAL, LACTOLOSE, PANTOZOL, PREDNISOLON, SIMVASTATIN, SIOFOR, TOREM, WARFARIN
Adverse Events (AE) Preferred term	1. Cardiac failure
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 10JUN2011 (165) - 21JUN2011 (176)
Duration of AE	1. 12
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100343021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100343021/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/77/WHITE/GERMANY/YES
Medical history	Chronic obstructive pulmonary disease, Cor pulmonale, Emphysema, Oesophagitis, Gastrointestinal haemorrhage, Benign prostatic hyperplasia, Hypertension, Abdominal pain upper, Acute myocardial infarction, Coronary artery disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALVESCO, ATROVENT, BRIANYL, BRONCHOSPASMIN, CALCIGEN D, ENOXAPARIN, LACTULOSE, MORPHIN, NOVAMINSULFON, OXYGEN, PANTOPRAZOL, PARACETAMOL, PREDNISOLON, RAMIPRIL, SALBUTAMOL, SPIRIVA, TAMSULOSIN, TILIDIN, TORASEMID, WARFARIN
Adverse Events (AE) Preferred term	1. Infective exacerbation of chronic obstructive airways disease 2. Hypercapnia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/NO/YES
Start/stop date of event with relative date	1. 06FEB2011 (18) - 10FEB2011 (22) 2. 09FEB2011 (21) - --------- (.)
Duration of AE	1. 5 2. .
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE
Outcome of event	1. DEATH 2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100363006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100363006/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/56/WHITE/GERMANY/YES
Medical history	Anaemia macrocytic, Back pain, Cardiac failure chronic, Coronary artery disease, Gastrooesophageal reflux disease, Hypertension, Spinal osteoarthritis, Osteoarthritis, Nicotine dependence, Dyslipidaemia, Hypothyroidism
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMIODARON, ARTHOTEC, ASS, ENALAPRIL, JURNISTA, LYRICA, METOPROLOL, NOVALGIN, PANTOZOL, SIMVASTATIN, TOREM, ZOLDEM
Adverse Events (AE) Preferred term	1. Angina unstable 2. Cardiac failure acute 3. Tracheobronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. SEVERE/YES/YES/YES 3. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 09APR2010 (206) - 12APR2010 (209) 2. 14AUG2010 (333) - 18AUG2010 (337) 3. 29SEP2010 (379) - 05OCT2010 (385)
Duration of AE	1. 4 2. 5 3. 7
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. F
Action taken	1. OTHER 2. NONE 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-100363006[2)]	ACUTE DECOMPENSATED HEART FAILURE（PT：急性心不全） 治験担当医はリバーロキサバンと報告事象との関連性があると判断した。弊社は、合併症（うっ血性心不全、脂質異常症、心房細動等の心疾患）に起因したものであり、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100363012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100363012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/64/WHITE/GERMANY/YES
Medical history	Gastric ulcer, Glucose tolerance impaired, Hiatus hernia, Hypertension, Hyperuricaemia, Gastrooesophageal reflux disease, Renal cyst
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, ASS, BISOPROLOL, ENOXAPARIN, NOVAMIN, PANTOZOL, RAMIPRIL, WARFARIN
Adverse Events (AE) Preferred term	1. Skin necrosis 2. Rib fracture
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/YES/YES 2. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 15SEP2010 (8) - 30SEP2010 (23) 2. 04JUL2011 (300) - --------- (.)
Duration of AE	1. 16 2. .
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100393003/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/77/WHITE/GERMANY/YES
Medical history	Angina pectoris, Glaucoma, Hypertension, Hyperthyroidism, Spinal osteoarthritis, Benign prostatic hyperplasia, Cataract, Sinus bradycardia, Thrombocytosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC, ASS, CARVEDILOL, CLEXANE, DELIX, DELIX PLUS, FRAXIPARIN, HEPATHROMB, IRENAT, TAVANIC, VOLTAREN, VOLTAREN-GEL
Adverse Events (AE) Preferred term	1. Prostatic specific antigen increased 2. Prostatic specific antigen increased 3. Skeletal injury
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --APR2009 (.) - --------- (.) 2. 27NOV2009 (326) - 28NOV2009 (327) 3. 17DEC2009 (346) - --------- (.)
Duration of AE	1. . 2. 2 3. .
Dose on AE onset	1. 2. 20 mg 3. 20 mg
Dose status on AE onset	1. 2. I 3. .
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED 3. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. RESOLVED 3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393034

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100393034/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/72/WHITE/GERMANY/YES
Medical history	Hypertension, Hypothyroidism, Pneumonia, Basal cell carcinoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC 600, BISOPROLOL, CIPROFLOXACIN, CLEXANE, DEXAMYTREX, FELODIPIN, HYDROCHLOROTHIAZID, RAMIPRIL, THYRONAJOD, UNACID PD, WARFARIN
Adverse Events (AE) Preferred term	1. Prostatic specific antigen increased 2. Eyelid oedema 3. Prostate cancer 4. Diabetes mellitus 5. Hypertension 6. Vertigo
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 06NOV2009 (109) - --------- (.) 2. 20NOV2009 (123) - --------- (.) 3. 21DEC2009 (154) - --------- (.) 4. 21DEC2009 (154) - --------- (.) 5. 01APR2010 (255) - --------- (.) 6. 04AUG2010 (380) - 05AUG2010 (381)
Duration of AE	1. . 2. . 3. . 4. . 5. . 6. 2
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. I 4. I 5. . 6. F
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED 2. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393034

Parameter	Value
	3. STUDY DRUG DISCONTINUED AND RESTARTED
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. IMPROVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393042

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100393042/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/72/WHITE/GERMANY/YES
Medical history	Coronary artery disease, Hypertension, Hyperthyroidism, Back pain, Prostate cancer, Tachycardia, Prostatectomy, Intervertebral disc protrusion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPIN, ASS, ASS PROTECT, ATACAND [CANDESARTAN CILEXETIL], BELOC ZOK, BELOC ZOK MITE, CEFUROXIM, ENOXAPARIN, HYDROCHLOROTHIAZIDE, IBUPROFEN, IRENAT, MICARDIS, NOVALGIN, OMEPRAZOL, PLAVIX, SIMVASTATIN, THIAMAZOL, WARFARIN
Adverse Events (AE) Preferred term	1. Arrhythmia 2. Flushing 3. Bradycardia 4. Ventricular tachycardia 5. Coronary artery stenosis 6. Mitral valve incompetence 7. Aortic valve incompetence 8. Tricuspid valve incompetence 9. Renal failure 10. Hypokalaemia 11. Atrial fibrillation 12. Ischaemic cardiomyopathy 13. Wound complication 14. Atrial fibrillation 15. Hypercholesterolaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MODERATE/NO/NO/YES 13. MILD/NO/NO/YES 14. MODERATE/NO/YES/YES 15. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 13SEP2009 (20) - 14SEP2009 (21) 2. 13SEP2009 (20) - 14SEP2009 (21) 3. 14SEP2009 (21) - 21SEP2009 (28) 4. 16SEP2009 (23) - 23SEP2009 (30) 5. 16SEP2009 (23) - 23SEP2009 (30) 6. 16SEP2009 (23) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393042

Parameter	Value
	7. 16SEP2009 (23) - --------- (.)
	8. 16SEP2009 (23) - --------- (.)
	9. 16SEP2009 (23) - 28MAY2010 (277)
	10. 16SEP2009 (23) - 23SEP2009 (30)
	11. 16SEP2009 (23) - 21SEP2009 (28)
	12. 16SEP2009 (23) - --------- (.)
	13. 21SEP2009 (28) - 21SEP2009 (28)
	14. 04OCT2009 (41) - 06OCT2009 (43)
	15. 15OCT2009 (52) - --------- (.)
Duration of AE	1. 2
	2. 2
	3. 8
	4. 8
	5. 8
	6. .
	7. .
	8. .
	9. 255
	10. 8
	11. 6
	12. .
	13. 1
	14. 3
	15. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393042

Parameter	Value
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Action taken	1. NONE
	2. NONE
	3. OTHER
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. OTHER
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. UNCHANGED
	8. UNCHANGED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. IMPROVED
	13. RESOLVED
	14. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393042

Parameter	Value
	15. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-100393042[1),1),1)]	CORONARY STENOSIS（PT：冠動脈狭窄） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、合併症（冠動脈疾患）によるものであり、ワルファリンとの因果関係は否定できると考える。 RECURRENT EPISODE OF PAROXYSMAL ATRIAL FIBRILLATION（PT：心房細動） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、合併症（冠動脈疾患）によるものであり、ワルファリンとの因果関係は否定できると考える。 SLOW VENTRICULAR TACHYCARDIA（PT：心室性頻脈） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、合併症（冠動脈疾患）によるものであり、ワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393044

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100393044/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/GERMANY/YES
Medical history	Aortic valve sclerosis, Appendicectomy, Atrioventricular block, Bile duct cancer, Carotid artery stenosis, Cholecystectomy, Colon polypectomy, Coronary artery disease, Oedema peripheral, Hyperlipidaemia, Hypertension, Hypertrophic cardiomyopathy, Bundle branch block left, Leiomyosarcoma, Metastases to liver, Metastases to lymph nodes, Mitral valve incompetence, Tricuspid valve incompetence, Metastases to peritoneum, Perirectal abscess, Bile duct obstruction
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASS, CIPROBAY, CISPLATIN, CONCOR, DELIX, ENOXAPARIN, FRESH FROZEN PLASMA, GEMCITABIN, KONAKION MM, NEXIUM, PHOTOFRIN, ROCEPHIN, SORTIS, TOREM, TRYASOL CODEINE MITE, WARFARIN
Adverse Events (AE) Preferred term	1. Cough 2. Conjunctival haemorrhage 3. Oedema peripheral 4. International normalised ratio increased 5. Conjunctival haemorrhage 6. Neoplasm malignant 7. International normalised ratio increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/YES/YES/YES 5. MILD/YES/NO/YES 6. SEVERE/NO/YES/YES 7. MODERATE/YES/NO/YES
Start/stop date of event with relative date	1. --DEC2009 (.) - --------- (.) 2. 21SEP2009 (11) - 02OCT2009 (22) 3. 17DEC2009 (98) - --------- (.) 4. 01FEB2010 (144) - 02FEB2010 (145) 5. 01FEB2010 (144) - --FEB2010 (.) 6. 30MAR2010 (201) - 30MAR2010 (201) 7. 30MAR2010 (201) - --------- (.)
Duration of AE	1. . 2. 12 3. . 4. 2 5. . 6. 1 7. .
Dose on AE onset	1. 2. 3. 4. 5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393044

Parameter	Value
	6.
	7.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. IMPROVED
	4. RESOLVED
	5. RESOLVED
	6. DEATH
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-10039 3044[1)]	ELEVATED INR（PT：国際標準比増加） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併用薬（ワルファリン)によるものであり、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393046

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100393046/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/GERMANY/YES
Medical history	Chronic obstructive pulmonary disease, Arteriogram coronary, Gastrooesophageal reflux disease, Hypercholesterolaemia, Hyperlipidaemia, Hypertension, Hyperuricaemia, Insomnia, Osteoarthritis, Osteoporosis, Postmenopause, Renal failure chronic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, AMLODIPIN, ARCOXIA, BUPIVACAIN, CLEXANE, LIMPTAR, LORAZEPAM, OMEPRAZOL, PROVAS, PYOLOSIN SALVE, RUDOTEL, SIMVABETA, TORASEMID, TRIAMCINOLON, VIVINOX, ZOLPIDEM
Adverse Events (AE) Preferred term	1. Skin lesion 2. Hepatic steatosis 3. Nephrosclerosis 4. Aortic arteriosclerosis 5. Insomnia 6. Dyspnoea 7. Wound 8. Respiratory failure 9. Carbon dioxide increased 10. Mitral valve incompetence 11. Tricuspid valve incompetence 12. Osteoarthritis 13. Osteoarthritis 14. Osteoarthritis 15. Hypertension 16. Osteoarthritis 17. Joint effusion 18. Rectal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MODERATE/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MILD/NO/NO/YES 15. MILD/NO/NO/YES 16. MODERATE/NO/YES/YES 17. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393046

Parameter	Value
	18. MILD/YES/NO/YES
Start/stop date of event with relative date	1. -----2010 (.) - --------- (.)
	2. 05OCT2009 (14) - --------- (.)
	3. 05OCT2009 (14) - --------- (.)
	4. 05OCT2009 (14) - --------- (.)
	5. 19OCT2009 (28) - 19OCT2009 (28)
	6. 15NOV2009 (55) - 15NOV2009 (55)
	7. 25NOV2009 (65) - 30NOV2009 (70)
	8. 26NOV2009 (66) - --------- (.)
	9. 26NOV2009 (66) - --------- (.)
	10. 21DEC2009 (91) - --------- (.)
	11. 21DEC2009 (91) - --------- (.)
	12. 05JAN2010 (106) - 27APR2010 (218)
	13. 05JAN2010 (106) - --------- (.)
	14. 15APR2010 (206) - --------- (.)
	15. 15APR2010 (206) - --------- (.)
	16. 28APR2010 (219) - 06MAY2010 (227)
	17. 12JUL2010 (294) - --------- (.)
	18. 24AUG2010 (337) - 24AUG2010 (337)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. 1
	6. 1
	7. 6
	8. .
	9. .
	10. .
	11. .
	12. 113
	13. .
	14. .
	15. .
	16. 9
	17. .
	18. 1
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393046

Parameter	Value
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. I
	17. .
	18. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393046

Parameter	Value
	16. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	17. NONE
	18. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. UNCHANGED
	10. UNCHANGED
	11. UNCHANGED
	12. WORSENED
	13. UNCHANGED
	14. UNCHANGED
	15. UNCHANGED
	16. RESOLVED
	17. UNCHANGED
	18. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393047

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100393047/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/32/WHITE/GERMANY/YES
Medical history	Obesity, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT, CLEXANE, ENOXAPARIN, NOVALGIN, PARACETAMOL, SULTANOL, UMCKALOABO, UNACID, UNACID PD, VALETTE, WARFARIN
Adverse Events (AE) Preferred term	1. Nasopharyngitis 2. Cough 3. Cervical polyp 4. Cervical polyp
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 31MAR2010 (139) - 08APR2010 (147) 2. 15JUL2010 (245) - 01AUG2010 (262) 3. 18AUG2010 (279) - 08SEP2010 (300) 4. 08SEP2010 (300) - 08SEP2010 (300)
Duration of AE	1. 9 2. 18 3. 22 4. 1
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. STUDY DRUG DISCONTINUED AND RESTARTED 4. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. WORSENED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393047

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393053

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100393053/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/65/WHITE/GERMANY/YES
Medical history	Angiosclerosis, Decreased appetite, Oesophageal carcinoma, Mitral valve incompetence, Spinal osteoarthritis, Pleural effusion, Tremor, Tricuspid valve incompetence, Aortic valve incompetence, Aortic elongation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC, ANTELEPSIN, BERLOSIN, BUSCOPAN, CLEXANE, ELECTROLYT INFUSION E153, ELECTROLYT INFUSION E154, ELECTROLYT INFUSION G5%, ENOXAPARIN, GELAFUSAL, GRANULOCYTIC CONCENTRATE, KABIVEN PERI, KONAKION, NACL 0.9%, NOVALGIN, NOVAMIN, PANTOZOL, PASPERTIN, PERFALGAN, RINGER INFUSION, TAVANIC, TAZOBAC, WARFARIN
Adverse Events (AE) Preferred term	1. Ileus paralytic 2. Abdominal pain 3. Metastases to pleura 4. Oedema peripheral 5. Pneumonia 6. Pleural effusion 7. Dysphonia 8. Conjunctival haemorrhage 9. International normalised ratio increased 10. International normalised ratio increased 11. Pleural effusion 12. Pleural effusion 13. C-reactive protein increased 14. Oedema
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/NO/YES 2. SEVERE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. SEVERE/NO/YES/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/YES/NO/YES 9. MODERATE/YES/NO/YES 10. MODERATE/YES/NO/YES 11. MODERATE/NO/YES/YES 12. MODERATE/NO/YES/YES 13. SEVERE/NO/NO/NO 14. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --JAN2011 (.) - --------- (.) 2. --JAN2011 (.) - --------- (.) 3. --DEC2010 (.) - 28JAN2011 (374) 4. 29JAN2010 (10) - --------- (.) 5. 09MAR2010 (49) - 19MAR2010 (59) 6. 11MAR2010 (51) - 17MAR2010 (57)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393053

Parameter	Value
	7. 19MAR2010 (59) - --------- (.)
	8. 07APR2010 (78) - 26APR2010 (97)
	9. 03AUG2010 (196) - 09AUG2010 (202)
	10. 30AUG2010 (223) - 30AUG2010 (223)
	11. 13DEC2010 (328) - 15DEC2010 (330)
	12. 22DEC2010 (337) - 28JAN2011 (374)
	13. 16JAN2011 (362) - --------- (.)
	14. 17JAN2011 (363) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. 11
	6. 7
	7. .
	8. 20
	9. 7
	10. 1
	11. 3
	12. 38
	13. .
	14. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393053

Parameter	Value
	9.
	10.
	11.
	12.
	13.
	14.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	6. OTHER
	7. NONE
	8. NONE
	9. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	10. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	11. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	12. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. DEATH
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. DEATH
	13. UNCHANGED
	14. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-10039 3053[1)]	PLEURAL CARCINOSIS（PT：胸膜転移） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、ワルファリン投与中止後約 9 か月を経ての発現であり、時間的関連性がないため、ワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393057

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100393057/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/GERMANY/YES
Medical history	Adenocarcinoma, Cholecystectomy, Haemorrhoids, Hepatomegaly, Hydronephrosis, Hysterectomy, Metastases to liver, Metastases to lymph nodes, Omentectomy, Osteoporosis, Urinary tract infection, Ureteric stenosis, Lymphadenectomy, Nephrostomy, Postmenopause, Lymphocele, Lymphocele, Lymphocele, Lymphocele, Lymphocele, Adhesiolysis, Spinal osteoarthritis, Varicose vein operation, Ureterolysis procedure, Osteochondrosis, Salpingo-oophorectomy bilateral
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALENDRONSÄURE, BIFITERAL, CARBOPLATIN, CIPROBAY, CLEXANE, COTRIM FORTE, DEXAMETHASON, ELECTROLYT INFUSION, ENOXAPARIN, FRAXIPARIN, GRANOZYTE, JURNISTA, KEVATRIL, KONAKION, MONOEMBOLEX, NACL 0.9%, NOVALGIN, PACLITAXEL, PANTOZOL, PASPERTIN, RANITIDIN, TAVANIC, TAVEGIL, WARFARIN
Adverse Events (AE) Preferred term	1. Nausea 2. Leukopenia 3. Pyrexia 4. Subileus 5. Nephritis 6. Urinary tract infection 7. Endometrial cancer
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 06MAY2010 (2) - 07MAY2010 (3) 2. 03JUL2010 (60) - 05JUL2010 (62) 3. 04JUL2010 (61) - 04JUL2010 (61) 4. 22AUG2010 (110) - 26AUG2010 (114) 5. 08DEC2010 (218) - 10JAN2011 (251) 6. 12FEB2011 (284) - --------- (.) 7. 10MAY2011 (371) - --------- (.)
Duration of AE	1. 2 2. 3 3. 1 4. 5 5. 34 6. . 7. .
Dose on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393057

Parameter	Value
	5.
	6.
	7.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393061

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100393061/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/84/WHITE/GERMANY/YES
Medical history	Aortic valve sclerosis, Cardiac failure, Emphysema, Haemangioblastoma, Hypertension, Mitral valve sclerosis, Aortic dilatation, Spinal osteoarthritis, Renal neoplasm
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPIN, LOSARTAN
Adverse Events (AE) Preferred term	1. Pancreatic carcinoma 2. Hypokalaemia 3. Pain 4. Blood bilirubin increased 5. Benign prostatic hyperplasia 6. Hepatic steatosis 7. Nephrolithiasis 8. Gastrooesophageal reflux disease 9. Hypokalaemia 10. Acute prerenal failure 11. Stent malfunction 12. Cholangitis 13. Bronchospasm
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/NO 10. MILD/NO/NO/NO 11. SEVERE/NO/NO/NO 12. SEVERE/NO/NO/NO 13. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 01OCT2010 (60) - --------- (.) 2. 01OCT2010 (60) - 11OCT2010 (70) 3. 01OCT2010 (60) - --------- (.) 4. 01OCT2010 (60) - --------- (.) 5. 01OCT2010 (60) - --------- (.) 6. 01OCT2010 (60) - --------- (.) 7. 01OCT2010 (60) - --------- (.) 8. 01OCT2010 (60) - 01OCT2010 (60) 9. 03DEC2010 (123) - 13DEC2010 (133) 10. 03DEC2010 (123) - 05DEC2010 (125) 11. 03DEC2010 (123) - --------- (.) 12. 03DEC2010 (123) - 21DEC2010 (141)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393061

Parameter	Value
	13. 04DEC2010 (124) - 08DEC2010 (128)
Duration of AE	1. .
	2. 11
	3. .
	4. .
	5. .
	6. .
	7. .
	8. 1
	9. 11
	10. 3
	11. .
	12. 19
	13. 5
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
Dose status on AE onset	1. F
	2. F
	3. F
	4. F
	5. F
	6. F
	7. F
	8. F
	9. F
	10. F
	11. F
	12. F
	13. F
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393061

Parameter	Value
	5. NONE
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. IMPROVED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. UNCHANGED
	12. RESOLVED
	13. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393069

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100393069/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/76/WHITE/GERMANY/YES
Medical history	Abdominal pain, Nausea, Spinal osteoarthritis, Abnormal faeces, Hip arthroplasty, Hip arthroplasty, Postmenopause, Female genital operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBROXOL, AMLODIPIN, ANTITHROMBIN, BERLOSIN, CLAFORAN, CLEXANE, DIPIDOLOR, FALITHROM, FRAXIPARIN, INSULIN, KALINOR, LASIX, METRONIDAZOL, NITROSPRAY, PARACETAMOL, PASPERTIN, PLASMA CONCENTRATE, PPSB, RAMIPRIL, RANITIDIN, VITAMIN K, VOMEX, XUSAL
Adverse Events (AE) Preferred term	1. Subileus 2. Hypertension 3. Nausea 4. Colon cancer 5. Hypokalaemia 6. Rash 7. Rash 8. Rash 9. Rash 10. Rash
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES 6. MODERATE/YES/NO/YES 7. MODERATE/YES/NO/YES 8. MODERATE/YES/NO/YES 9. MODERATE/YES/NO/YES 10. MODERATE/YES/NO/YES
Start/stop date of event with relative date	1. --MAR2011 (.) - 11MAR2011 (18) 2. 09MAR2011 (16) - --------- (.) 3. 09MAR2011 (16) - 23MAR2011 (30) 4. 11MAR2011 (18) - 23MAR2011 (30) 5. 17MAR2011 (24) - 22MAR2011 (29) 6. 01APR2011 (39) - 04MAY2011 (72) 7. 01APR2011 (39) - 04MAY2011 (72) 8. 01APR2011 (39) - 04MAY2011 (72) 9. 01APR2011 (39) - 04MAY2011 (72) 10. 01APR2011 (39) - 04MAY2011 (72)
Duration of AE	1. . 2. . 3. 15 4. 13 5. 6

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393069

Parameter	Value
	6. 34
	7. 34
	8. 34
	9. 34
	10. 34
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. I
	5. I
	6. .
	7. .
	8. .
	9. .
	10. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393069

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393072

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100393072/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/34/WHITE/GERMANY/YES
Medical history	Seasonal allergy, Bone pain, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Nasopharyngitis 2. Hyperbilirubinaemia 3. Bone pain 4. Pain in extremity 5. Oropharyngeal pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/NO 5. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 17MAR2011 (8) - 25MAR2011 (16) 2. 01JUL2011 (114) - --------- (.) 3. 29AUG2011 (173) - 30AUG2011 (174) 4. 20SEP2011 (195) - --------- (.) 5. 26SEP2011 (201) - 26SEP2011 (201)
Duration of AE	1. 9 2. . 3. 2 4. . 5. 1
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. NONE 2. NONE 3. NONE 4. NONE 5. NONE
Outcome of event	1. RESOLVED 2. IMPROVED 3. RESOLVED 4. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100393072

Parameter	Value
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100403004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100403004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/86/WHITE/GERMANY/YES
Medical history	Anaemia, Atrial flutter, Basal cell carcinoma, Glaucoma, Hypertension, Iron deficiency anaemia, Benign prostatic hyperplasia, Varicose vein, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASS, ASS 100, BENURON, DELIX 2,5MG PLUS, DELIX 5MG, FERRO SANOL, NOSE SALVE NOS, NOVAMINSULFON, PANTOZOL
Adverse Events (AE) Preferred term	1. Epistaxis 2. Epistaxis 3. Epistaxis 4. Epistaxis 5. Epistaxis 6. Rib fracture
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. MILD/YES/NO/YES 4. MILD/YES/YES/YES 5. MILD/YES/NO/YES 6. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 24AUG2009 (6) - 24AUG2009 (6) 2. 10SEP2009 (23) - 10SEP2009 (23) 3. 01OCT2009 (44) - --OCT2009 (.) 4. 08DEC2009 (112) - 11DEC2009 (115) 5. 08FEB2010 (174) - 08FEB2010 (174) 6. 16MAY2010 (271) - 17MAY2010 (272)
Duration of AE	1. 1 2. 1 3. . 4. 4 5. 1 6. 2
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. .
Action taken	1. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100403004

Parameter	Value
	2. NONE
	3. NONE
	4. OTHER
	5. REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100403007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100403007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/48/WHITE/GERMANY/YES
Medical history	Hypertension, Hypothyroidism, Iron deficiency anaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPIN, CLEXANE, ENOXAPARIN, ERYFER [FERROUS SULFATE ALONE.], L THYROXIN, WARFARIN
Adverse Events (AE) Preferred term	1. Headache 2. Iron deficiency 3. Menorrhagia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 19SEP2009 (2) - 19SEP2009 (2) 2. 01OCT2009 (14) - --------- (.) 3. 20FEB2010 (156) - 24FEB2010 (160)
Duration of AE	1. 1 2. . 3. 5
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
Outcome of event	1. RESOLVED 2. UNCHANGED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100403011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100403011/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/45/WHITE/GERMANY/YES
Medical history	Hypercholesterolaemia, Hypertension, Lower limb fracture, Tonsillectomy, Ligament rupture, Latex allergy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, ENOXAPARIN, SIMVASTATIN, WARFARIN
Adverse Events (AE) Preferred term	1. Congenital renal cyst 2. Presyncope 3. Cough 4. Tachypnoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 25NOV2009 (1) - --------- (.) 2. 30NOV2009 (6) - 02DEC2009 (8) 3. 29MAR2010 (125) - 26MAY2010 (183) 4. 21APR2010 (148) - 26MAY2010 (183)
Duration of AE	1. . 2. 3 3. 59 4. 36
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. NONE 3. NONE 4. NONE
Outcome of event	1. UNCHANGED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100403011

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100403018

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100403018/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/56/WHITE/GERMANY/YES
Medical history	Ankle fracture, Asthma, Drug hypersensitivity, Tibia fracture, Foot fracture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATACAND [CANDESARTEN CILEXETIL], BETAHISTIN, CORTISON, HAES 3%, PULMICORT, RANTIDIN, SALBUTAMÓL, SYMBICORT, TRENTAL
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Hypertension 3. Sudden hearing loss 4. Venous insufficiency
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --SEP2010 (.) - --DEC2010 (.) 2. 24AUG2010 (27) - 04AUG2011 (372) 3. 10MAR2011 (225) - 04AUG2011 (372) 4. 04AUG2011 (372) - --------- (.)
Duration of AE	1. . 2. 346 3. 148 4. .
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. F
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY,OTHER 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100403018

Parameter	Value
	4. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100403021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100403021/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/73/WHITE/GERMANY/YES
Medical history	Joint stiffness, Aortic arteriosclerosis, Aortic stenosis, Cataract, Pulmonary arterial pressure increased, Inguinal hernia, Inguinal hernia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DICLOFENAC, ENOXAPARIN, NOVALGIN, WARFARIN
Adverse Events (AE) Preferred term	1. Cough 2. Oedema peripheral 3. Basal cell carcinoma 4. Contusion 5. Nasopharyngitis 6. Dyspnoea 7. Cataract
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --OCT2010 (.) - --OCT2010 (.) 2. 08OCT2010 (57) - 16DEC2010 (126) 3. 10DEC2010 (120) - 10DEC2010 (120) 4. 23DEC2010 (133) - 23DEC2010 (133) 5. 02JAN2011 (143) - 10JAN2011 (151) 6. 09FEB2011 (181) - 10FEB2011 (182) 7. 21MAR2011 (221) - 21MAR2011 (221)
Duration of AE	1. . 2. 70 3. 1 4. 1 5. 9 6. 2 7. 1
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100403021

Parameter	Value
	4.
	5.
	6.
	7.
Action taken	1. NONE
	2. NONE
	3. OTHER
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100403024

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100403024/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/57/WHITE/GERMANY/YES
Medical history	Food allergy, Foot fracture, Forearm fracture, Pneumonia, Ejection fraction decreased, Obesity, Sleep apnoea syndrome, Right ventricular failure, Coronary artery disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASS, BELOC ZOK MITE, BLOPRESS, DELIX, ENOXAPARIN, FRAGMIN P FORTE, SIMVASTATION, SPIRONOLACTON, UNFRACTIONATED HEPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Cough 2. Hypertension 3. Ejection fraction decreased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES
Start/stop date of event with relative date	1. --JUL2011 (.) - --------- (.) 2. --SEP2010 (.) - -----2010 (.) 3. 24NOV2010 (64) - 26NOV2010 (66)
Duration of AE	1. . 2. . 3. 3
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. UNCHANGED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100423003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100423003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/66/WHITE/GERMANY/YES
Medical history	Cardiomyopathy, Rhinitis, Coronary artery disease, Hypercholesterolaemia, Hypertension, Intervertebral disc degeneration, Mitral valve incompetence, Obesity, Osteoarthritis, Restless legs syndrome, Sleep apnoea syndrome, Knee arthroplasty, Knee arthroplasty, Tricuspid valve incompetence, Aortic valve incompetence, Adrenal neoplasm
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLSALICYLACID, ALDACTONE [SPIRONOLACTONE], AMOXICILLIN, DOMPERIDON, ENOXAPARIN, MADOPAR, METAMIZOL, METOPROLOL, MOXIFLOXACIN, NITREDIPIN, PREGABALIN, RAMIPRIL, SORTIS, THROMBIN, TILIDIN, WARFARIN
Adverse Events (AE) Preferred term	1. Vascular pseudoaneurysm 2. Haematoma 3. Thrombophlebitis 4. Haematoma 5. Haematoma 6. Sinusitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/YES/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/YES/YES/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 13SEP2010 (6) - 15SEP2010 (8) 2. 16SEP2010 (9) - 27SEP2010 (20) 3. 21SEP2010 (14) - 27SEP2010 (20) 4. 27SEP2010 (20) - 28SEP2010 (21) 5. 28SEP2010 (21) - 28DEC2010 (112) 6. 06DEC2010 (90) - 16DEC2010 (100)
Duration of AE	1. 3 2. 12 3. 7 4. 2 5. 92 6. 11
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100423003

Parameter	Value
	5.
	6.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY,OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. WORSENED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-100423003[2)]	PAINFUL INCREASE HEMATOMA RIGHT GROIN（PT：血腫） 治験担当医はエノキサパリンと報告事象との関連性があると判断した。弊社は、エノキサパリン投与中止 15 日後の発現であり、時間的関連性がないため、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100423005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100423005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/64/WHITE/GERMANY/YES
Medical history	Coronary artery disease, Hypertension, Hypothyroidism, Menopause, Palpitations, Phlebectomy, Medical diet
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETHYLSALIC ACID, AMLODIPIN, DECORTIN H, ENOXAPARIN, KLIOGEST, L-THYROXIN, PANTOZOL, PENTOXIFILLIN, SILICEA, SODIUMPANGAMAT, VALSARTAN, WARFARIN
Adverse Events (AE) Preferred term	1. Alopecia 2. Hot flush 3. Nausea 4. Vertigo 5. Vertigo 6. Intervertebral disc protrusion 7. Constipation
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --APR2011 (.) - --------- (.) 2. --APR2011 (.) - --------- (.) 3. 17MAR2011 (7) - 22MAR2011 (12) 4. 17MAR2011 (7) - 07JUL2011 (119) 5. 18MAR2011 (8) - 25MAR2011 (15) 6. 28APR2011 (49) - --------- (.) 7. 01MAY2011 (52) - 14JUN2011 (96)
Duration of AE	1. . 2. . 3. 6 4. 113 5. 8 6. . 7. 45
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100423005

Parameter	Value
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100433001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/53/WHITE/GERMANY/YES
Medical history	Appendicitis, Gastritis, Hepatitis A, Hiatus hernia, Hypertension, Hypothyroidism, Migraine, Pleurisy, Pneumonia, Cholelithiasis, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, CONCOR, ENAHEXAL, ENOXAPARIN, KLACID, L-THYROXIN 100, MOVICOL, NOVAMIN GH. [METAMIZOL], PANTOZOL, RANITIDIN, TRAMAL, UNACID PD, WARFARIN
Adverse Events (AE) Preferred term	1. Hepatitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 09JAN2010 (4) - 28JAN2010 (23)
Duration of AE	1. 20
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100433003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/67/WHITE/GERMANY/YES
Medical history	Osteoarthritis, Osteoarthritis, Benign prostatic hyperplasia, Osteonecrosis, Gastritis, Hypertension, Constipation, Right ventricular failure, Splenic rupture, Obesity, Thyroidectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BISOPROLOL, CEFUROXIM, DIPIDOLOR, ELEKTROLYT-INFUSIONSLOESUNG 153, ENOXAPARIN, GENERAL ANAESTHESIA, HAES, L-THYROXIN, LIDOCAIN, MONOEMBOLEX, MOVICOL, NOVAMIN, PANTOZOL 40, PERFALGAN, TOREM 5, VOLTAREN DISP., WARFARIN
Adverse Events (AE) Preferred term	1. Pain in extremity 2. Osteonecrosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --MAR2010 (.) - --------- (.) 2. 07DEC2010 (294) - 08DEC2010 (295)
Duration of AE	1. . 2. 2
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. OTHER 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. WORSENED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100433005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/83/WHITE/GERMANY/YES
Medical history	Angina pectoris, Cardiac failure chronic, Hypertension, Renal failure chronic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLIN, ASS 100, BIFITERAL, CONCOR 5, ENOXAPARIN, ISOKET 120, KLACID 500, LIDOCAIN, PANTOZOL 40, PENTALONG 80, TOREM 10, TRYASOL, WARFARIN
Adverse Events (AE) Preferred term	1. Gastritis 2. Diverticulum gastric 3. Cough 4. Varices oesophageal 5. Cholelithiasis 6. Hepatic steatosis 7. Gastrointestinal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 01MAR2010 (5) - --------- (.) 2. 01MAR2010 (5) - --------- (.) 3. 01MAR2010 (5) - --------- (.) 4. 01MAR2010 (5) - --------- (.) 5. 02MAR2010 (6) - --------- (.) 6. 02MAR2010 (6) - --------- (.) 7. 03MAR2010 (7) - 04MAR2010 (8)
Duration of AE	1. . 2. . 3. . 4. . 5. . 6. . 7. 2
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433005

Parameter	Value
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. IMPROVED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-100433005[3)]	ANEMIA（PT：出血性貧血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発の胃腸出血に起因したと考え、エノキサパリン及びワルファリンとの因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100433006/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/73/WHITE/GERMANY/YES
Medical history	Rectal cancer, Chronic obstructive pulmonary disease, Glaucoma, Metastases to liver, Hypertension, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	5-FU, ADDEL N, ATROPIN, BISOPROLOL 5, CEFUROXIM, DEXAMETHASON, EUGALAC, FREKAVIT LIPOSOLUBLE, FREKAVIT WATERSOLUBLE, GRANSITRON, IRINOTECAN, JURNISTA, MCP, MIRTAZAPIN 15, NEOFOLIN, NOVAMIN, PANTOZOL, SPIRIVA, STILNOX, STRUCTOKABIVEN, THEOPHYLLIN, VIANI FORTE, VOMEX A, XALACOM
Adverse Events (AE) Preferred term	1. Cachexia 2. Rectal cancer 3. Constipation 4. Sleep disorder 5. Chronic obstructive pulmonary disease 6. Anaemia 7. Hepatic pain 8. Depressed mood 9. Oedema peripheral 10. Candidiasis 11. Cardiac arrest
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. SEVERE/NO/NO/YES 7. MODERATE/NO/YES/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/NO 10. MODERATE/NO/NO/NO 11. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. --NOV2010 (.) - --------- (.) 2. --NOV2010 (.) - 02DEC2010 (203) 3. 14MAY2010 (1) - --------- (.) 4. 14MAY2010 (1) - --------- (.) 5. 01NOV2010 (172) - --------- (.) 6. 08NOV2010 (179) - --------- (.) 7. 08NOV2010 (179) - --------- (.) 8. 08NOV2010 (179) - --------- (.) 9. 13NOV2010 (184) - --------- (.) 10. 28NOV2010 (199) - --------- (.) 11. 02DEC2010 (203) - 02DEC2010 (203)
Duration of AE	1. . 2. . 3. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433006

Parameter	Value
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. 1
Dose on AE onset	1.
	2.
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. F
	10. F
	11. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
Outcome of event	1. UNCHANGED
	2. DEATH
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433006

Parameter	Value
	4. RESOLVED
	5. IMPROVED
	6. IMPROVED
	7. IMPROVED
	8. IMPROVED
	9. IMPROVED
	10. UNCHANGED
	11. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100433008/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/77/WHITE/GERMANY/YES
Medical history	Cardiac failure chronic, Pyelonephritis chronic, Diabetes mellitus, Gastritis, Hypercholesterolaemia, Hypertension, Hysterectomy, Pharyngeal cyst, Renal atrophy, Hepatic steatosis, Cholelithiasis, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, ALDACTONE [SPIRONOLACTONE], AMLODIPIN, AMOXICILLIN, ASS, BISOPROLOL, CIPROBAY, CPS POWDER, DIGITOXIN, ENOXAPARIN, EUGALAC, HAEMITON, KLACID, LORZAAR, MOVICOL, NOVAMIN, OMEP, PANTOZOL, PROTAPHANE, SIMVASTATIN, TOREM, WARFARIN
Adverse Events (AE) Preferred term	1. Vertigo 2. Back pain 3. Hyperkalaemia 4. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 12MAY2011 (336) - 20MAY2011 (344) 2. 12MAY2011 (336) - --------- (.) 3. 12MAY2011 (336) - 13MAY2011 (337) 4. 18MAY2011 (342) - 22MAY2011 (346)
Duration of AE	1. 9 2. . 3. 2 4. 5
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. IMPROVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433008

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100433011/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/49/WHITE/GERMANY/YES
Medical history	Hypersensitivity, Osteoarthritis, Chronic obstructive pulmonary disease, Hypertension, Tobacco abuse
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASS 100, BLOPRESS, CONCOR 5, CONCOR 5MG, E 153, FAUSTAN, IBUPROFEN, IBUPROFEN 800, PANTOZOL 40, TAVEGIL, VOLTAREN RESINAT
Adverse Events (AE) Preferred term	1. Wound haemorrhage 2. Ligament rupture 3. Nasopharyngitis 4. Syncope
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 20JAN2011 (134) - 25JAN2011 (139) 2. 20JAN2011 (134) - --------- (.) 3. 29APR2011 (233) - -----2011 (.) 4. 10JUN2011 (275) - 21JUN2011 (286)
Duration of AE	1. 6 2. . 3. . 4. 12
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY,OTHER 3. NONE 4. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. IMPROVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433011

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100433013/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/60/WHITE/GERMANY/YES
Medical history	Hypertension, Hepatic steatosis, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPISOL, CONCOR, PANTOZOL, VOLTAREN
Adverse Events (AE) Preferred term	1. Clumsiness
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 19DEC2010 (27) - 24FEB2011 (94)
Duration of AE	1. 68
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-100433013[5)]	CLUMSY HAND SYNDROME（PT：不器用） 治験担当医はリバーロキサバンと報告事象との関連性はあると判断した。ドイツ本社安全性部門は、「不器用」は巧緻運動障害と考えられ、ラクナ梗塞による可能性が高いことから、リバーロキサバンとの因果関係は否定できると評価している。しかしながら、発現後の投与状況、合併症、治療内容を含めた臨床経過等の詳細情報が得られておらず、弊社では因果関係の評価は困難と考える。したがって、リバーロキサバンと報告事象との因果関係については否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100433014/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/46/WHITE/GERMANY/YES
Medical history	Pneumonia, Intervertebral disc protrusion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC 600, KONAKION, MONOEMBOLEX, NOVAMIN
Adverse Events (AE) Preferred term	1. Weight increased
	2. Antiphospholipid antibodies positive
	3. Hepatic steatosis
	4. Inflammatory pseudotumour
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/NO/YES
	4. MILD/NO/YES/YES
Start/stop date of event with relative date	1. --JUN2011 (.) - --------- (.)
	2. 06JAN2011 (3) - --------- (.)
	3. 06JAN2011 (3) - --------- (.)
	4. 11JUL2011 (189) - 20JUL2011 (198)
Duration of AE	1. .
	2. .
	3. .
	4. 10
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
Action taken	1. NONE
	2. NONE
	3. NONE
	4. OTHER
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433014

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433016

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100433016/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/83/WHITE/GERMANY/YES
Medical history	Benign prostatic hyperplasia, Emphysema, Gastritis, Goitre, Hypertension, Myocardial infarction, Nausea, Pneumonia, Hyperlipidaemia, Osteochondrosis, Peripheral arterial occlusive disease, Coronary artery disease, Tobacco abuse
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC 600, ASS 100, BISOPROLOL 5, ENALAPRIL 5, MONOEMBOLEX, MUCOSOLVAN, SIMVA 40, TRYASOL, UNACID PD
Adverse Events (AE) Preferred term	1. Haematuria 2. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MILD/YES/NO/NO
Start/stop date of event with relative date	1. 13FEB2011 (5) - 20FEB2011 (12) 2. 19APR2011 (70) - 20APR2011 (71)
Duration of AE	1. 8 2. 2
Dose on AE onset	1. 15 mg 2. 15 mg
Dose status on AE onset	1. . 2. F
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,STUDY DRUG DISCONTINUED PERMANENTLY,OTHER 2. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100433017/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/61/WHITE/GERMANY/YES
Medical history	Cataract, Hypothyroidism, Pneumonia, Intervertebral disc protrusion, Rheumatoid arthritis, Hepatic steatosis, Cholelithiasis, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC 600, ENBREL, FOLSÄURE, KLACID 500, L-THYROXIN, MTX, MUCOSOLVAN, NOVAMIN, PREDNISOLON, UNACID, VALOCORDIN
Adverse Events (AE) Preferred term	1. Acute myocardial infarction 2. Hypercholesterolaemia 3. Bacteraemia 4. Infection
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/NO 2. MODERATE/NO/NO/NO 3. MILD/NO/NO/NO 4. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 23SEP2011 (218) - 01OCT2011 (226) 2. 23SEP2011 (218) - --------- (.) 3. 24SEP2011 (219) - 01OCT2011 (226) 4. 28SEP2011 (223) - --OCT2011 (.)
Duration of AE	1. 9 2. . 3. 8 4. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. F 2. F 3. F 4. F
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. NONE
Outcome of event	1. RESOLVED 2. IMPROVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100433017

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100473005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100473005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/73/WHITE/GERMANY/YES
Medical history	Cataract, Cataract, Diverticulum intestinal, Hypertension, Benign prostatic hyperplasia, Silicosis, Sleep disorder, Lumbar vertebral fracture, Thoracic vertebral fracture, Renal failure chronic, Hypercholesterolaemia, Coronary artery disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC, ADUMBRAN, AMPHO-MORONAL, ASS, ATROVENT, BRICANYL, CEFUROXIM, CIPROBASICS, CLARITHROMYCIN, CORTISON, DECORTIN, ENOXAPARIN, IBUPRUFEN, ISDN, KLACID, MCP, MOLSIBETA, MORPHIN, NEBIVOLOL, NOVAMINSULFON, OMEBETA, OXIS, PANTOZOL, PASPERTIN, PULMICORT, RAMIPRIL, ROCEPHIN, SALBUTAMOL, SIMVABETA, SPIRIVA, TAZOBAC, WARFARIN, ZOPICLON
Adverse Events (AE) Preferred term	1. Bronchitis 2. Bronchitis 3. Infective exacerbation of chronic obstructive airways disease 4. Sleep disorder 5. Pneumonia 6. Arthralgia 7. Arthralgia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/YES/YES/YES 4. MILD/NO/NO/YES 5. MODERATE/YES/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 16OCT2010 (113) - 25NOV2010 (153) 2. 26NOV2010 (154) - 02JAN2011 (191) 3. 02JAN2011 (191) - 11JAN2011 (200) 4. 03JAN2011 (192) - 10JAN2011 (199) 5. 27JAN2011 (216) - 07FEB2011 (227) 6. 18MAY2011 (327) - 18MAY2011 (327) 7. 21MAY2011 (330) - 21MAY2011 (330)
Duration of AE	1. 41 2. 38 3. 10 4. 8 5. 12 6. 1 7. 1
Dose on AE onset	1. 2. 3. 4. 5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100473005

Parameter	Value
	6.
	7.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
	2. NONE
	3. REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
Outcome of event	1. IMPROVED
	2. WORSENED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-100473005[2),2)]	INFECTIOUS EXACERBATION OF COPD（PT：感染による慢性閉塞性気道疾患の増悪） 治験担当医はワルファリンと報告事象との関連性があると判断した。弊社は、合併症（珪肺症）によるものであり、ワルファリンとの因果関係は否定できると考える。 PNEUMONIA（PT：肺炎） 治験担当医はワルファリンと報告事象との関連性があると判断した。弊社は、合併症（珪肺症）によるものであり、ワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100473007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100473007/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/81/WHITE/GERMANY/YES
Medical history	Cataract, Retinal detachment, Eye haemorrhage, Gastritis, Hypoacusis, Haemorrhoids, Hepatitis A, Hypercholesterolaemia, Hypertension, Osteoporosis, Musculoskeletal pain, Urinary tract infection, Vertigo, Breast haematoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACOIN, ALENDRONSÄURE, ARLEVERT, ASS, BIFITERAL, CALCIUM, DORMICUM, MOVIPREP, OLMETEC, PANTOZOL, SIMVA, VOCADO
Adverse Events (AE) Preferred term	1. Constipation 2. Hypertension 3. Hepatic enzyme increased 4. Headache 5. Nausea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. SEVERE/YES/YES/YES 4. MILD/YES/NO/YES 5. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 30AUG2010 (8) - 02SEP2010 (11) 2. 06SEP2010 (15) - --NOV2010 (.) 3. 25NOV2010 (95) - 21DEC2010 (121) 4. 25NOV2010 (95) - 06JAN2011 (137) 5. 25NOV2010 (95) - 16DEC2010 (116)
Duration of AE	1. 4 2. . 3. 27 4. 43 5. 22
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY,OTHER 3. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER 4. NONE 5. NONE
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100473007

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100473011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/100473011/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/69/WHITE/GERMANY/YES
Medical history	Hypertension, Hyperuricaemia, Intervertebral disc protrusion, Lipids increased, Goitre, Hypothyroidism, Varicose vein, Osteoarthritis, Osteoarthritis, Cholelithiasis, Obesity, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC, ADUMBRAN, ALLOPURINOL, ARIXTRA, ATACAND [CANDESARTAN CILEXETIL], BLOPRESS, CARMEN, CONCOR, ENOXAPARIN, IMERON, L-THYROXIN, NACL 0.9%, NAPROXEN, NITRENDIPIN, NOVALGIN, PIRETANID, SPIRONOLACTON, TARGIN/ NALOXON, TARGIN/NALOXON, TORASEMID, WARFARIN
Adverse Events (AE) Preferred term	1. Chest discomfort 2. Oedema peripheral 3. Muscle spasms 4. Pain in extremity 5. Headache 6. Hypertension 7. Sleep apnoea syndrome 8. Sleep apnoea syndrome 9. Toothache
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/YES/NO/YES 4. MILD/YES/NO/YES 5. MILD/YES/NO/YES 6. MODERATE/YES/YES/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/YES/NO/YES
Start/stop date of event with relative date	1. --JUN2011 (.) - --------- (.) 2. --MAY2011 (.) - 09JUN2011 (206) 3. 14NOV2010 (-1) - 25NOV2010 (10) 4. 20NOV2010 (5) - 23NOV2010 (8) 5. 21NOV2010 (6) - 17FEB2011 (94) 6. 13JAN2011 (59) - 26JAN2011 (72) 7. 13JAN2011 (59) - 29JAN2011 (75) 8. 29JAN2011 (75) - --------- (.) 9. 24MAR2011 (129) - 28MAR2011 (133)
Duration of AE	1. . 2. . 3. 12 4. 4 5. 89 6. 14 7. 17 8. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100473011

Parameter	Value
	9. 5
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. NONE
	2. OTHER
	3. OTHER
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY,OTHER
	7. OTHER
	8. OTHER
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. IMPROVED
	8. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 100473011

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-100473011[2)]	AGGRAVATED HYPERTENSION（PT：高血圧） 治験担当医はワルファリンと報告事象との関連性があると判断した。弊社は、合併症（高血圧）によるものであり、ワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120023005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/120023005/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/74/WHITE/UNITED KINGDOM/YES
Medical history	Appendicectomy, Asthma, Cerebrovascular accident, Emphysema, Hypercholesterolaemia, Back pain, Peripheral vascular disorder, Sciatica
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, BECLOMETHASONE, CO-DYDRAMOL, ENOXAPARIN, IPRATROPIUM, PARACETAMOL, SALBUTAMOL, SIMVASTATIN
Adverse Events (AE) Preferred term	1. Emphysema 2. Chronic obstructive pulmonary disease 3. Dyspnoea 4. Actinic keratosis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. SEVERE/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 16FEB2009 (14) - --------- (.) 2. 16FEB2009 (14) - --------- (.) 3. 30MAR2009 (56) - 30MAR2009 (56) 4. 20MAY2009 (107) - --------- (.)
Duration of AE	1. . 2. . 3. 1 4. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. I 2. I 3. . 4. .
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. NONE 4.
Outcome of event	1. UNCHANGED 2. IMPROVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120023005

Parameter	Value
	4. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120023007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/120023007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/63/BLACK/UNITED KINGDOM/YES
Medical history	Synovial cyst, Bursitis, Ankle fracture, Gout, Haemorrhoids, Leukocytoclastic vasculitis, Osteoarthritis, Osteoarthritis, Psoriasis, Rash, Monarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, AQUEOUS CREAM [EMULSIFYING OINTMENT, PHENOXYETHANOL], CLOBTASONE BUTYRATE CREAM, CO-CODAMOL, DICLFENAC, ENOXAPARIN, PARACETAMOL, WARFARIN
Adverse Events (AE) Preferred term	1. Rectal haemorrhage 2. Chest pain 3. Fall 4. Aspartate aminotransferase increased 5. Rectal haemorrhage 6. Chest pain 7. Aspartate aminotransferase increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/YES/NO/YES 6. SEVERE/NO/YES/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 01JUN2009 (62) - 01JUN2009 (62) 2. 02JUN2009 (63) - 03JUN2009 (64) 3. 31AUG2009 (153) - 31AUG2009 (153) 4. 03SEP2009 (156) - 07DEC2009 (251) 5. 04NOV2009 (218) - 04NOV2009 (218) 6. 04DEC2009 (248) - 05DEC2009 (249) 7. 07DEC2009 (251) - --------- (.)
Duration of AE	1. 1 2. 2 3. 1 4. 96 5. 1 6. 2 7. .
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120023007

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. OTHER
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED
	6. REMEDIAL DRUG THERAPY
	7. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120023013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/120023013/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/57/WHITE/UNITED KINGDOM/YES
Medical history	Aortic stenosis, Cholecystectomy, Cardiac failure chronic, Diverticulum, Essential hypertension, Colectomy, Hiatus hernia, Hypercholesterolaemia, Hyperkalaemia, Retinopathy hypertensive, Hypotension, Myocardial ischaemia, Obesity, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPINE, ASPIRIN, BENDROFLUMETHIAZIDE, BISOPROLOL, BUMETANIDE, DICLOFENAC, DOXASOCIN, DOXAZOCIN, ENOXAPARIN, FERROUS FUMARATE, FLUCLOXACILLIN, FRUSEMIDE, FUCIDIN CREAM, INSULATARD, METALOZONE, NOVORAPID, OMEPRAZOLE, PARACETAMOL, POTASSIUM INJECTION, RAMIPRIL, SANDO -K, SENNA, SIMVASTATIN, SODIUM CHLORIDE, TRAMADOL, ZANTAC
Adverse Events (AE) Preferred term	1. Heart rate irregular 2. International normalised ratio increased 3. Rash 4. Catheter site phlebitis 5. Hypokalaemia 6. Atrial fibrillation 7. Syncope 8. Operative haemorrhage 9. Anaemia 10. Cardiac failure 11. Hypertension 12. Hypoglycaemia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. SEVERE/NO/NO/YES 7. SEVERE/NO/YES/YES 8. MODERATE/YES/YES/YES 9. MILD/NO/NO/YES 10. SEVERE/NO/YES/YES 11. MODERATE/NO/NO/YES 12. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 29JUL2009 (2) - 29JUL2009 (2) 2. 29JUL2009 (2) - 03AUG2009 (7) 3. 31JUL2009 (4) - --------- (.) 4. 06AUG2009 (10) - -----2009 (.) 5. 06AUG2009 (10) - 09AUG2009 (13) 6. 14AUG2009 (18) - 14AUG2009 (18) 7. 16AUG2009 (20) - 20AUG2009 (24) 8. 20AUG2009 (24) - 20AUG2009 (24) 9. 21AUG2009 (25) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120023013

Parameter	Value
	10. 16OCT2009 (81) - 19OCT2009 (84)
	11. 17OCT2009 (82) - 19OCT2009 (84)
	12. 18OCT2009 (83) - 19OCT2009 (84)
Duration of AE	1. 1
	2. 6
	3. .
	4. .
	5. 4
	6. 1
	7. 5
	8. 1
	9. .
	10. 4
	11. 3
	12. 2
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120023013

Parameter	Value
	6. NONE
	7. OTHER
	8. OTHER
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120023014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/120023014/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/81/BLACK/UNITED KINGDOM/YES
Medical history	Anaemia, Constipation, Gastrointestinal disorder, Gout, Hypercholesterolaemia, Hypertension, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, AMLODIPINE, ASPIRIN, ATENOLOL, CLOPIDROGEL, CODEINE PHOSPHATE, DEXTROSE 5%, ENOXAPARIN, GLYCERYL TRINITRATE, PARACETAMOL, PICOLAX, SODIUM CHLORIDE INTRAVENOUS FLUIDS, WARFARIN
Adverse Events (AE) Preferred term	1. Pleuritic pain 2. Troponin increased 3. Acute coronary syndrome 4. Joint injury 5. Chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 01SEP2009 (23) - 10SEP2009 (32) 2. 01SEP2009 (23) - -----2009 (.) 3. 06SEP2009 (28) - 06SEP2009 (28) 4. 29SEP2009 (51) - 29SEP2009 (51) 5. 29SEP2009 (51) - 29SEP2009 (51)
Duration of AE	1. 10 2. . 3. 1 4. 1 5. 1
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY 4. NONE 5. NONE
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120023014

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120023018

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/120023018/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/64/WHITE/UNITED KINGDOM/YES
Medical history	Asthma, Chronic obstructive pulmonary disease, Peptic ulcer, Sinus tachycardia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CARBOCISTEINE, ENOXAPARIN, IPRATROPIUM, LANSOPRAZOLE, PARACETAMOL, SALBUTAMOL, SERETIDE 250, VERAPAMIL, WARFARIN
Adverse Events (AE) Preferred term	1. Haematuria 2. Granuloma 3. Contusion 4. Upper gastrointestinal haemorrhage 5. Scrotal haematoma 6. Catheter site haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --MAY2010 (.) - 13MAY2010 (121) 2. 22JAN2010 (10) - 18MAY2010 (126) 3. 07APR2010 (85) - --APR2010 (.) 4. 09APR2010 (87) - -----2010 (.) 5. 16APR2010 (94) - --APR2010 (.) 6. 11MAY2010 (119) - 11MAY2010 (119)
Duration of AE	1. . 2. 117 3. . 4. . 5. . 6. 1
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120023018

Parameter	Value
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-120023018[4)]	UPPER GASTROINTESTINAL BLEEDING（PT：上部消化管出血） 治験担当医は、合併症（消化性潰瘍）によるものであり、否定できると判断した。弊社は、エノキサパリン及びワルファリン投与と報告事象発現との時間的関連性及び抗凝固作用から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120023019

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/120023019/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/35/WHITE/UNITED KINGDOM/YES
Medical history	Bone graft, Hypercholesterolaemia, Hypertension, Obesity, Arthralgia, Bone lesion, Pain in extremity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BENDROFLUMETHIAZIDE, BETAHISTINE, CODEINE PHOSPHATE, ENOXAPARIN, GAVISCON, LOSARTAN, OMEPRAZOLE, PARACETAMOL, SENEKOT, SIMVASTATIN, WARFARIN
Adverse Events (AE) Preferred term	1. Constipation 2. Vertigo 3. Gastritis 4. Upper limb fracture 5. Subcutaneous haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES 5. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 13FEB2010 (25) - 13FEB2010 (25) 2. 15FEB2010 (27) - 15FEB2010 (27) 3. 24APR2010 (95) - 24APR2010 (95) 4. 02JUN2010 (134) - 01JUL2010 (163) 5. 02JUN2010 (134) - 16JUL2010 (178)
Duration of AE	1. 1 2. 1 3. 1 4. 30 5. 45
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 5. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120023019

Parameter	Value
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-120023019[2)]	HAEMATOMA LEFT KNEE（PT：血腫） 治験担当医はエノキサパリンと報告事象との関連性があると判断した。弊社は、エノキサパリン投与約 4 ヵ月半後の発現であり、時間的関連性がないため、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120033002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/120033002/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/80/BLACK/UNITED KINGDOM/YES
Medical history	Metastases to bone, Cerebrovascular accident, Chest pain, Cough, Haemoglobin decreased, Diabetes mellitus, Hypercholesterolaemia, Hypertension, Arthralgia, Multiple allergies, Nausea, Pneumonia, Pyrexia, Dyspnoea, Vertigo, Prostate cancer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLCYTOSEINE, ACTRAPID, ADRENALINE, AMOXICILLIN, ASPIRIN, AUGMENTIN, BENDROFLUAZIDE, BICALUTAMIDE, CETERAZINE, CLARITHROMYCIN, CODEINE, CYCLIZINE, DOMPERIDONE, DOXAZOSIN, DOXYCYCLINE, ENALAPRIL, ENOXAPARIN, FERROUS SULFATE, FUROSEMIDE, GAVISCON, GENTAMYCIN, GLICLAZIDE, METFORMIN, METOCLOPRAMIDE, MIDAZOLAM, NIFEDIPINE M/R, NORMAL SALINE, OMEPRAZOLE, PANTOPRAZOLE, PARACETAMOL, PROCHLORPERAZINE, PROCHLORPERAZINE MALEATE, VITAMIN K, WARFARIN, XYLOCAINE SPRAY, ZOLADEX
Adverse Events (AE) Preferred term	1. Nausea 2. Gastric ulcer haemorrhage 3. Anaemia 4. Melaena 5. Diarrhoea 6. Vomiting 7. Haematemesis 8. Tachycardia 9. Subdural haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/YES/YES 3. MODERATE/YES/NO/YES 4. MODERATE/YES/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/YES/NO/YES 8. MILD/NO/NO/YES 9. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. --JUL2008 (.) - --------- (.) 2. 06JUN2008 (1) - 28AUG2008 (84) 3. 07JUN2008 (2) - --------- (.) 4. 09JUN2008 (4) - 13JUN2008 (8) 5. 12JUN2008 (7) - --------- (.) 6. 13JUN2008 (8) - 13JUN2008 (8) 7. 13JUN2008 (8) - 13JUN2008 (8) 8. 13JUN2008 (8) - 13JUN2008 (8) 9. 01DEC2008 (179) - 17FEB2009 (257)
Duration of AE	1. . 2. 84 3. . 4. 5

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120033002

Parameter	Value
	5. .
	6. 1
	7. 1
	8. 1
	9. 79
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	3. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
	4. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	5. NONE
	6. NONE
	7. STUDY DRUG DISCONTINUED AND RESTARTED
	8. NONE
	9. OTHER
Outcome of event	1. INSUFFICIENT FOLLOW-UP
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. INSUFFICIENT FOLLOW-UP
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120033002

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120033003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/120033003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/65/WHITE/UNITED KINGDOM/YES
Medical history	Anaemia, Cervix carcinoma, Creatinine renal clearance decreased, Menopause, Abdominal pain upper, Metastases to stomach
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DICLOFENAC, ENOXAPARIN, OMEPRAZOLE, PARACETAMOL, WARFARIN
Adverse Events (AE) Preferred term	1. International normalised ratio increased 2. International normalised ratio increased 3. Depression 4. Fatigue 5. Dyspnoea 6. Oedema 7. International normalised ratio increased 8. Cervix carcinoma
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/YES/NO/YES 8. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 17JUN2008 (8) - 19JUN2008 (10) 2. 23JUN2008 (14) - 01JUL2008 (22) 3. 01JUL2008 (22) - --------- (.) 4. 01JUL2008 (22) - --------- (.) 5. 04JUL2008 (25) - --------- (.) 6. 04JUL2008 (25) - --------- (.) 7. 18JUL2008 (39) - --JUL2008 (.) 8. 11AUG2008 (63) - 26AUG2008 (78)
Duration of AE	1. 3 2. 9 3. . 4. . 5. . 6. . 7. . 8. 16
Dose on AE onset	1. 2. 3. 4. 5. 6.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 120033003

Parameter	Value
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED
	2. DOSE OF STUDY DRUG REDUCED
	3. OTHER
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED
	7. RESOLVED
	8. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140153001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140153001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/24/WHITE/UNITED STATES/YES
Medical history	Asthma, Cellulitis, Migraine, Pulmonary hypertension, Dyspnoea, Tinea pedis, Oedema peripheral
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETAMINOPHEN/CODEINE, ADVAIR, CLINDAMYCIN, DILAUDID, ENOXAPARIN, FENTANYL, HEPARIN, HYDROCODONE/APAP, IVC FILTER, KCL, LAMISIL, LASIX, LEVAQUIN, MORPHINE, MULTIVITAMIN, NORCO, PERCOCET, POTASSIUM CHLORIDE, PROTONIX, ROCEPHIN, SENOKOT, SEPTRA, TINACTIN, VERSED, WARFARIN
Adverse Events (AE) Preferred term	1. Haemoptysis 2. Cough 3. Abscess soft tissue 4. Abscess limb 5. Tinea pedis 6. Tinea manuum 7. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 12SEP2007 (1) - 14SEP2007 (3) 2. 12SEP2007 (1) - 16SEP2007 (5) 3. 01OCT2007 (20) - 11OCT2007 (30) 4. 11OCT2007 (30) - --------- (.) 5. 20OCT2007 (39) - --------- (.) 6. 20OCT2007 (39) - --------- (.) 7. 10NOV2007 (60) - --------- (.)
Duration of AE	1. 3 2. 5 3. 11 4. . 5. . 6. . 7. .
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140153001

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	2. OTHER
	3. REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. WORSENED
	4. IMPROVED
	5. IMPROVED
	6. IMPROVED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-140153001[1),4)]	ABSCESS IN PRE-TIBIAL SPACE RIGHT LEG（PT：四肢膿瘍） 治験担当医は報告事象とエノキサパリンとの因果関係評価を行っていない。弊社は、合併症（蜂巣炎及び膿瘍）によるものであり、エノキサパリンとの因果関係は否定できると考える。 HEMOPTYSIS（PT：喀血） 治験担当医は、原疾患（肺塞栓症）及び合併症（肺高血圧症）によるものであり、否定できると判断した。弊社は、エノキサパリン及びワルファリン投与と報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140153009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140153009/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/31/WHITE/UNITED STATES/YES
Medical history	Pulmonary infarction, Thoracic outlet syndrome, Pleural effusion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	COLACE, DEPROVERA, DILAUDID, DOCUSATE SODIUM, ENOXAPARIN, FERROUS GLUCONATE, FISH OIL, GABIPENTEN, IMMODIUM, INSULIN, LORTAB, LOVASTATIN, MULTI VITAMINS, MYCOLOG CREAM, ORTHOTRICYCLEN LO, OXYCODONE, PREDNISONE, SENNA S, SENNAGEN, SOLUMEDROL, TORADOL, TYLENOL #3, TYLENOL #4, UNFRACTIONATED HEPARIN, VITAMIN B COMPLEX100, VITAMIN D, WARFARIN, ZOFRAN
Adverse Events (AE) Preferred term	1. Insomnia 2. Constipation 3. Fatigue 4. Constipation 5. Application site rash 6. Haemoptysis 7. Hyperglycaemia 8. Pleuritic pain 9. Hyperglycaemia 10. Nausea 11. Nerve compression 12. Anaemia 13. Chest pain 14. Hypotension 15. Nausea 16. Constipation 17. Pleural effusion 18. Pulmonary infarction 19. Chills 20. Diarrhoea 21. Upper respiratory tract infection 22. Hyperlipidaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/YES/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MILD/NO/NO/YES 13. SEVERE/NO/YES/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140153009

Parameter	Value
	14. MODERATE/NO/NO/YES
	15. MODERATE/NO/NO/YES
	16. MILD/NO/NO/YES
	17. MODERATE/NO/NO/YES
	18. MODERATE/NO/NO/YES
	19. MODERATE/NO/NO/YES
	20. MODERATE/NO/NO/YES
	21. MILD/NO/NO/YES
	22. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --FEB2009 (.) - --------- (.)
	2. 06DEC2008 (1) - 15DEC2008 (10)
	3. 06DEC2008 (1) - --------- (.)
	4. 06DEC2008 (1) - 09DEC2008 (4)
	5. 07DEC2008 (2) - 16DEC2008 (11)
	6. 08DEC2008 (3) - 20FEB2009 (77)
	7. 09DEC2008 (4) - 09DEC2008 (4)
	8. 11DEC2008 (6) - 15DEC2008 (10)
	9. 12DEC2008 (7) - 13DEC2008 (8)
	10. 12DEC2008 (7) - 13DEC2008 (8)
	11. 15DEC2008 (10) - --------- (.)
	12. 24DEC2008 (19) - --------- (.)
	13. 24DEC2008 (19) - 27DEC2008 (22)
	14. 24DEC2008 (19) - 25DEC2008 (20)
	15. 24DEC2008 (19) - 25DEC2008 (20)
	16. 24DEC2008 (19) - 29DEC2008 (24)
	17. 25DEC2008 (20) - 15JUN2009 (192)
	18. 25DEC2008 (20) - 15JUN2009 (192)
	19. 23FEB2009 (80) - 12MAR2009 (97)
	20. 23FEB2009 (80) - 15JUN2009 (192)
	21. 15APR2009 (131) - 22APR2009 (138)
	22. 15APR2009 (131) - --------- (.)
Duration of AE	1. .
	2. 10
	3. .
	4. 4
	5. 10
	6. 75
	7. 1
	8. 5
	9. 2
	10. 2
	11. .
	12. .
	13. 4

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140153009

Parameter	Value
	14. 2
	15. 2
	16. 6
	17. 173
	18. 173
	19. 18
	20. 113
	21. 8
	22. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140153009

Parameter	Value
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. NONE
	18. REMEDIAL DRUG THERAPY
	19. NONE
	20. REMEDIAL DRUG THERAPY
	21. NONE
	22. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. UNCHANGED
	12. UNCHANGED
	13. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140153009

Parameter	Value
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-140153009[1),1)]	INCREASE IN RT SIDED CHEST PAIN（PT：胸痛） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、原疾患（肺塞栓症）によるものと考えられるため、ワルファリンとの因果関係は否定できると考える。 WORSENING RIGHT PLEURITIC PAIN（PT：胸膜痛） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併用薬（Steroid)によるものと考えられるため、ワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140153012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140153012/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/67/WHITE/UNITED STATES/YES
Medical history	Anaemia, Anxiety, Atrial fibrillation, Breast cancer, Constipation, Depression, Gastrooesophageal reflux disease, Hypothyroidism, Hysterectomy, Insomnia, Neuralgia, Neuropathy peripheral, Obesity, Plantar fasciitis, Restless legs syndrome, Sciatica, Vitamin B12 deficiency, Fibromyalgia, Lumbar radiculopathy, Back pain, Attention deficit/hyperactivity disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBIEN CR, CALCIUM CARBONATE, CYMBALTA, DEPLIN (L METHYLFOLATE, DILAUDID, DUCOSATE, HYDROCODONE, LEVOQUIN, LORAZEPAM, LYRICA, METHYLPHENIDATE, MIRAPEX, MOTRIN, OMEPRAZOLE, OXYCODONE, PERCOCET, ROBAXIN, SENNA, SYNTHROID, VIT B 12, VIT D
Adverse Events (AE) Preferred term	1. Plantar fasciitis 2. Muscle spasms 3. Contusion 4. Fall 5. Fall 6. Wound haemorrhage 7. Wound haemorrhage 8. Fall 9. Pain in extremity 10. Urinary tract infection 11. Haemorrhoidal haemorrhage 12. Excoriation 13. Upper respiratory tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. SEVERE/NO/YES/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --JUL2009 (.) - 25OCT2009 (181) 2. 09MAY2009 (12) - 09MAY2009 (12) 3. 24MAY2009 (27) - 02JUN2009 (36) 4. 24MAY2009 (27) - 24MAY2009 (27) 5. 28MAY2009 (31) - 28MAY2009 (31) 6. 14JUN2009 (48) - 26JUN2009 (60) 7. 14JUN2009 (48) - 26JUN2009 (60)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140153012

Parameter	Value
	8. 14JUN2009 (48) - 14JUN2009 (48)
	9. 22JUN2009 (56) - 25JUN2009 (59)
	10. 22JUN2009 (56) - 25JUN2009 (59)
	11. 18AUG2009 (113) - 18AUG2009 (113)
	12. 22OCT2009 (178) - 23OCT2009 (179)
	13. 04NOV2009 (191) - --------- (.)
Duration of AE	1. .
	2. 1
	3. 10
	4. 1
	5. 1
	6. 13
	7. 13
	8. 1
	9. 4
	10. 4
	11. 1
	12. 2
	13. .
Dose on AE onset	1.
	2. 15 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140153012

Parameter	Value
	13. F
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. NONE
	13. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140163030

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140163030/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/86/WHITE/UNITED STATES/YES
Medical history	Gastrooesophageal reflux disease, Anaemia, Blood cholesterol increased, Hypothyroidism, Hysterectomy, Blood pressure increased, Knee arthroplasty, Thrombocytopenia, Seasonal allergy, Infrequent bowel movements, Hernia repair
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, AVALIDE, CALCIUM SUPPLEMENT, CLARINEX [INGREDIENTS ARE LORATADINE + PSEUDOPHEDERINE SULFATE], FOLVITE, METAMUCIL, MULTIVITAMINS, NASONEX, NORVASC, PREMARIN, PROTONIX, SYNTHROID, TRICOR, ZANTAC
Adverse Events (AE) Preferred term	1. Gastrointestinal haemorrhage 2. Occult blood positive 3. Gastrooesophageal reflux disease 4. Muscle haemorrhage 5. Gastrointestinal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 29AUG2008 (11) - 23OCT2008 (66) 2. 29AUG2008 (11) - 31AUG2008 (13) 3. 17SEP2008 (30) - 31OCT2008 (74) 4. 22OCT2008 (65) - 31OCT2008 (74) 5. 24OCT2008 (67) - 31OCT2008 (74)
Duration of AE	1. 56 2. 3 3. 45 4. 10 5. 8
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. F
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY 2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 3. REMEDIAL DRUG THERAPY 4. NONE 5. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140163030

Parameter	Value
Outcome of event	1. WORSENED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140163046

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140163046/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/57/WHITE/UNITED STATES/YES
Medical history	Anxiety, Blood cholesterol increased, Haemoglobin decreased, Hysterectomy, Blood pressure increased, Dyspepsia, Lung disorder, Obesity, Osteoporosis, Retroperitoneal cancer, Sarcoma uterus, Urogenital disorder, Seasonal allergy, Ankle operation, Haematocrit decreased
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPRAZOLAM, CALCIUM CITRATE, EVISTA, FEOSOL, FISH OIL, LASIX, LIPITOR, LOTREL, MULTIVITAMIN, NEXIUM, RESCON [CHLORPHENAMINE MAL + PSEUDOEPHEDRINE], TAMOXIFEN, ZYCAM
Adverse Events (AE) Preferred term	1. Osteonecrosis 2. Compression fracture 3. Dyspepsia 4. Gingival bleeding 5. Musculoskeletal stiffness 6. Joint stiffness 7. Joint stiffness 8. Contusion 9. Arthralgia 10. Coital bleeding 11. Coital bleeding
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES 10. MILD/YES/NO/YES 11. MILD/YES/NO/YES
Start/stop date of event with relative date	1. --SEP2009 (.) - 14DEC2009 (251) 2. --SEP2009 (.) - 14DEC2009 (251) 3. 10APR2009 (3) - 10APR2009 (3) 4. 11APR2009 (4) - 11APR2009 (4) 5. 12APR2009 (5) - 14APR2009 (7) 6. 12MAY2009 (35) - --------- (.) 7. 14MAY2009 (37) - --------- (.) 8. 03JUL2009 (87) - 07JUL2009 (91) 9. 04JUL2009 (88) - 07JUL2009 (91) 10. 19SEP2009 (165) - 19SEP2009 (165) 11. 03OCT2009 (179) - 03OCT2009 (179)
Duration of AE	1. . 2. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140163046

Parameter	Value
	3. 1
	4. 1
	5. 3
	6. .
	7. .
	8. 5
	9. 4
	10. 1
	11. 1
Dose on AE onset	1.
	2.
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	2. OTHER
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140163046

Parameter	Value
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. INSUFFICIENT FOLLOW-UP
	7. INSUFFICIENT FOLLOW-UP
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140173001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140173001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/57/WHITE/UNITED STATES/YES
Medical history	Acute respiratory distress syndrome, Drug hypersensitivity, Drug hypersensitivity, Anaemia, Anxiety, Bronchiectasis, Cellulitis, Diabetes mellitus, Drug hypersensitivity, Drug hypersensitivity, Drug hypersensitivity, Pain in extremity, Skin ulcer, Glaucoma, Basedow's disease, Hyperlipidaemia, Hysterectomy, Neuropathy peripheral, Ovarian cancer, Pneumonia, Pneumothorax, Salpingo-oophorectomy, Thrombocytopenia, Arterial bypass operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADVAIR, ALBUTEROL, ALLEGRA, ALOXI, AMIPICILLIN/SULBACTAM, ATARAX [HYDROXYZINE], ATIVAN, ATROVENT, AZITHROMYCIN, BACTRIM [SULFAMETHOXAZOLE], BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE ALONE.], CLINDAMYCIN, COMPAZINE, D5 LR, DARVOCET, DEMEROL, DILAUDID, ENOXAPARIN, FAMOTIDINE, FENTANYL, FISH OIL, GABAPENTIN, GLIPIZIDE, GUAR GUM, HYDROMORPHONE, INSULIN, LACTATED RINGERS, LACTOBACILLUS [CULTURELLE], LEVAQUIN, LIDOCAINE, LOPERAMIDE, MAGNESIUM SULFATE, METHIMAZOLE, NYSTATIN, OXYGEN, PHENERGAN, PIPERACILLIN/TAZOBACTAM, POTASSIUM CHLORIDE, PREDNISONE, SPIRIVA, TAXOL, TOPOTECAN, TYLENOL #3, VANCOMYCIN, WARFARIN, XALATAN, ZOCOR, ZOFRAN, ZOLOFT, ZOSYN
Adverse Events (AE) Preferred term	1. Small intestinal obstruction 2. Osteomyelitis 3. Cellulitis 4. Diarrhoea
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 05DEC2007 (28) - 09DEC2007 (32) 2. 05MAR2008 (119) - 18MAR2008 (132) 3. 05MAR2008 (119) - 29APR2008 (174) 4. 06MAR2008 (120) - 19MAR2008 (133)
Duration of AE	1. 5 2. 14 3. 56 4. 14
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. REMEDIAL DRUG THERAPY,OTHER 3. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140173001

Parameter	Value
	4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140173016

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140173016/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/65/WHITE/UNITED STATES/YES
Medical history	Basal cell carcinoma, Incontinence, Knee arthroplasty, Menopause, Obesity, Pneumonia, Radius fracture, Tinnitus, Tonsillectomy, Tuberculin test positive, Uterine prolapse, Wisdom teeth removal, Breast calcifications, Seasonal allergy, Pilonidal sinus repair
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETAMINOPHEN, CALTRATE [CALCIUM, VITAMIN D], CHELATED ZINC, COD LIVER OIL, FISH OIL, FLAXSEED OIL, GELATIN, GLUCOSAMINE CHONDROITIN, INFLUENZA VACCINE, LIPOFLAVONOID, LORATADINE, PNEUMACOCAL VACCINE, RED YEAST RICE, TRIMO-SAN VAGINAL JELLY, VITAMIN C ROSE HIP
Adverse Events (AE) Preferred term	1. Vaginal haemorrhage 2. Pelvic pain 3. Dyspnoea exertional 4. Palpitations 5. Tremor 6. Breast mass 7. Uterine prolapse
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 08NOV2010 (21) - 08NOV2010 (21) 2. 08NOV2010 (21) - 08NOV2010 (21) 3. 21NOV2010 (34) - 24NOV2010 (37) 4. 21NOV2010 (34) - 24NOV2010 (37) 5. 22NOV2010 (35) - 24NOV2010 (37) 6. 25JAN2011 (99) - 26JAN2011 (100) 7. 24MAY2011 (218) - 25MAY2011 (219)
Duration of AE	1. 1 2. 1 3. 4 4. 4 5. 3 6. 2 7. 2
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140173016

Parameter	Value
	7. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. I
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED
	2. NONE
	3. OTHER
	4. OTHER
	5. NONE
	6. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	7. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140203001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/66/WHITE/UNITED STATES/YES
Medical history	Generalised oedema, Ascites, Blood calcium decreased, Cholelithiasis, Diarrhoea, Oedema peripheral, Hypertension, Microalbuminuria, Nausea, Ovarian cancer, Blood potassium decreased, Restless legs syndrome, Hysterectomy, Vomiting, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACIPHEX, ATIVAN, COSYNTROPIN, ENOXAPARIN, FUROSEMIDE, LEVOFLOXACIN, LORTAB, MAGNESIUM OXIDE, MEGACE, METOPROLOL XL, POTASSIUM BICARBONATE, PREVACID, PYRIDIUM, REQUIP, WARFARIN, ZALEPLON
Adverse Events (AE) Preferred term	1. Anxiety 2. Bladder spasm 3. Hyponatraemia 4. Inappropriate antidiuretic hormone secretion 5. Adrenal insufficiency 6. Hypocoagulable state 7. Bladder pain 8. International normalised ratio increased 9. Intra-abdominal haemorrhage 10. Malignant ascites 11. Anaemia 12. Lactic acidosis 13. Metabolic acidosis 14. Renal failure acute 15. White blood cell count increased 16. Blood creatinine increased 17. Hypotension 18. Hyperkalaemia 19. Blood glucose decreased 20. Skin irritation 21. Abdominal pain 22. Pain in extremity 23. Pruritus 24. Sedation 25. Decreased appetite
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. SEVERE/YES/NO/YES 7. MODERATE/NO/NO/YES 8. SEVERE/NO/NO/YES 9. SEVERE/NO/YES/YES 10. SEVERE/NO/YES/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203001

Parameter	Value
	11. MODERATE/NO/NO/YES
	12. MODERATE/NO/NO/YES
	13. MODERATE/NO/NO/YES
	14. MODERATE/NO/YES/YES
	15. MODERATE/NO/NO/YES
	16. MODERATE/NO/NO/YES
	17. MODERATE/NO/NO/YES
	18. MODERATE/NO/NO/YES
	19. MODERATE/NO/NO/YES
	20. MILD/NO/NO/NO
	21. MODERATE/NO/NO/NO
	22. MILD/NO/NO/NO
	23. MILD/NO/NO/NO
	24. MODERATE/NO/NO/NO
	25. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 17JUL2007 (1) - --------- (.)
	2. 18JUL2007 (2) - --------- (.)
	3. 19JUL2007 (3) - --------- (.)
	4. 19JUL2007 (3) - --------- (.)
	5. 19JUL2007 (3) - --------- (.)
	6. 20JUL2007 (4) - 21JUL2007 (5)
	7. 20JUL2007 (4) - --------- (.)
	8. 20JUL2007 (4) - 21JUL2007 (5)
	9. 21JUL2007 (5) - 21JUL2007 (5)
	10. 21JUL2007 (5) - 29JUL2007 (13)
	11. 21JUL2007 (5) - --------- (.)
	12. 21JUL2007 (5) - --------- (.)
	13. 21JUL2007 (5) - --------- (.)
	14. 21JUL2007 (5) - --------- (.)
	15. 21JUL2007 (5) - --------- (.)
	16. 21JUL2007 (5) - --------- (.)
	17. 21JUL2007 (5) - --------- (.)
	18. 21JUL2007 (5) - 21JUL2007 (5)
	19. 21JUL2007 (5) - 21JUL2007 (5)
	20. 24JUL2007 (8) - --------- (.)
	21. 25JUL2007 (9) - --------- (.)
	22. 26JUL2007 (10) - --------- (.)
	23. 26JUL2007 (10) - --------- (.)
	24. 26JUL2007 (10) - --------- (.)
	25. 27JUL2007 (11) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203001

Parameter	Value
	5. .
	6. 2
	7. .
	8. 2
	9. 1
	10. 9
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
	18. 1
	19. 1
	20. .
	21. .
	22. .
	23. .
	24. .
	25. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203001

Parameter	Value
	24.
	25.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED PERMANENTLY
	7. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY,OTHER
	12. NONE
	13. NONE
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. NONE
	17. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203001

Parameter	Value
	18. REMEDIAL DRUG THERAPY
	19. REMEDIAL DRUG THERAPY
	20. REMEDIAL DRUG THERAPY
	21. REMEDIAL DRUG THERAPY
	22. NONE
	23. REMEDIAL DRUG THERAPY
	24. REMEDIAL DRUG THERAPY
	25. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED
	10. DEATH
	11. UNCHANGED
	12. UNCHANGED
	13. UNCHANGED
	14. UNCHANGED
	15. UNCHANGED
	16. UNCHANGED
	17. UNCHANGED
	18. RESOLVED
	19. RESOLVED
	20. UNCHANGED
	21. UNCHANGED
	22. UNCHANGED
	23. UNCHANGED
	24. UNCHANGED
	25. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-140203001[4)]	ABDOMINAL BLEEDING（PT：腹腔内出血） 治験担当医は、合併症（卵巣癌悪化による腹水）によるものであり、否定できると判断した。弊社は、エノキサパリン及びワルファリンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203016

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140203016/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/54/WHITE/UNITED STATES/YES
Medical history	Arachnoiditis, Headache, Dyspepsia, Nervous system disorder, Joint dislocation reduction, Fibromyalgia, Caesarean section, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, AUGMENTIN, COENZYME Q-10, DIOVAN, DIOVAN [HYDROCHLOROTHIAZIDE + VALSARTAN], ENOXAPARIN, LANTUS, MORPHINE SULFATE, MOTRIN, MULTIVITAMIN, MYLANTA [ALUMINUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE], NOVOLOG, TYLENOL [ACETAMINOPHEN], VITAMIN E, WARFARIN, ZINC, ZOSYN
Adverse Events (AE) Preferred term	1. Feeling cold 2. Pain in extremity 3. Muscle spasms 4. Oedema peripheral 5. Syncope 6. Chest pain 7. Dyspnoea 8. Cough 9. Back pain 10. Non-cardiac chest pain 11. Hypertension 12. Hyperglycaemia 13. Pneumonia 14. Diabetes mellitus 15. Pain in extremity 16. Non-cardiac chest pain 17. Hypoaesthesia 18. Collateral circulation
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/YES/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MODERATE/NO/YES/YES 14. MODERATE/NO/NO/YES 15. MILD/NO/NO/YES 16. MODERATE/NO/YES/YES 17. MODERATE/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203016

Parameter	Value
	18. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 16DEC2007 (2) - 11APR2008 (119)
	2. 25DEC2007 (11) - 02JAN2008 (19)
	3. 25DEC2007 (11) - 02JAN2008 (19)
	4. 25DEC2007 (11) - 02JAN2008 (19)
	5. 26DEC2007 (12) - 26DEC2007 (12)
	6. 26DEC2007 (12) - 14JAN2008 (31)
	7. 26DEC2007 (12) - 16FEB2008 (64)
	8. 26DEC2007 (12) - 16FEB2008 (64)
	9. 26DEC2007 (12) - 30DEC2007 (16)
	10. 14JAN2008 (31) - 16JAN2008 (33)
	11. 14JAN2008 (31) - --------- (.)
	12. 14JAN2008 (31) - 23JAN2008 (40)
	13. 14JAN2008 (31) - 24FEB2008 (72)
	14. 15JAN2008 (32) - 23JAN2008 (40)
	15. 17FEB2008 (65) - 18APR2008 (126)
	16. 17MAR2008 (94) - 25JUN2008 (194)
	17. 17MAR2008 (94) - 17MAR2008 (94)
	18. 09JUL2008 (208) - --------- (.)
Duration of AE	1. 118
	2. 9
	3. 9
	4. 9
	5. 1
	6. 20
	7. 53
	8. 53
	9. 5
	10. 3
	11. .
	12. 10
	13. 42
	14. 9
	15. 62
	16. 101
	17. 1
	18. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203016

Parameter	Value
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. REMEDIAL DRUG THERAPY,OTHER
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203016

Parameter	Value
	16. REMEDIAL DRUG THERAPY
	17. NONE
	18. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. WORSENED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. UNCHANGED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140203023/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/64/WHITE/UNITED STATES/YES
Medical history	Anxiety, Chest pain, Cholecystectomy, Chronic obstructive pulmonary disease, Coronary artery disease, Hypertension, Hysterectomy, Myocardial infarction, Nasal congestion, Dyspnoea
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADVAIR, ASPIRIN, CALCIUM, COREG, ECOTRIN, ENOXAPARIN, HALLS LOZENGE, HYDROCHLOROTHIAZIDE, IMDUR, K-LYTE, LIPITOR, LORTAB, METOPROLOL, MUCINEX, NIFEDIAC, NORVASC, PEPCID, PHENAZOPYRIDINE HCL, PHENERGAN WITH CODEINE, PLAVIX, PREDNISONE, PRINIVIL, PRINZIDE, PROTONIX, PROVENTIL, SPIRIVA, SURFAK, TUSSIONEX, VITAMIN C, WARFARIN, XOPENEX, ZITHROMAX, ZYRTEC
Adverse Events (AE) Preferred term	1. Leukocytosis 2. Dyspnoea 3. Dizziness 4. Hypokalaemia 5. Pollakiuria 6. Joint swelling 7. Diarrhoea 8. Cough
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 04MAY2008 (5) - 05MAY2008 (6) 2. 22JUN2008 (54) - 02JUL2008 (64) 3. 22JUN2008 (54) - 26JUN2008 (58) 4. 27JUN2008 (59) - 27JUN2008 (59) 5. 21SEP2008 (145) - 26SEP2008 (150) 6. 07OCT2008 (161) - 19FEB2009 (296) 7. 25DEC2008 (240) - 02JAN2009 (248) 8. 18FEB2009 (295) - 25FEB2009 (302)
Duration of AE	1. 2 2. 11 3. 5 4. 1 5. 6 6. 136 7. 9 8. 8
Dose on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203023

Parameter	Value
	3.
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140203029/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/79/WHITE/UNITED STATES/YES
Medical history	Decreased appetite, Bladder cancer, Chest discomfort, Cough, Hyperkalaemia, Dyspnoea, Urostomy, Weight decreased, Pulmonary mass, Nicotine dependence, Prostatectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DECADRON, DUONEB, ENOXAPARIN, FERROUS SULFATE, LEVAQUIN, LEVOFLOXACIN, MULTI-VITAMIN, PROTONIX, SURFAK, TIAZAC, TIKOSYN, WARFARIN
Adverse Events (AE) Preferred term	1. Atrial fibrillation 2. Lung neoplasm malignant
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 20JUL2008 (2) - 21JUL2008 (3) 2. 21JUL2008 (3) - --------- (.)
Duration of AE	1. 2 2. .
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203055

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140203055/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/83/WHITE/UNITED STATES/YES
Medical history	Anaemia, Anxiety, Aortic stenosis, Atrial fibrillation, Bradycardia, Bradypnoea, Cerebral haemorrhage, Chest X-ray abnormal, Chills, Cardiac failure congestive, Coronary artery disease, Diarrhoea, Fatigue, Pyrexia, Foot deformity, Hyperlipidaemia, Hypertension, Hypotension, Hypothyroidism, Hypoxia, Hysterectomy, Localised infection, Mitral valve incompetence, Obesity, Myocardial infarction, Oedema, Oedema peripheral, Osteoarthropathy, Pain in extremity, Pulmonary hypertension, Respiratory arrest, Sepsis, Skin irritation, Sleep apnoea syndrome, Osteoarthritis, Pollakiuria, Uterine cancer, Vertigo, Viral infection, Asthenia, Catheterisation cardiac, Carotid bruit, Tricuspid valve incompetence, Left ventricular hypertrophy, Troponin increased, Decreased appetite, Thyroidectomy, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTOS, ADVAIR, ASPIRIN, ATIVAN, BUSPAR, CADUET, DIGOXIN, DIOVAN, FERROUS SULFATE, FOLIC ACID, FUROSEMIDE, INSULIN, LACTOBACILLUS NOS, LEVOFLOXACIN, LIPITOR, LISINOPRIL, MAGNESIUM, METOPROLOL, MINOXIDIL, NORVASC, NYSTATIN, PROTONIX, PROVENTIL, SURFAK, SYNTHROID, VITAMIN C, VITAMIN D, XANAX, ZICAM
Adverse Events (AE) Preferred term	1. Cough 2. Oedema peripheral 3. Epistaxis 4. Dyspnoea 5. Pneumonia 6. Epistaxis 7. Epistaxis 8. Oedema peripheral 9. Contusion 10. Joint swelling 11. Tendon injury 12. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/YES/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/YES/NO/YES 7. MILD/YES/NO/YES 8. ./NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 05FEB2010 (31) - 01MAR2010 (55) 2. 10FEB2010 (36) - 03MAY2010 (118) 3. 11FEB2010 (37) - 11FEB2010 (37) 4. 12FEB2010 (38) - 01MAR2010 (55) 5. 12FEB2010 (38) - 14FEB2010 (40)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203055

Parameter	Value
	6. 06MAR2010 (60) - 06MAR2010 (60)
	7. 08MAR2010 (62) - 08MAR2010 (62)
	8. 10MAR2010 (64) - 12APR2010 (97)
	9. 25MAR2010 (79) - 06APR2010 (91)
	10. 06APR2010 (91) - 11APR2010 (96)
	11. 06APR2010 (91) - 11APR2010 (96)
	12. 15JUN2010 (161) - 15JUN2010 (161)
Duration of AE	1. 25
	2. 83
	3. 1
	4. 18
	5. 3
	6. 1
	7. 1
	8. 34
	9. 13
	10. 6
	11. 6
	12. 1
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
Action taken	1. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203055

Parameter	Value
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203057

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140203057/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/43/BLACK/UNITED STATES/YES
Medical history	Ankle fracture, Cholecystectomy, Cholelithiasis, Hypertension, Pain, Pneumobilia, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETAMINOPHEN, BYSTOLIC, ECOTRIN, LORTAB 7.5/500, MORPHINE SULFATE, NAPROXEN, NEXIUM, NITROGLYCERIN, PERCOCET, PROTONIX
Adverse Events (AE) Preferred term	1. Abdominal discomfort 2. Musculoskeletal pain 3. Chest pain 4. Non-cardiac chest pain 5. Dyspnoea 6. Anaemia 7. Pain in extremity 8. Pain in extremity 9. Helicobacter gastritis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/YES/NO 5. MILD/NO/NO/NO 6. MILD/NO/NO/NO 7. MILD/NO/NO/NO 8. MILD/NO/NO/NO 9. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 28JAN2010 (9) - 28FEB2010 (40) 2. 28JAN2010 (9) - 28FEB2010 (40) 3. 29JAN2010 (10) - 31JAN2010 (12) 4. 31JUL2010 (193) - 02AUG2010 (195) 5. 31JUL2010 (193) - 02AUG2010 (195) 6. 01AUG2010 (194) - --------- (.) 7. 02AUG2010 (195) - 09AUG2010 (202) 8. 02AUG2010 (195) - 09AUG2010 (202) 9. 11AUG2010 (204) - --------- (.)
Duration of AE	1. 32 2. 32 3. 3 4. 3 5. 3 6. . 7. 8 8. 8 9. .
Dose on AE onset	1. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203057

Parameter	Value
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. F
	5. F
	6. F
	7. F
	8. F
	9. F
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203058

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140203058/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/36/WHITE/UNITED STATES/YES
Medical history	Anxiety, Asthma, Breast cancer, Depression, Hysterectomy, Insomnia, Seasonal allergy, Lymphadenectomy, Breast lump removal, Chemotherapy, Central venous catheterisation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBIEN CR, AUGMENTIN, BENADRYL, COLACE, DILAUDID, DULCOLAX [BISACODYL], ENOXAPARIN, KLONOPIN, LEXAPRO, MULTIVITAMIN, PEPCID, PROTONIX, PYRIDIUM, ROZEREM, SINGULAIR, TORADOL, TYLENOL [ACETAMINOPHEN], VITAMIN B COMPLEX, WARFARIN
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Flank pain 3. Nephrolithiasis 4. Abdominal pain 5. Vomiting 6. Dysuria 7. Pruritus 8. Wound haemorrhage 9. Ligament sprain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 09MAR2010 (22) - 13MAR2010 (26) 2. 23MAR2010 (36) - 12APR2010 (56) 3. 23MAR2010 (36) - 12APR2010 (56) 4. 23MAR2010 (36) - 12APR2010 (56) 5. 23MAR2010 (36) - 23MAR2010 (36) 6. 23MAR2010 (36) - 12APR2010 (56) 7. 24MAR2010 (37) - 24MAR2010 (37) 8. 03JUL2010 (138) - 22JUL2010 (157) 9. 03JUL2010 (138) - 19JUL2010 (154)
Duration of AE	1. 5 2. 21 3. 21 4. 21 5. 1 6. 21 7. 1 8. 20

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203058

Parameter	Value
	9. 17
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203058

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203061

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140203061/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/44/WHITE/UNITED STATES/YES
Medical history	Ankle fracture, Ankle fracture, Anxiety, Chest pain, Chest discomfort, Chills, Constipation, Cough, Speech disorder, Dizziness, Dyspnoea, Pyrexia, Hypothyroidism, Leukocytosis, Arthralgia, Pallor, Restless legs syndrome, Tachycardia, Asthenia, Seasonal allergy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETAMINOPHEN, ALLEGRA, ALTEPLASE, ATROVENT, BIOTIN, CALCIUM CARBONATE, CLARITIN, DILAUDID, DULCOLAX [BISACODYL], ENOXAPARIN, FISH OIL, FLONASE, K-DUR, K-LYTE, KEFLEX, LASIX, MAGNESIUM OXIDE, MIRAPEX, MORPHINE SULFATE, OXYCONTIN, PERCOCET 5/325, PROTONIX, ROCEPHIN, SYNTHROID, TORADOL, VANCOMYCIN, VITAMIN K, WARFARIN, XANAX, XOPENEX, ZOSYN
Adverse Events (AE) Preferred term	1. Pleuritic pain 2. Lung infiltration 3. Pleural effusion 4. International normalised ratio increased 5. Liver function test abnormal 6. Mitral valve incompetence 7. Tricuspid valve incompetence 8. Pulmonary hypertension 9. Pneumothorax 10. Sinusitis 11. Haemoptysis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/NO 2. SEVERE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/YES/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 24JUN2010 (1) - 16JUL2010 (23) 2. 25JUN2010 (2) - 15JUL2010 (22) 3. 25JUN2010 (2) - 15JUL2010 (22) 4. 27JUN2010 (4) - 29JUN2010 (6) 5. 27JUN2010 (4) - 30JUN2010 (7) 6. 30JUN2010 (7) - --------- (.) 7. 30JUN2010 (7) - --------- (.) 8. 30JUN2010 (7) - 16JUL2010 (23) 9. 09JUL2010 (16) - 14JUL2010 (21) 10. 14NOV2010 (144) - 01JAN2011 (192) 11. 10DEC2010 (170) - 10DEC2010 (170)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203061

Parameter	Value
Duration of AE	1. 23
	2. 21
	3. 21
	4. 3
	5. 4
	6. .
	7. .
	8. 17
	9. 6
	10. 49
	11. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140203061

Parameter	Value
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140313014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140313014/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/UNITED STATES/YES
Medical history	Rhinitis allergic, Anaemia, Gastrooesophageal reflux disease, Hypertension, Hypothyroidism, Lung consolidation, Menopause, Mitral valve incompetence, Pneumonia, Pulmonary hypertension, Stent placement, Tricuspid valve incompetence, Lung cancer metastatic, Tobacco user
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPINE, AVALIDE, ENOXAPARIN, FOLIC ACID, LEVAQUIN, LORATADINE, NASOCORT, OXYCONTIN, PREDNISONE, PREMARIN, PROTONIX, SYNTHROID, WARFARIN
Adverse Events (AE) Preferred term	1. Pleural effusion 2. Lung cancer metastatic
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. --JUN2008 (.) - --------- (.) 2. 01JUN2008 (4) - 13AUG2008 (77)
Duration of AE	1. . 2. 74
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER 2. REMEDIAL DRUG THERAPY
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140313019

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140313019/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/58/WHITE/UNITED STATES/YES
Medical history	Chest pain, Hiatus hernia, Hypothyroidism, Lung infiltration, Obesity, Pleural effusion, Seasonal allergy, Osteoarthritis, Dyslipidaemia, Thyroid operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLEGRA, ASPIRIN, BENADRYL, IBUPROFEN, LEVAQUIN, LEVOXYL, PLAVIX, TOPROL, VALIUM, ZOCOR
Adverse Events (AE) Preferred term	1. Angina unstable 2. Coronary artery disease
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/YES/NO/YES
Start/stop date of event with relative date	1. 18SEP2008 (43) - 18SEP2008 (43) 2. 28SEP2008 (53) - --------- (.)
Duration of AE	1. 1 2. .
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140313022

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140313022/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/37/WHITE/UNITED STATES/YES
Medical history	Abdominal pain, Anaemia, Appendicectomy, Chills, Constipation, Depression, Pyrexia, Cervix carcinoma stage 0, Nausea, Pleural effusion, Hysterectomy, Lymphadenectomy, Bladder neck suspension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANCEF, DARVOCET, ENOXAPARIN, INVANZ, TORADOL, WARFARIN, ZOFRAN, ZOLOFT
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Hypercoagulation 3. Groin abscess 4. Anaemia 5. Chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 12JAN2009 (7) - 12JAN2009 (7) 2. 13JAN2009 (8) - --------- (.) 3. 19JAN2009 (14) - 21JAN2009 (16) 4. 19JAN2009 (14) - --MAR2009 (.) 5. 06APR2009 (91) - 06APR2009 (91)
Duration of AE	1. 1 2. . 3. 3 4. . 5. 1
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. OTHER 2. NONE 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 4. NONE 5. NONE
Outcome of event	1. RESOLVED 2. IMPROVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140313022

Parameter	Value
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140313044

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140313044/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/37/WHITE/UNITED STATES/YES
Medical history	Depression, Neck pain, Surgery, Female sterilisation, Tobacco user, Shoulder operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CHANTIX, CLONIDINE, LOVENOX, MULTIVITAMIN, NAPROXEN, SEROQUEL, TRAZODONE, TYLENOL [ACETAMINOPHEN], ZOLOFT
Adverse Events (AE) Preferred term	1. Alanine aminotransferase increased
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 17NOV2009 (15) - 23NOV2009 (21)
Duration of AE	1. 7
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140313051

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140313051/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/BLACK/UNITED STATES/YES
Medical history	Anxiety, Cholecystectomy, Coronary artery disease, Depression, Hypertension, Hypokalaemia, Hysterectomy, Renal impairment, Nausea, Osteoarthritis, Bronchial hyperreactivity, Fibromyalgia, Coronary artery bypass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALBUTEROL, CELEBREX, DILAUDID, ENOXAPARIN, NEURONTIN, NORVASC, SEROQUEL, WARFARIN, ZOFRAN
Adverse Events (AE) Preferred term	1. Failure to thrive 2. Depression
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/NO/YES
Start/stop date of event with relative date	1. 18MAR2010 (3) - 10APR2010 (26) 2. 18MAR2010 (3) - --------- (.)
Duration of AE	1. 24 2. .
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY 2. NONE
Outcome of event	1. DEATH 2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140313052

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140313052/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/59/WHITE/UNITED STATES/YES
Medical history	Ankylosing spondylitis, Back pain, Cholecystectomy, Chronic obstructive pulmonary disease, Pancreatitis chronic, Crohn's disease, Diabetes mellitus, Endocarditis, Syncope, Colectomy, Hypothyroidism, Inguinal hernia repair, Intervertebral disc operation, Neuropathy peripheral, Umbilical hernia repair, Osteopenia, Rotator cuff repair, Dyslipidaemia, Aortic valve repair, Intervertebral disc degeneration
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANCEF, ARIXTRA, BALSALAZIDE, BETHANECHOL, CYANOCALAMIN, CYMBALTA, ENOXAPARIN, FENTANYL, FLEXORIL, FOLIC ACID, HYDROCODONE/ACETAMINOPHEN, LANTUS, LEVOTHYROXINE SODIUM, METHOTREXATE, MVI, NEURONTIN, NOVOLOG, PANCREASE, PENTASA, PREDNISONE, VITAMIN D, WARFARIN, ZINC
Adverse Events (AE) Preferred term	1. Intervertebral disc degeneration 2. Post procedural haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 06DEC2010 (238) - 12DEC2010 (244) 2. 09DEC2010 (241) - 15DEC2010 (247)
Duration of AE	1. 7 2. 7
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140313060

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140313060/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/79/WHITE/UNITED STATES/YES
Medical history	Appendicectomy, Cholecystectomy, Electrolyte imbalance, Hypertension, Insulin resistance, Bronchial hyperreactivity, Hysterectomy, Fungal infection, Upper limb fracture, Hernia repair
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT, COLACE, DILAUDID, ENOXAPARIN, HEPARIN, HYDROCODONE/ACETAMINOPHEN, LASIX, MAGNESIUM SULFATE, MAXZIDE/HYDROCHLOROTHIAZIDE, MYCOSTATIN, NORVASC, OMEPRAZOLE, POTASSIUM CHLORIDE, ROCEPHIN, SIMETHICONE, SODIUM PHOSPHATE, TENORMIN, VANCOMYCIN, VITAMIN K, WARFARIN
Adverse Events (AE) Preferred term	1. Abdominal discomfort 2. Oedema 3. Abdominal discomfort 4. Retroperitoneal haematoma 5. Leukocytosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/YES/YES/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 20AUG2010 (2) - 21AUG2010 (3) 2. 20AUG2010 (2) - 15SEP2010 (28) 3. 25AUG2010 (7) - 01SEP2010 (14) 4. 26AUG2010 (8) - 01SEP2010 (14) 5. 26AUG2010 (8) - 30AUG2010 (12)
Duration of AE	1. 2 2. 27 3. 8 4. 7 5. 5
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 5. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140313060

Parameter	Value
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140313066

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140313066/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/46/WHITE/UNITED STATES/YES
Medical history	Acne, Depression, Gastrooesophageal reflux disease, Hypothyroidism
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	LEXAPRO, MINOCYCLINE, MORPHINE, PRILOSEC, SYNTHROID, TORADOL, ZOFRAN
Adverse Events (AE) Preferred term	1. Dysfunctional uterine bleeding
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 10DEC2010 (3) - 20DEC2010 (13)
Duration of AE	1. 11
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140313072

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140313072/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/51/WHITE/UNITED STATES/YES
Medical history	Anxiety, Attention deficit/hyperactivity disorder, Benign prostatic hyperplasia, Coronary artery disease, Depression, Hypertension, Insulin resistance, Pleural effusion, Thrombocytopenia, Coronary arterial stent insertion, Gastrooesophageal reflux disease, Coronary artery bypass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADDERALL, ASPIRIN, ATIVAN, AVODART, BYSTOLIC, HYDROCODONE, JANUVIA, NITROGLYCERIN, PLAVIX, PREVACID, UNFRACTIONATED HEPARIN, WELLBUTRIN
Adverse Events (AE) Preferred term	1. Acute myocardial infarction
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 18JUN2011 (100) - 19JUN2011 (101)
Duration of AE	1. 2
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. I
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140323003/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/28/WHITE/UNITED STATES/YES
Medical history	Anxiety, Chest pain, Hypothyroidism, Infertility, Lower limb fracture, Pharyngitis, Dyspnoea, Tachycardia, Tonsillitis, Limb operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CEFAPIME, MORPHINE, ROCEPHIN, SYNTHROID, UNFRACTIONATED HEPARIN, VICODIN, ZITHROMAX
Adverse Events (AE) Preferred term	1. Pneumonia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 17OCT2007 (14) - 21OCT2007 (18)
Duration of AE	1. 5
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140323009/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/77/WHITE/UNITED STATES/YES
Medical history	Colon cancer, Diabetes mellitus, Gout, Hypertension, Hypothyroidism, Lung neoplasm malignant, Pneumonectomy, Knee arthroplasty, Urethral stent insertion, Colectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLONIDINE, MAALOX, MAGNESIUM CITRATE, METFORMIN, MULTIVITAMIN, NITROGYLCERIN, PROCARDIA, PROTONIX, SYNTHROID, VITAMIN C, VITAMIN E
Adverse Events (AE) Preferred term	1. Constipation 2. Abdominal pain upper 3. Non-cardiac chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 12APR2008 (79) - 15APR2008 (82) 2. 15APR2008 (82) - 16APR2008 (83) 3. 15APR2008 (82) - 20APR2008 (87)
Duration of AE	1. 4 2. 2 3. 6
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140323012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/67/BLACK/UNITED STATES/YES
Medical history	Back pain, Depression, Diabetes mellitus, Hyperhidrosis, Headache, Hypertension, Menopause, Nausea, Neck pain, Neuropathy peripheral, Osteoarthritis, Dyspnoea, Non-cardiac chest pain, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACIPHEX, DURAGESIC, ENOXAPARIN, LEXAPRO, LISINOPRIL, MORPHINE SULFATE, NEURONTIN, UNFRACTIONATED HEPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Non-cardiac chest pain 2. Anxiety
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 25FEB2008 (26) - 27FEB2008 (28) 2. 25FEB2008 (26) - 27FEB2008 (28)
Duration of AE	1. 3 2. 3
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. OTHER 2. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140323020/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/22/WHITE/UNITED STATES/YES
Medical history	Ligament operation, Pain in extremity, Oedema peripheral, Ligament rupture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADVIL [IBUPROFEN ONLY], ANCEF, CEFAZOLIN, ENOXAPARIN, FENTANYL, MORPHINE, OXYCONTIN, PERCOCET, WARFARIN
Adverse Events (AE) Preferred term	1. Pain in extremity 2. Haemarthrosis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/YES/YES/YES
Start/stop date of event with relative date	1. 12MAY2008 (8) - 15MAY2008 (11) 2. 13MAY2008 (9) - 13MAY2008 (9)
Duration of AE	1. 4 2. 1
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323048

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140323048/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/39/WHITE/UNITED STATES/YES
Medical history	Anxiety, Chest pain, Chronic obstructive pulmonary disease, Hypercholesterolaemia, Insomnia, Obesity, Tobacco abuse, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ABILIFY, ADVAIR, AMBIEN, AMIODARONE, ANCEF, ASPIRIN, ATIVAN, COLACE, CRESTOR, DARVOCET N, ENOXAPARIN, HEPARIN, INSULIN, K-DUR, KEFLEX, LASIX, LOPRESSOR, MAGNESIUM OXIDE, MUPIROCIN NASAL OINTMENT, NICODERM, NITROGLYCERIN, NORVASC, PLAVIX, SYMBICORT, TORADOL, TUMS [CALCIUM+MAGNESIUM CARBONATE], VITAMIN C, WARFARIN, ZOCOR
Adverse Events (AE) Preferred term	1. Coronary artery disease 2. Staphylococcal infection 3. Constipation 4. Hypertension 5. Hyperglycaemia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 25SEP2009 (59) - 04OCT2009 (68) 2. 30SEP2009 (64) - 04OCT2009 (68) 3. 01OCT2009 (65) - 03OCT2009 (67) 4. 01OCT2009 (65) - 04OCT2009 (68) 5. 03OCT2009 (67) - 04OCT2009 (68)
Duration of AE	1. 10 2. 5 3. 3 4. 4 5. 2
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323048

Parameter	Value
Outcome of event	5. REMEDIAL DRUG THERAPY 1. RESOLVED 2. RESOLVED 3. RESOLVED 4. RESOLVED 5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323054

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140323054/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/UNITED STATES/YES
Medical history	Abdominal pain, Cholecystitis acute, Cholecystectomy, Depression, Diabetes mellitus, Hypercholesterolaemia, Hypertension, Hypokalaemia, Hysterectomy, Lactic acidosis, Metastases to liver, Obesity, Breast cancer metastatic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACCUPRIL, CEPHALEXIN, CHEMOTHERAPY, K-DUR, LASIX, METFORMIN, NIFEDIPINE, NORMAL SALINE, NORTRIPTYLINE, PAXIL, PERCOCET, VANCOMYCIN
Adverse Events (AE) Preferred term	1. Dehydration 2. Cellulitis 3. Sepsis 4. Renal failure acute 5. White blood cell count increased 6. International normalised ratio increased 7. Hepatic failure 8. Breast cancer metastatic 9. Metastases to liver
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. SEVERE/NO/YES/YES 8. SEVERE/NO/YES/YES 9. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 15DEC2009 (33) - --------- (.) 2. 15DEC2009 (33) - --------- (.) 3. 15DEC2009 (33) - --------- (.) 4. 15DEC2009 (33) - --------- (.) 5. 15DEC2009 (33) - --------- (.) 6. 15DEC2009 (33) - --------- (.) 7. 23DEC2009 (41) - --------- (.) 8. 23DEC2009 (41) - 23DEC2009 (41) 9. 23DEC2009 (41) - 23DEC2009 (41)
Duration of AE	1. . 2. . 3. . 4. . 5. . 6. . 7. . 8. 1 9. 1

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323054

Parameter	Value
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. F
	8. F
	9. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. NONE
	8. STUDY DRUG DISCONTINUED PERMANENTLY
	9. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED
	7. UNCHANGED
	8. DEATH

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323054

Parameter	Value
	9. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323061

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140323061/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/40/BLACK/UNITED STATES/YES
Medical history	Asthma, Iron deficiency anaemia, Obesity, Pleuritic pain, Upper respiratory tract infection, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALBUTEROL, FERROUS SULFATE, HYDROMORPHONE, PEPCID, VICODIN
Adverse Events (AE) Preferred term	1. Pleuritic pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 26FEB2010 (6) - 01MAR2010 (9)
Duration of AE	1. 4
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323063

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140323063/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/69/WHITE/UNITED STATES/YES
Medical history	Anaemia, Cerebrovascular accident, Hemiparesis, Hyperlipidaemia, Hypertension, Hypothyroidism, Hemiplegia, Menopause, Obesity, Schizophrenia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETAMINOPHEN AND PROPOXPHENE, ATIVAN, COZAAR, DARVOCET, ENOXAPARIN, HYDROCHLOROTHIAZIDE, KDUR, LIPITOR, MULTIVITAMIN, SYNTHROID, WARFARIN, ZYPREXA
Adverse Events (AE) Preferred term	1. Rotator cuff syndrome 2. Ischaemic stroke
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/YES/YES/YES
Start/stop date of event with relative date	1. 10APR2010 (43) - --------- (.) 2. 02MAY2010 (65) - 20MAY2010 (83)
Duration of AE	1. . 2. 19
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. REMEDIAL DRUG THERAPY 2. OTHER
Outcome of event	1. UNCHANGED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-140323063[2)]	ISCHEMIC STROKE（PT：虚血性脳卒中） 治験担当医はリバーロキサバンと報告事象との関連性があると判断した。弊社は、複数の既往の心疾患を有しており、薬効欠如とも考えられることから、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323064

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140323064/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/66/WHITE/UNITED STATES/YES
Medical history	Agitation, Appendicectomy, Benign prostatic hyperplasia, Carpal tunnel decompression, Carpal tunnel decompression, Back pain, Coronary artery disease, Decubitus ulcer, Dementia, Depression, Intervertebral disc operation, Hip arthroplasty, Hip arthroplasty, Hyperlipidaemia, Insomnia, Myocardial infarction, Pneumonia, Spinal laminectomy, Gait disturbance, Surgery, Arteriosclerosis coronary artery, Coronary arterial stent insertion, Deep brain stimulation, Peripheral nerve operation, Peripheral nerve operation, Parkinson's disease, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARICEPT, ASPIRIN, ATIVAN, BACTRIM DS, CARBIDOPA,LEVODOPA, CEFTIN, CEFTRIAXONE, CIPROFLOXACIN, COREG, ENOXAPARIN, FLOMAX (TAMSULOSIN HYDROCHLORIDE), FOLIC ACID, HYDROCODONE, IMDUR, LEXAPRO, LUNESTA, MUCINEX, PROTONIX, SEROQUEL, STALEVO, TORADOL, TRIMETHOPRIM, WARFARIN, ZITHROMAX, ZOCOR
Adverse Events (AE) Preferred term	1. Musculoskeletal pain 2. Neck pain 3. Pneumonia 4. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 24JUL2010 (84) - --------- (.) 2. 24JUL2010 (84) - --------- (.) 3. 05JAN2011 (249) - 24JAN2011 (268) 4. 05JAN2011 (249) - 24JAN2011 (268)
Duration of AE	1. . 2. . 3. 20 4. 20
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. UNCHANGED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323064

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323065

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140323065/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/UNITED STATES/YES
Medical history	Anxiety, Appendicectomy, Liver disorder, Chronic obstructive pulmonary disease, Dehydration, Hiatus hernia, Hypertension, Hysterectomy, Knee arthroplasty, Nausea, Pneumonia, Tachycardia, Tonsillectomy, Gait disturbance, Surgery, Lung neoplasm, Back pain, Drug hypersensitivity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BYSTOLIC, CIPROFLOXACIN, DIAZEPAM, ENOXAPARIN, FLEXERIL, HYDRALAZINE, HYDROCHLOROTHIAZIDE, LACTATED RINGERS, MAALOX, MARCAINE WITH EPINEPHRINE, METRONIDAZOLE, MORPHINE, PERCOCET, PROTONIX, TORADOL, VALIUM, VENA CAVA FILTER, VICODIN, VITAMIN K, WARFARIN, ZOFRAN
Adverse Events (AE) Preferred term	1. Cholecystitis 2. Pancreatitis 3. Cholelithiasis 4. Nausea 5. Hepatic steatosis 6. Cholangitis 7. Non-cardiac chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --AUG2010 (.) - 13AUG2010 (72) 2. 08AUG2010 (67) - 13AUG2010 (72) 3. 08AUG2010 (67) - 13AUG2010 (72) 4. 08AUG2010 (67) - 14AUG2010 (73) 5. 08AUG2010 (67) - 13AUG2010 (72) 6. 08AUG2010 (67) - 14AUG2010 (73) 7. 08AUG2010 (67) - 09AUG2010 (68)
Duration of AE	1. . 2. 6 3. 6 4. 7 5. 6 6. 7 7. 2
Dose on AE onset	1. 2. 3. 4. 5. 6.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140323065

Parameter	Value
	7.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. OTHER
	2. REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. OTHER
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140343003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140343003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/78/HISPANIC/UNITED STATES/YES
Medical history	Benign prostatic hyperplasia, Blepharospasm, Dermal cyst, Diffuse large B-cell lymphoma, Diverticulum, Dyspnoea, Hepatic enzyme increased, Dry eye, Gastrooesophageal reflux disease, Hypertension, Gastrectomy, Hyperparathyroidism primary, Onychomycosis, Osteopenia, Lung neoplasm
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLIN/CLAVULANATE, ATENOLOL, BOTOLIUM TOXIN TYPE A, CLOTRIMAZOLE 1%/BETAMETHASONE 0.05%, CODEINE, DEXTROMETHORPHAN/GUAIFENESIN, ENOXAPARIN, ENOXOPARIN, FINASTERIDE, FUROSEMIDE, GABAPENTIN, HYDROXYPROPYLMETHYLCELLULOSE 0.5 %, OMEPRAZOLE, WARFARIN
Adverse Events (AE) Preferred term	1. Infected dermal cyst 2. Productive cough 3. Bronchospasm 4. Confusional state 5. Lung neoplasm 6. Cough 7. Haemoptysis 8. Lung adenocarcinoma
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 28JAN2010 (24) - 26FEB2010 (53) 2. 24FEB2010 (51) - --MAR2010 (.) 3. 04MAR2010 (59) - 18MAR2010 (73) 4. 01APR2010 (87) - 01APR2010 (87) 5. 18AUG2010 (226) - 08DEC2010 (338) 6. 29SEP2010 (268) - 25OCT2010 (294) 7. 07DEC2010 (337) - 15DEC2010 (345) 8. 07DEC2010 (337) - --------- (.)
Duration of AE	1. 30 2. . 3. 15 4. 1 5. 113 6. 27 7. 9 8. .
Dose on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140343003

Parameter	Value
	3.
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	6. REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED
	8. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. WORSENED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140343004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140343004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/86/WHITE/UNITED STATES/YES
Medical history	Rhinitis allergic, Iridocyclitis, Benign prostatic hyperplasia, Hypertension, Memory impairment, Nephrolithiasis, Neuropathy peripheral, Open angle glaucoma, Peptic ulcer, Thrombocytopenia, Type 2 diabetes mellitus, Dyslipidaemia, Vocal cord leukoplakia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACYCLOVIR, AMLODIPINE, BRIMONIDINE 0.2%, D/W 10%, DONEPEZIL, DORZOLAMIDE/TIMOLOL, FINASTERIDE, FLUNISOLIDE, GABAPENTIN, INSULIN NOVOLIN 70/30, LOSARTAN, MULTIVITAMIN, OMEPRAZOLE, PREDNISOLONE 1%, PREDNISONE, SIMVASTATIN, TERAZOSIN, TRAVOPROST Z 0.004%
Adverse Events (AE) Preferred term	1. Hypoglycaemia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 31MAY2010 (50) - 31MAY2010 (50)
Duration of AE	1. 1
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140353001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/60/WHITE/UNITED STATES/YES
Medical history	Anxiety, Cardiovascular disorder, Carotid artery stenosis, Cataract, Cerebrovascular accident, Depression, Hyperlipidaemia, Insomnia, Menopause, Migraine, Panic attack, Urinary tract infection, Tobacco user, Type 1 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, DEMEROL, ENOXAPARIN, HYDROCODONE/APAP, IBUPROFEN, LANTUS INSULIN, METFORMIN, NICOTINE PATCH, NOVOLOG INSULIN, PAXIL, PERCOCET, PHENERGAN, WARFARIN, ZOCOR
Adverse Events (AE) Preferred term	1. Nephrolithiasis 2. Subdural haematoma 3. Vomiting 4. Nausea 5. Constipation
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/YES/YES/YES 3. MODERATE/NO/NO/NO 4. MODERATE/NO/NO/NO 5. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 08MAR2008 (153) - 12MAR2008 (157) 2. 28MAR2008 (173) - 15APR2008 (191) 3. 06APR2008 (182) - 06APR2008 (182) 4. 12APR2008 (188) - 15APR2008 (191) 5. 13APR2008 (189) - 13APR2008 (189)
Duration of AE	1. 5 2. 19 3. 1 4. 4 5. 1
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER 3. NONE 4. REMEDIAL DRUG THERAPY 5. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353001

Parameter	Value
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140353005/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/20/BLACK/UNITED STATES/YES
Medical history	Drug hypersensitivity, Drug hypersensitivity, Drug hypersensitivity, Dysmenorrhoea, Insomnia, Nephrolithiasis, Epicondylitis, Migraine, Nausea
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBIEN, ATENOLOL, ATIVAN, AVELOX, BENADRYL, HYDROCODONE, HYDROMORPHONE, IBUPROFEN, MIRALAX, MORPHINE, NARCAN, OXYCODONE, OXYCODONE/APAP, PHENERGAN, PROGESTERONE, PROTONIX, PROZAC, SENOKOT, TYLENOL [PARACETAMOL], VANCOMYCIN, VENTOLIN, XANAX, XOPENEX, ZOFRAN
Adverse Events (AE) Preferred term	1. Depression 2. Overdose 3. Tachycardia 4. Menorrhagia 5. Pulmonary infarction 6. Cholelithiasis 7. Drug hypersensitivity 8. Overdose 9. Menorrhagia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/YES/NO/YES
Start/stop date of event with relative date	1. --MAR2008 (.) - --------- (.) 2. 22FEB2008 (1) - 22FEB2008 (1) 3. 22FEB2008 (1) - 22FEB2008 (1) 4. 26FEB2008 (5) - 02MAR2008 (10) 5. 26FEB2008 (5) - 28MAR2008 (36) 6. 27FEB2008 (6) - 17JUN2008 (117) 7. 27FEB2008 (6) - 27FEB2008 (6) 8. 14MAR2008 (22) - 24MAR2008 (32) 9. 25MAR2008 (33) - 28MAR2008 (36)
Duration of AE	1. . 2. 1 3. 1 4. 6 5. 32 6. 112 7. 1 8. 11

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353005

Parameter	Value
	9. 4
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. I
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. STUDY DRUG DISCONTINUED AND RESTARTED
	9. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353005

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140353008/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/67/BLACK/UNITED STATES/YES
Medical history	Abdominal pain, Coronary artery bypass, Coronary artery disease, Diabetes mellitus, Deep vein thrombosis, Hyperlipidaemia, Hypertension, Hysterectomy, Myocardial infarction, Obesity, Osteoporosis, Drug hypersensitivity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, BENAZEPTIL/HCTZ, CLARITIN, ENOXAPARIN, HYDROXYZINE, JANUVIA, LIPITOR, NIACIN, NIASPAN, NOVOLOG INSULIN, PEPCID, PREDNISONE, PROTONIX, SOLU-MEDROL, TOPROL XL, WARFARIN, ZOCOR
Adverse Events (AE) Preferred term	1. Drug hypersensitivity
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 01JUN2008 (3) - 12JUN2008 (14)
Duration of AE	1. 12
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140353013/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/UNITED STATES/YES
Medical history	Pyrexia, Hyperlipidaemia, Hypothyroidism, Hysterectomy, Myalgia, Lung disorder, Drug hypersensitivity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTONEL, AMPICILLIN, COLCHICINE, COUMADIN, DIFLUCAN, ENOXAPARIN, FUROSEMIDE, HYDROCODONE/APAP, LIPITOR, NICOTINE PATCH, NYSTATIN, PERCOCET, PREDNISONE, SYNTHROID, VITAMIN D, WARFARIN, ZOCOR, ZOLOFT
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Pyrexia 3. Dehydration 4. Atrial fibrillation 5. Dyspnoea 6. Diarrhoea 7. Adverse drug reaction 8. Pulmonary oedema 9. Candidiasis 10. Dyspnoea 11. Myalgia 12. Epistaxis 13. Gout 14. Depression 15. Tachycardia 16. Mental status changes
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/YES/YES 8. MODERATE/NO/YES/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MILD/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MILD/NO/NO/YES 15. MODERATE/NO/YES/YES 16. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 30AUG2008 (4) - 12SEP2008 (17) 2. 08SEP2008 (13) - 09SEP2008 (14) 3. 08SEP2008 (13) - 18SEP2008 (23) 4. 08SEP2008 (13) - 18SEP2008 (23) 5. 08SEP2008 (13) - 18SEP2008 (23)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353013

Parameter	Value
	6. 08SEP2008 (13) - 18SEP2008 (23)
	7. 08SEP2008 (13) - 18SEP2008 (23)
	8. 10SEP2008 (15) - 18SEP2008 (23)
	9. 13SEP2008 (18) - 18SEP2008 (23)
	10. 13OCT2008 (48) - 20OCT2008 (55)
	11. 15OCT2008 (50) - --------- (.)
	12. 18OCT2008 (53) - 18OCT2008 (53)
	13. 18OCT2008 (53) - --------- (.)
	14. 28OCT2008 (63) - 25DEC2008 (121)
	15. 04DEC2008 (100) - 17DEC2008 (113)
	16. 04DEC2008 (100) - 17DEC2008 (113)
Duration of AE	1. 14
	2. 2
	3. 11
	4. 11
	5. 11
	6. 11
	7. 11
	8. 9
	9. 6
	10. 8
	11. .
	12. 1
	13. .
	14. 59
	15. 14
	16. 14
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
Dose status on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353013

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. NONE
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. NONE
	16. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. UNCHANGED
	12. RESOLVED
	13. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353013

Parameter	Value
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
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1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140353020/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/34/WHITE/UNITED STATES/YES
Medical history	Cellulitis, Ankle operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CARAFATE, COLACE, ENOXAPARIN, FLEXERIL, HEPARIN DRIP, HYDROCODONE, HYDROMORPHONE, MIRALAX, MORPHINE SULFATE, PERCOCET, PROTONIX, TORADOL, ULTRAM, VICODIN, WARFARIN, ZOFRAN
Adverse Events (AE) Preferred term	1. Muscle spasms 2. Pulmonary infarction 3. Nausea
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 26MAY2009 (3) - 27MAY2009 (4) 2. 27MAY2009 (4) - 30MAY2009 (7) 3. 28MAY2009 (5) - 29MAY2009 (6)
Duration of AE	1. 2 2. 4 3. 2
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353022

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140353022/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/71/BLACK/UNITED STATES/YES
Medical history	Anxiety, Breast mass, Cataract, Colonoscopy, Gastrointestinal disorder, Gout, Hiatus hernia, Hypertension, Hypokalaemia, Thyroid neoplasm, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETAMINOPHEN, ATARAX, ATENOLOL/CHLORTHALIDONE 50/25, AZOR, CALCIUM, CARDIZEM DRIP, COLCHICINE, DILITIAZEM, DILTIAZEM, ENOXAPARIN, HEPARIN, KAPIDEX, LOPRESSOR, LORAZEPAM, POTASSIUM CHLORIDE, PROTONIX, UNFRACTIONATED HEPARIN, WARFARIN, ZANTAC
Adverse Events (AE) Preferred term	1. Atrial fibrillation 2. Oedema peripheral
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 08JUL2009 (1) - 12JUL2009 (5) 2. 01OCT2009 (86) - 07DEC2009 (153)
Duration of AE	1. 5 2. 68
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353024

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140353024/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/54/WHITE/UNITED STATES/YES
Medical history	Gastrooesophageal reflux disease, Rhinitis allergic, Anaemia, Prostatitis, Hyperlipidaemia, Hypertension, Insomnia, Mallory-Weiss syndrome, Peptic ulcer, Polyarthritis, Seasonal allergy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMELODIPINE/BENZEPRIL 5/20, AMLODIPINE BESYLATE- VALSARTAN, ASPIRIN, AXID, CALCIUM CARBONATE, CLARITIN, FISH OIL SUPPLEMENT, IBUPROFEN, INFLUENZA VACCINE, LOTREL, MEDROL, MOBIC, NORVASC, OSTEO BIFLEX, PEPCID, TYLENOL [PARACETAMOL], ZOLPIDEM
Adverse Events (AE) Preferred term	1. Pericarditis 2. Swollen tongue 3. Wound haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 08AUG2009 (11) - 09NOV2010 (469) 2. 09AUG2009 (12) - 10AUG2009 (13) 3. 19SEP2009 (53) - 19SEP2009 (53)
Duration of AE	1. 459 2. 2 3. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140353029/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/43/WHITE/UNITED STATES/YES
Medical history	Irritable bowel syndrome, Migraine, Mitral valve prolapse, Blood triglycerides increased, Vesicoureteric reflux, Seasonal allergy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLIN, BIOTIN, CALCIUM + D, CLARITIN, ENOXAPARIN, FENOFIBRATE, FISH OIL, HYDROMORPHONE, IBUPROFEN, MIDRIN, MULTIVITAMIN, PROTONIX, STADOL, TYLENOL (PARACETAMOL), VERAMYST, VITAMIN D3, WARFARIN
Adverse Events (AE) Preferred term	1. Chest pain 2. Dyspnoea 3. Oedema peripheral 4. Chest pain 5. Pain in extremity
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 13OCT2009 (40) - 17OCT2009 (44) 2. 13OCT2009 (40) - 17OCT2009 (44) 3. 11JAN2010 (130) - 27JAN2010 (146) 4. 13JAN2010 (132) - 05MAR2010 (183) 5. 15JAN2010 (134) - 05MAR2010 (183)
Duration of AE	1. 5 2. 5 3. 17 4. 52 5. 50
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. NONE 4. NONE 5. NONE
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353029

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353033

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140353033/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/21/WHITE/UNITED STATES/YES
Medical history	Headache, Obesity, Tobacco abuse
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETAMINOPHEN, ATROVENT, ENOXAPARIN, FIORICET, MUCINEX OTC, NASOGEL, NICOTINE PATCH, OXYCODONE, P-CEFTRIAXONE [ROCEPHIN & DEXTROSE. INDIC:ANTIBIOTIC PROPHYLAXIS], PROTONIX, VERAMYST, VICODIN (HYDROCODONE-ACETAMINOPHEN), WARFARIN, Z-PAK
Adverse Events (AE) Preferred term	1. Pregnancy 2. Rhinitis seasonal 3. Post abortion haemorrhage 4. Pharyngitis streptococcal
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. -----2010 (.) - 04MAR2010 (87) 2. 25DEC2009 (18) - 08JUN2010 (183) 3. 04MAR2010 (87) - 04MAR2010 (87) 4. 25MAY2010 (169) - 29MAY2010 (173)
Duration of AE	1. . 2. 166 3. 1 4. 5
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. NONE 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140353033

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-140353033[4)]	SPONTANEOUS ABORTION（PT：自然流産） 治験担当医は、因果関係は否定できると判断した。弊社は、妊娠中のワルファリン投与は胎児死亡率が高い事が知られていることから、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140363003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140363003/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/50/BLACK/UNITED STATES/YES
Medical history	Appendicectomy, Arrhythmia, Mammoplasty, Hysterectomy, Insomnia, Ventricular extrasystoles, Ventricular extrasystoles, Ventricular extrasystoles, Ventricular extrasystoles, Sciatica, Sinus bradycardia, Angiogram, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETAMINOPHEN, LUNESTA, OMEPRAZOLE, OXYCODONE, PHENERGAN, SODIUM BICARBONATE
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Chest pain 3. Cough
Intensity/ Relationship to study drug /SAE/TE	1. ././YES/YES 2. ././YES/YES 3. ././YES/YES
Start/stop date of event with relative date	1. 26DEC2008 (4) - --------- (.) 2. 26DEC2008 (4) - --------- (.) 3. 26DEC2008 (4) - --------- (.)
Duration of AE	1. . 2. . 3. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. NONE 2. NONE 3. NONE
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. INSUFFICIENT FOLLOW-UP 3. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-140363003[1),1),1)]	CHEST PAIN（PT：胸痛） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、事象に関連した検査値、臨床経過、転帰等の詳細な情報が不足しており、本剤と本事象との因果関係を評価するのは困難であるため、リバーロキサバンとの因果関係は否定できると考える。また、その後患者が治験から脱落したため、追加情報を得ることは不可能であった。 COUGH（PT：咳嗽） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、事象に関連した検査値、臨床経過、転帰等の詳細な情報が不足しており、本剤と本事象との因果関係を評価するのは困難であるため、リバーロキサバンとの因果関係は否定できると考える。また、その後患者が治験から脱落したため、追加情報を得ることは不可能であった。 DYSPNEA（PT：呼吸困難） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、事象に関連した検査値、臨床経過、転帰等の詳細な情報が不足しており、本剤と本事象との因果関係を評価するのは困難であるため、リバーロキサバンとの因果関係は否定できると考える。また、その後患者が治験から脱落したため、追加情報を得ることは不可能であった。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140363005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140363005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/62/WHITE/UNITED STATES/YES
Medical history	Angina pectoris, Anxiety, Aortic valve incompetence, Appendicectomy, Arthritis, Asthma, Atrial fibrillation, Cardiomyopathy, Chest pain, Cholecystectomy, Bronchitis chronic, Chronic obstructive pulmonary disease, Coronary artery bypass, Coronary artery disease, Diverticulitis, Dyspnoea, Gastritis, Generalised oedema, Hot flush, Hypercholesterolaemia, Hypertension, Hypertriglyceridaemia, Insomnia, Nephrolithiasis, Mitral valve incompetence, Mitral valve prolapse, Myocardial ischaemia, Palpitations, Post-traumatic stress disorder, Supraventricular extrasystoles, Ventricular extrasystoles, Scoliosis, Sleep apnoea syndrome, Supraventricular tachycardia, Catheterisation cardiac, Tricuspid valve incompetence, Knee operation, Left ventricular hypertrophy, Acute coronary syndrome, Coronary arterial stent insertion, Coronary arterial stent insertion, Coronary arterial stent insertion, Coronary arterial stent insertion, Hernia repair, Shoulder operation, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANGIOMAX, ASPIRIN, BACITRACIN, BENADRYL, CRESTOR, CYMBALTA, DARVOCET-N, ENOXAPARIN, FENTANYL, FLEXERIL, HEPARIN, IMODIUM, KDUR, LASIX, LIDOCAINE 1%, LOPRESSOR, LORTAB, LOVENOX, MULTAQ, NEXIUM, NITROGLYCERIN, NITROGLYCERINE, OXYGEN, PEPCID, PLAVIX, RESTORIL, TRICOR, TRILIPIX, TYLENOL [ACETAMINOPHEN], VALIUM, VERSED, VYTORIN, WARFARIN, XANAX, ZANTAC
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Contusion 3. Gingival bleeding 4. Cervicobrachial syndrome 5. Cervical spinal stenosis 6. Nausea 7. Dyspnoea 8. Anxiety 9. Gastroenteritis 10. Supraventricular tachycardia 11. Coronary artery disease 12. Acute myocardial infarction 13. Cardiomyopathy 14. Gingival bleeding 15. Ventricular tachycardia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. SEVERE/NO/YES/YES 11. SEVERE/NO/YES/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140363005

Parameter	Value
	12. SEVERE/NO/YES/YES
	13. MILD/NO/NO/YES
	14. MILD/NO/NO/YES
	15. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 28JUN2009 (3) - 02JUL2009 (7)
	2. 30JUN2009 (5) - 07JUL2009 (12)
	3. 07JUL2009 (12) - 18JUL2009 (23)
	4. 12JUL2009 (17) - --------- (.)
	5. 12JUL2009 (17) - --------- (.)
	6. 14JUL2009 (19) - 15JUL2009 (20)
	7. 01AUG2009 (37) - 06OCT2009 (103)
	8. 05AUG2009 (41) - 16OCT2009 (113)
	9. 21SEP2009 (88) - 24SEP2009 (91)
	10. 04OCT2009 (101) - 09OCT2009 (106)
	11. 04OCT2009 (101) - 06OCT2009 (103)
	12. 05OCT2009 (102) - 05OCT2009 (102)
	13. 05OCT2009 (102) - 10OCT2009 (107)
	14. 04NOV2009 (132) - 08NOV2009 (136)
	15. 30DEC2009 (188) - 30DEC2009 (188)
Duration of AE	1. 5
	2. 8
	3. 12
	4. .
	5. .
	6. 2
	7. 67
	8. 73
	9. 4
	10. 6
	11. 3
	12. 1
	13. 6
	14. 5
	15. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140363005

Parameter	Value
	11.
	12.
	13.
	14.
	15.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. STUDY DRUG DISCONTINUED AND RESTARTED
	11. NONE
	12. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	13. NONE
	14. NONE
	15. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140363005

Parameter	Value
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140373011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140373011/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/28/WHITE/UNITED STATES/YES
Medical history	Anaemia, Cervix carcinoma, Constipation, Flatulence, Hypertension, Hypervolaemia, Hypocalcaemia, Hypokalaemia, Hyponatraemia, Hysterectomy, Road traffic accident, Nausea, Osteomyelitis, Sputum discoloured, Procedural pain, Jaw operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CALCIUM, CEFTRIAXONE, COLACE, LOPRESSOR, MYLICON, PEPCID, PERCOCET, POTASSIUM, ZITHROMAX, ZOFRAN
Adverse Events (AE) Preferred term	1. Post procedural haemorrhage 2. Vaginal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 11MAY2008 (10) - 14MAY2008 (13) 2. 19MAY2008 (18) - 01JUN2008 (31)
Duration of AE	1. 4 2. 14
Dose on AE onset	1. 15 mg 2. 15 mg
Dose status on AE onset	1. . 2. F
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY 2. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140373051

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140373051/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/62/WHITE/UNITED STATES/YES
Medical history	Essential tremor, Breast cancer, Coagulopathy, Cough, Hyperlipidaemia, Hypertension, Insomnia, Mastectomy, Nausea, Palpitations, Pyrexia, Syncope, Catheterisation cardiac, Hip surgery, Malignant melanoma, Anaemia of chronic disease, Limb injury, Acute myocardial infarction
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, ATIVAN, COLACE, ENOXAPARIN, HYCODAN COUGH SYRUP [HYDROCODONE BITARTRATE], LASIX, METOPROLOL, MORPHINE, NORCO, PEPCID, PHENERGAN, POTASSIUM CHOLORIDE, SOTALOL, TESSALON PEARLS, VYTORIN, WARFARIN
Adverse Events (AE) Preferred term	1. Respiratory arrest
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 31AUG2009 (3) - 31AUG2009 (3)
Duration of AE	1. 1
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. NONE
Outcome of event	1. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140413007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140413007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/49/WHITE/UNITED STATES/YES
Medical history	Atrial septal defect, Ankle fracture, Foot fracture, Pain in extremity, Blood cholesterol increased, Dyspnoea, Fatigue, Hypertension, Insomnia, Myocardial infarction, Obesity, Pain in extremity, Tachycardia, Blood triglycerides increased, Wheezing, Oedema peripheral, Headache, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETAMINOPHEN, ACTIVASE, AFRIN OXYMETAZOLINE HCL 0.05%, ALBUTEROL, ALBUTEROL/IPRATROPIUM, AMBIEN, AMBIEN ZOLPIDEM, ASPIRIN, ATIVAN LORAZEPAM, ATROVENT, AUGMENTIN, COLACE, DILAUDID, DIOVAN, ENOXAPARIN, FOLIC ACID, HEPARIN, HYDROCHLOROTHIAZIDE, IBUPROFEN, INTEGRILIN, IVC FILTER, LOPRESSOR, LOVENOX, MORPHINE, MOTRIN, MULTIVITAMIN, NEXIUM, NICOTINE PATCH, READI-CAT BARIUM SULFATE 1.2%, THIAMINE, THIAMINE HCL, UNASYN, VICODIN, VICODIN ES, WARFARIN, ZOCOR
Adverse Events (AE) Preferred term	1. Depression 2. Embolism arterial 3. Anxiety 4. Cardiomyopathy 5. Contusion 6. Nasal congestion 7. Ischaemic stroke 8. Dizziness 9. Headache 10. Tremor 11. Lacunar infarction 12. Eye pain 13. Vision blurred 14. Vitreous floaters 15. Scrotal abscess 16. Tremor 17. Nausea 18. Dysarthria 19. Hypoaesthesia 20. Wheezing 21. Insomnia 22. Oedema peripheral 23. Asthenia 24. Haemorrhoidal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/YES/YES 8. MODERATE/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140413007

Parameter	Value
	9. MODERATE/NO/NO/YES
	10. MILD/NO/NO/YES
	11. MILD/NO/YES/YES
	12. MODERATE/NO/NO/YES
	13. MILD/NO/NO/YES
	14. MILD/NO/NO/YES
	15. MILD/NO/NO/YES
	16. MILD/NO/NO/YES
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MILD/NO/NO/YES
	20. MILD/NO/NO/YES
	21. MILD/NO/NO/YES
	22. MILD/NO/NO/YES
	23. MILD/NO/NO/YES
	24. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --MAY2009 (.) - --------- (.)
	2. 01APR2009 (1) - 03APR2009 (3)
	3. 03APR2009 (3) - 07APR2009 (7)
	4. 06APR2009 (6) - --------- (.)
	5. 08APR2009 (8) - 01JUL2009 (92)
	6. 10APR2009 (10) - 20APR2009 (20)
	7. 17APR2009 (17) - 24APR2009 (24)
	8. 17APR2009 (17) - 19APR2009 (19)
	9. 17APR2009 (17) - --------- (.)
	10. 17APR2009 (17) - 17APR2009 (17)
	11. 18APR2009 (18) - 22MAY2009 (52)
	12. 19APR2009 (19) - 23APR2009 (23)
	13. 19APR2009 (19) - 20APR2009 (20)
	14. 21APR2009 (21) - --------- (.)
	15. 22APR2009 (22) - 06MAY2009 (36)
	16. 21MAY2009 (51) - 22MAY2009 (52)
	17. 21MAY2009 (51) - 22MAY2009 (52)
	18. 21MAY2009 (51) - --JUL2009 (.)
	19. 21MAY2009 (51) - --------- (.)
	20. 01JUL2009 (92) - --------- (.)
	21. 02JUL2009 (93) - 08JUL2009 (99)
	22. 03JUL2009 (94) - 05JUL2009 (96)
	23. 10JUL2009 (101) - --------- (.)
	24. 03AUG2009 (125) - --------- (.)
Duration of AE	1. .
	2. 3
	3. 5
	4. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140413007

Parameter	Value
	5. 85
	6. 11
	7. 8
	8. 3
	9. .
	10. 1
	11. 35
	12. 5
	13. 2
	14. .
	15. 15
	16. 2
	17. 2
	18. .
	19. .
	20. .
	21. 7
	22. 3
	23. .
	24. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140413007

Parameter	Value
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
Action taken	1. OTHER
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED
	8. STUDY DRUG DISCONTINUED AND RESTARTED
	9. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	10. NONE
	11. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	12. NONE
	13. NONE
	14. NONE
	15. REMEDIAL DRUG THERAPY,OTHER
	16. NONE
	17. NONE
	18. NONE
	19. NONE
	20. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140413007

Parameter	Value
	21. REMEDIAL DRUG THERAPY
	22. NONE
	23. NONE
	24. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. IMPROVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. UNCHANGED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. IMPROVED
	20. UNCHANGED
	21. RESOLVED
	22. RESOLVED
	23. UNCHANGED
	24. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140423008/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/69/WHITE/UNITED STATES/YES
Medical history	Rhinitis allergic, Asbestosis, Carpal tunnel decompression, Chronic obstructive pulmonary disease, Hepatic steatosis, Gastrooesophageal reflux disease, Glaucoma, Hypercholesterolaemia, Hypertension, Knee arthroplasty, Pulmonary fibrosis, Restless legs syndrome, Sleep apnoea syndrome, Spinal column stenosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADVAIR, DOCUSATE SODIUM, NIACIN-SIMVASTATIN, PRILOSEC, PROVENTIL, SPIRIVA, SYMBICORT, VOLTAREN, XALANTAN
Adverse Events (AE) Preferred term	1. Diverticulitis 2. Melaena 3. Diverticulitis 4. Renal cancer 5. Iron deficiency anaemia 6. Vitamin B12 deficiency 7. Lymphadenopathy mediastinal 8. Renal failure
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 08NOV2008 (17) - --------- (.) 2. 09NOV2008 (18) - 12NOV2008 (21) 3. 22NOV2008 (31) - 26NOV2008 (35) 4. 25NOV2008 (34) - --------- (.) 5. 10DEC2008 (49) - --------- (.) 6. 10DEC2008 (49) - --------- (.) 7. 10DEC2008 (49) - --------- (.) 8. 20DEC2008 (59) - --------- (.)
Duration of AE	1. . 2. 4 3. 5 4. . 5. . 6. . 7. . 8. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423008

Parameter	Value
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. F
Action taken	1. OTHER
	2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	3. OTHER
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
Outcome of event	1. INSUFFICIENT FOLLOW-UP
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. INSUFFICIENT FOLLOW-UP
	7. INSUFFICIENT FOLLOW-UP
	8. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-140423008[4)]	MELENA（PT：メレナ） 治験担当医は、合併症（憩室炎）及び併用薬（Predinasolone)によるものであり、否定できると判断した。弊社は、リバーロキサバン投与と報告事象発現との時間的関連性及び抗凝固作用から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140423009/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/19/BLACK/UNITED STATES/YES
Medical history	Asthma, Dysmenorrhoea, Iron deficiency anaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DILAUDID, ESTRADIOL, FERROUS GLOCONATE, FLAGYL, GYNELOTRIMIN, MONISTAT, MORPHINE, NORELGESTROMIN, PERCOCET, ROCEPHIN, TYLENOL [ACETAMINOPHEN], ZOFRAN, ZOPHREN
Adverse Events (AE) Preferred term	1. Amenorrhoea 2. Nausea 3. Pneumonia 4. Pleural effusion 5. Nausea 6. Vulvovaginal mycotic infection 7. Pain in extremity 8. Upper respiratory tract infection 9. Insomnia 10. Upper respiratory tract infection 11. Vaginal infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/NO 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --FEB2009 (.) - --------- (.) 2. 27OCT2008 (1) - 27OCT2008 (1) 3. 30OCT2008 (4) - 11NOV2008 (16) 4. 03NOV2008 (8) - 05NOV2008 (10) 5. 03NOV2008 (8) - 05NOV2008 (10) 6. 07NOV2008 (12) - 13NOV2008 (18) 7. 17NOV2008 (22) - 19DEC2008 (54) 8. 19DEC2008 (54) - 27JAN2009 (93) 9. 24DEC2008 (59) - 29JAN2009 (95) 10. 16MAR2009 (141) - 20MAR2009 (145) 11. 15JUN2009 (232) - 22JUN2009 (239)
Duration of AE	1. . 2. 1 3. 13 4. 3

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423009

Parameter	Value
	5. 3
	6. 7
	7. 33
	8. 40
	9. 37
	10. 5
	11. 8
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423009

Parameter	Value
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140423013/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/70/WHITE/UNITED STATES/YES
Medical history	Atrial fibrillation, Cardiac failure chronic, Hydronephrosis, Hyperlipidaemia, Hypertension, Benign prostatic hyperplasia, Prostatitis, Syncope, Thrombocytopenia, Bladder outlet obstruction
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMIODRAONE, BETAPACE, CARDIAZEM, CIPRO, DIOVAN, ENOXAPARIN, FLOMAX [TAMSULOSIN], LANOXIN, PRAVACHOL, PRINIVIL, PROSCAR, VENA CAVA FILTER, WARFARIN
Adverse Events (AE) Preferred term	1. Atrial fibrillation 2. Hypotension 3. Transient ischaemic attack
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 13NOV2008 (3) - 16DEC2008 (36) 2. 13NOV2008 (3) - 13NOV2008 (3) 3. 27NOV2008 (17) - 28NOV2008 (18)
Duration of AE	1. 34 2. 1 3. 2
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. REMEDIAL DRUG THERAPY 3. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423016

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140423016/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/42/BLACK/UNITED STATES/YES
Medical history	Alcohol abuse, Back pain, Depression, Hyperlipidaemia, Hypertension, Obesity, Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, ATIVAN, DEXEDSTOMIDINE, FLEXERIL, HYDROCHLOROTHIAZIDE, LISINOPRIL, METHADONE, MORPHINE, MULTIVITIMINS, NORVASC, OXYCODONE, PAMELOR, PROZAC, THIAMINE, ZOCOR
Adverse Events (AE) Preferred term	1. Back pain 2. Back pain 3. Alcohol poisoning 4. Non-cardiac chest pain 5. Blood creatinine increased
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 14MAR2009 (32) - 23MAR2009 (41) 2. 13MAY2009 (92) - 21MAY2009 (100) 3. 01JUN2009 (111) - 02JUN2009 (112) 4. 04JUL2009 (144) - 05JUL2009 (145) 5. 04JUL2009 (144) - 05JUL2009 (145)
Duration of AE	1. 10 2. 9 3. 2 4. 2 5. 2
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. NONE 2. NONE 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY,OTHER 5. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423016

Parameter	Value
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140423017/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/84/WHITE/UNITED STATES/YES
Medical history	Cardiac pacemaker insertion, Cochlea implant, Chronic obstructive pulmonary disease, Colectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADVAIR, AZITHROMYCIN, CLARITIN, COLACE, FLONASE, HEPARIN, INSULIN, PREDNISONE, PROVENTIL, SOLUMEDROL, SPIRIVA, UNFRACTIONATED HEPARIN, ZANTAC
Adverse Events (AE) Preferred term	1. Nasal congestion 2. Arthralgia 3. Chronic obstructive pulmonary disease 4. Blood glucose increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/YES/YES 4. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 14FEB2009 (2) - 16FEB2009 (4) 2. 27MAR2009 (43) - 13APR2009 (60) 3. 23APR2009 (70) - 26APR2009 (73) 4. 24APR2009 (71) - 25APR2009 (72)
Duration of AE	1. 3 2. 18 3. 4 4. 2
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. I
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423017

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140423021/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/53/WHITE/UNITED STATES/YES
Medical history	Asthma, Cellulitis, Diabetes mellitus, Hyperlipidaemia, Hypertension, Obesity, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, AVALIDE, BENADRYL, CRESTOR, DILAUDID, DISALCID, HUMALOG INSULIN, LANTUS, NITROBID [GLYCERYL TRINITRATE], NOVALOG, PEPCID, PERCOCET, PREDNISONE, PRINIVIL, PROVENTIL, ROCEPHIN, ROCHEPHIN, SOLUMEDROL, SYMBICORT, TETANUS TOXOID, TRICOR, VANCOCIN, ZITHROMAX, ZOFRAN
Adverse Events (AE) Preferred term	1. Asthma 2. Cellulitis 3. Blood glucose increased 4. Joint effusion 5. Non-cardiac chest pain 6. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 14MAY2009 (9) - 18MAY2009 (13) 2. 28JUN2009 (54) - 30JUN2009 (56) 3. 28JUN2009 (54) - 30JUN2009 (56) 4. 28JUN2009 (54) - 28JUN2009 (54) 5. 28SEP2009 (146) - 30SEP2009 (148) 6. 29OCT2009 (177) - 21NOV2009 (200)
Duration of AE	1. 5 2. 3 3. 3 4. 1 5. 3 6. 24
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423021

Parameter	Value
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY
	4. OTHER
	5. REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140423023/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/62/WHITE/UNITED STATES/YES
Medical history	Anaemia, Cardiac pacemaker insertion, Cardiac failure chronic, Coronary artery disease, Diabetes mellitus, Deafness, Haemothorax, Hyperlipidaemia, Hypertension, Obesity, Atrial fibrillation, Pleural effusion, Pneumothorax, Renal artery stenosis, Rib fracture, Sleep apnoea syndrome
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, CATAPRES, COREG, CRESTOR, FLAGYL, HYDRALAZINE, HYDROCHLORTHIAZIDE, ISORDIL, LANTUS, LASIX, LEVAQUIN, LISINOPRIL, MORPHINE, PERCOCET, POTASSIUM
Adverse Events (AE) Preferred term	1. Dizziness 2. Colitis ischaemic 3. Rectal haemorrhage 4. Musculoskeletal chest pain 5. Pleural fibrosis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 02JUL2009 (7) - 27AUG2009 (63) 2. 10AUG2009 (46) - 15AUG2009 (51) 3. 10AUG2009 (46) - 15AUG2009 (51) 4. 22OCT2009 (119) - --------- (.) 5. 10NOV2009 (138) - --------- (.)
Duration of AE	1. 57 2. 6 3. 6 4. . 5. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. OTHER 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 3. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 4. OTHER 5. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423023

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423030

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140423030/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/66/WHITE/UNITED STATES/YES
Medical history	Anxiety, Chronic obstructive pulmonary disease, Gastrooesophageal reflux disease, Hysterectomy, Lung neoplasm malignant, Nausea, Vitamin D deficiency, Osteoarthritis, Breast lump removal
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETAMENIPHEN WITH CODIENE, ALIMTA, ALPRAZOLAM, ASPIRIN, CISPLTAIN, DILAUDID, FENTANYL, FOLIC ACID, FRAGMIN, HYDROMORPHONE, MECLIZINE HCL, MIDAZOLAM, PANTOPRAZOLE, PHENERGAN, POLYETHYLENE GLYCOL, VITAMIN B12, VITAMIN D, ZOFRAN
Adverse Events (AE) Preferred term	1. Gastroenteritis 2. Vomiting 3. Dysphagia 4. Bronchitis 5. Ligament sprain
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/YES/YES 3. SEVERE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 12FEB2010 (10) - 15FEB2010 (13) 2. 07MAR2010 (33) - 08MAR2010 (34) 3. 19MAR2010 (45) - 29MAR2010 (55) 4. 21MAR2010 (47) - 02APR2010 (59) 5. 25MAR2010 (51) - 28APR2010 (85)
Duration of AE	1. 4 2. 2 3. 11 4. 13 5. 35
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY,OTHER 4. NONE 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423030

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423032

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140423032/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/55/WHITE/UNITED STATES/YES
Medical history	Appendicectomy, Asthma, Gastrooesophageal reflux disease, Hypertension, Hysterectomy, Nausea, Convulsion, Cerebrovascular accident, Thoracotomy, Pain, Cystopexy, Spinal laminectomy, Anxiety disorder, Dyslipidaemia, Type 2 diabetes mellitus, Intervertebral disc degeneration
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLONAZEPAM, COLACE, DILAUDID, GLUCOPHAGE, LANTIS, LOFIBRA, LYRICA, METHADONE, MORPHINE, NARCAN, NEXIUM, NOVULOG INSULIN, OXYCODONE, REGLAN, RESTORIL, TRI-COR, VERAPAMIL
Adverse Events (AE) Preferred term	1. Non-cardiac chest pain 2. Depressed level of consciousness 3. Overdose
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/YES/YES 3. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 23MAR2010 (9) - 26MAR2010 (12) 2. 21MAY2010 (68) - 25MAY2010 (72) 3. 22SEP2010 (192) - 23SEP2010 (193)
Duration of AE	1. 4 2. 5 3. 2
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. F
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. REMEDIAL DRUG THERAPY,OTHER 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423036

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140423036/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/74/WHITE/UNITED STATES/YES
Medical history	Diabetes mellitus, Dizziness, Ankle fracture, Fungal skin infection, Haemorrhoid operation, Hyperlipidaemia, Hypertension, Hypomagnesaemia, Lumbar spinal stenosis, Obesity, Osteoarthritis, Paraplegia, Decubitus ulcer, Transient ischaemic attack, Vertigo, Vitamin D deficiency, Spinal fusion surgery, Bone cyst excision, Jaw operation, Shoulder operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANCEF, ASPIRIN, BACLOFEN, CALCIUM, DECADRON, DILAUDID, DOSS [DOCUSATE SODIUM], FELDENE, FORTAZ, GLUCOSAMINE, HYDROCHLORTHIAZIDE, KENALOG CREAM, L;EVAQUIN, LEVOQUIN, LINEZOLID, LIPITOR, LISINOPRIL, LOTENSION, LOTRIMIN CREAM, LOVENOX, MACROBID, MAGONATE, MECLIZINE, MIRALAX, MORPHINE, MULTIVITAMINS, MYCOSTATIN, NAPROSYN, NORVASC, OMEGA 3 FISH OIL, OXYCODONE, TORADOL, TYLENOL [ACETOMINOPHEN], VANCOCIN, VITAMIN D, ZANTAC
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Cough 3. Urinary retention 4. Meningioma 5. Sepsis 6. Gastric perforation 7. Atrial fibrillation
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES 5. SEVERE/NO/YES/YES 6. SEVERE/NO/YES/YES 7. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 26OCT2010 (128) - 05NOV2010 (138) 2. 26OCT2010 (128) - 26OCT2010 (128) 3. 26OCT2010 (128) - --------- (.) 4. 16FEB2011 (241) - 19FEB2011 (244) 5. 21MAR2011 (274) - 13APR2011 (297) 6. 23MAR2011 (276) - 23MAR2011 (276) 7. 28MAR2011 (281) - --------- (.)
Duration of AE	1. 11 2. 1 3. . 4. 4 5. 24 6. 1 7. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423036

Parameter	Value
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. I
	5. .
	6. F
	7. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY,OTHER
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY,OTHER
	6. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423037

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140423037/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/64/WHITE/UNITED STATES/YES
Medical history	Rhinitis allergic, Arthroscopy, Cardiac pacemaker insertion, Depression, Fibrocystic breast disease, Gastrooesophageal reflux disease, Atrioventricular block complete, Hernia hiatus repair, Hyperlipidaemia, Hysterectomy, Intervertebral disc disorder, Lymphoedema, Obesity, Neuropathy peripheral, Osteoarthritis, Sleep apnoea syndrome, Pain, Gastric banding
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETAMENIPHEN, ALLEGRA, ANCEF, AUGMENTIN, CELESTONE, CLARITIN, FENTANYL, FLEXERIL, HYDROCODONE, LEVAQUIN, MARCAIN 25%, MARCAINE, MIDODRINE, NORTRIPTYLINE, PAXIL, PEPCID, PRILOSEC, TRAMADOL, UNFRACTIONATED HEPARIN, VERSED, ZANTAC, ZOCOR
Adverse Events (AE) Preferred term	1. Intervertebral disc protrusion 2. Upper respiratory tract infection 3. Orthostatic hypotension 4. Urinary tract infection 5. Back pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. SEVERE/NO/NO/YES
Start/stop date of event with relative date	1. 24SEP2010 (94) - --------- (.) 2. 05JAN2011 (197) - 16JAN2011 (208) 3. 15FEB2011 (238) - 17FEB2011 (240) 4. 26APR2011 (308) - 02MAY2011 (314) 5. 26APR2011 (308) - 19MAY2011 (331)
Duration of AE	1. . 2. 12 3. 3 4. 7 5. 24
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423037

Parameter	Value
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140423043

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140423043/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/76/WHITE/UNITED STATES/YES
Medical history	Cataract, Chronic obstructive pulmonary disease, Endoscopic retrograde cholangiopancreatography, Hyperlipidaemia, Hypertension, Knee arthroplasty, Knee arthroplasty, Obesity, Osteoporosis, Pneumonia, Pulmonary fibrosis, Sarcoidosis, Female sterilisation, Seasonal allergy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXIL, AUGMENTIN, FLONASE, FOSAMAX, HEPARIN, HYDROCHLORTHIAZIDE, HYROCLORTHIAZIDE, METROPOLOL, METROPROLOL, MULTIVITAMIN, NORVASC, OSCAL, UNFRACTIONATED HEPARIN, VITAMIN C
Adverse Events (AE) Preferred term	1. Atrial fibrillation 2. Pharyngitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 07APR2011 (94) - --------- (.) 2. 07APR2011 (94) - 16APR2011 (103)
Duration of AE	1. . 2. 10
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140453002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140453002/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/64/HISPANIC/UNITED STATES/YES
Medical history	Appendicectomy, Bursitis, Gastric ulcer, Hiatus hernia, Hyperlipidaemia, Hypertension, Hypothyroidism, Prostatic specific antigen increased, Umbilical hernia repair, Cryptorchism, Hernia repair, Thyroidectomy, Gastrooesophageal reflux disease, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETAMINOPHEN (TYLENOL), ASPRIN, CRESTOR, ENALAPRIL, ENOXAPARIN, FAMOTIDINE (PEPCID, GLYBURIDE, LEVOTHYROXINE, METOPROLOL TARTATE, MORPHINE SULFATE, NITROGLYCERIN, PLAVIX, PREVACID, REGULAR INSULIN, SODIUM CHLORIDE 0.9% (SALINE), WARFARIN, ZOCOR
Adverse Events (AE) Preferred term	1. Coronary artery disease 2. Oedema peripheral 3. Chest pain 4. Blood bilirubin increased 5. Conjunctival haemorrhage 6. Colonic polyp 7. Haemorrhoids 8. Nasal congestion 9. Pharyngitis 10. Cough
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/NO 9. MILD/NO/NO/NO 10. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 31MAY2010 (14) - --------- (.) 2. 31MAY2010 (14) - 04JUN2010 (18) 3. 31MAY2010 (14) - 04JUN2010 (18) 4. 15JUL2010 (59) - 19AUG2010 (94) 5. 30NOV2010 (197) - 12DEC2010 (209) 6. 07DEC2010 (204) - 07DEC2010 (204) 7. 07DEC2010 (204) - --------- (.) 8. 14JUN2011 (393) - 16JUN2011 (395) 9. 14JUN2011 (393) - 16JUN2011 (395) 10. 14JUN2011 (393) - 16JUN2011 (395)
Duration of AE	1. . 2. 5 3. 5 4. 36

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140453002

Parameter	Value
	5. 13
	6. 1
	7. .
	8. 3
	9. 3
	10. 3
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED
	3. DOSE OF STUDY DRUG REDUCED,STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140453002

Parameter	Value
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140463003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140463003/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/50/BLACK/UNITED STATES/YES
Medical history	Drug abuse, Coronary artery disease, Gastrooesophageal reflux disease, Hypercholesterolaemia, Hypertension, Pain in extremity, Obesity, Sleep apnoea syndrome, Insulin-requiring type 2 diabetes mellitus, Intervertebral disc protrusion, Back pain, Erectile dysfunction, Coronary arterial stent insertion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACCUPRIL, AMIODARONE, AMITRIPTYLINE, ASPIRIN, ATROPINE, AUGMENTIN, CLINDAMYCIN 2%, CLOTRIMAZOL 1%, ENOXAPARIN, FLEXERIL, HYDROCODONE, LOPRESSOR, METFORMIN, METOPROLOL, MOBIC, NITROGLYCERINE, NOVOLIN 70/30, PANTOPRAZOLE, PEPCID, PLAVIX, PRAVACHOL, PREVACID, PROTONIX, TRAMADOL, ZESTRIL, ZOCOR
Adverse Events (AE) Preferred term	1. Chest pain 2. Arthralgia 3. Gastrooesophageal reflux disease 4. Atrial fibrillation 5. Procedural hypertension 6. Muscular weakness 7. Arthralgia 8. Headache 9. Headache 10. Chest pain 11. Gastrooesophageal reflux disease 12. Arthralgia 13. Genital lesion 14. Arthralgia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/YES/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 15MAY2010 (92) - 17MAY2010 (94) 2. 15MAY2010 (92) - 17MAY2010 (94) 3. 15MAY2010 (92) - 17MAY2010 (94) 4. 17MAY2010 (94) - 17MAY2010 (94) 5. 17MAY2010 (94) - 17MAY2010 (94) 6. 20MAY2010 (97) - 21MAY2010 (98)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140463003

Parameter	Value
	7. 16JUN2010 (124) - 20JUN2010 (128)
	8. 01SEP2010 (201) - 07SEP2010 (207)
	9. 19SEP2010 (219) - 21SEP2010 (221)
	10. 19SEP2010 (219) - 21SEP2010 (221)
	11. 19SEP2010 (219) - 21SEP2010 (221)
	12. 20SEP2010 (220) - 20SEP2010 (220)
	13. 03JAN2011 (325) - 25FEB2011 (378)
	14. 20FEB2011 (373) - --------- (.)
Duration of AE	1. 3
	2. 3
	3. 3
	4. 1
	5. 1
	6. 2
	7. 5
	8. 7
	9. 3
	10. 3
	11. 3
	12. 1
	13. 54
	14. .
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
Dose status on AE onset	1. I
	2. I
	3. I
	4. I
	5. I
	6. .
	7. .
	8. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140463003

Parameter	Value
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140473002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140473002/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/23/WHITE/UNITED STATES/YES
Medical history	Anaemia, Anxiety, Depression, Hypokalaemia, Insomnia, Migraine, Nausea, Ovarian cyst, Pyelonephritis, Rheumatoid arthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPRAZOLAM, ARAVA, ASPIRIN, ATENOLOL, CLORAZEPAM, COMPAZINE, CYMBLATA, ENOXAPARIN, FOLIC ACID, HYDROMORPHONE, KCL, KLOR-CON, LOVENOX, METHOTREXATE, MIRALAX, MULTIVITAMIN, OXYGEN, PERCOCET, REMICADE, REQUIP, SEROQUEL, SODIUM CHLORIDE, TOPOMAX, TYLENOL [ACETAMINOPHEN (PARACETAMOL)], UNFRACTIONATED HEPARIN, VITAMIN B 12, VITAMIN D, WARFARIN, ZOFRAN, ZOLIPIDEM
Adverse Events (AE) Preferred term	1. Sinus tachycardia 2. Hypokalaemia 3. Hypertension 4. Dyspnoea 5. Chest pain 6. Anxiety 7. Restless legs syndrome 8. Constipation 9. Abdominal pain upper 10. Headache 11. Asthenia 12. Pyrexia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/YES/YES 3. MILD/NO/YES/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/YES/YES 6. MODERATE/NO/YES/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 07MAY2010 (18) - --------- (.) 2. 07MAY2010 (18) - 15JUL2010 (87) 3. 07MAY2010 (18) - --------- (.) 4. 07MAY2010 (18) - 07MAY2010 (18) 5. 07MAY2010 (18) - 08MAY2010 (19) 6. 07MAY2010 (18) - 08MAY2010 (19) 7. 08JUN2010 (50) - --------- (.) 8. 13JUL2010 (85) - 17JUL2010 (89) 9. 13JUL2010 (85) - 17JUL2010 (89) 10. 16JUL2010 (88) - 17JUL2010 (89)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140473002

Parameter	Value
	11. 16JUL2010 (88) - 17JUL2010 (89)
	12. 21JUL2010 (93) - 21JUL2010 (93)
Duration of AE	1. .
	2. 70
	3. .
	4. 1
	5. 2
	6. 2
	7. .
	8. 5
	9. 5
	10. 2
	11. 2
	12. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140473002

Parameter	Value
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140473012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/140473012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/37/WHITE/UNITED STATES/YES
Medical history	Drug hypersensitivity, Constipation, Gastrooesophageal reflux disease, Hypothyroidism, Menorrhagia, Ovarian cyst, Drug hypersensitivity, Drug hypersensitivity, Gastric ulcer perforation, Gastric ulcer perforation, Radioactive iodine therapy, Knee operation, Drug hypersensitivity, Thyroidectomy, Post procedural swelling, Post procedural swelling, Thyroid cancer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBIEN, ATIVAN, CLARITHROMYCIN, COLACE, COMPAZINE, DILAUDID, ENOXAPARIN, EPOTETIN ALPHA, ESOMEPRAZOLE, IRON SUCROSE/SODIUM CHLORIDE, LEVAQUIN, METRONIDAZOLE, MIRALAX, MORPHINE, NEXIUM, ORTHO EVRA PATCH, OXYCODONE, PERCOCET, PRILOSEC, REGLAN, SENNA, SYNTHROID, TINESSA, TYLENOL [PARACETAMOL ALONE], WARFARIN, ZOFRAN
Adverse Events (AE) Preferred term	1. Blood thyroid stimulating hormone increased 2. Anaemia 3. Oedema 4. Insomnia 5. Hiatus hernia 6. Abdominal pain 7. Chest pain 8. Abdominal pain 9. Abdominal pain 10. Back pain 11. Nausea 12. Diarrhoea 13. Pyrexia 14. Headache 15. Vomiting 16. Anxiety 17. Depression
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. SEVERE/NO/YES/YES 10. SEVERE/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MODERATE/NO/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES 15. MODERATE/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140473012

Parameter	Value
	16. MODERATE/NO/NO/YES
	17. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 08MAR2011 (14) - 20JUL2011 (148)
	2. 25MAR2011 (31) - 28MAR2011 (34)
	3. 26MAR2011 (32) - 28MAR2011 (34)
	4. 26MAR2011 (32) - 27MAR2011 (33)
	5. 26MAR2011 (32) - --------- (.)
	6. 26MAR2011 (32) - 02APR2011 (39)
	7. 14JUN2011 (112) - 28JUN2011 (126)
	8. 22JUN2011 (120) - 25JUN2011 (123)
	9. 18AUG2011 (177) - 26AUG2011 (185)
	10. 18AUG2011 (177) - 25AUG2011 (184)
	11. 18AUG2011 (177) - 25AUG2011 (184)
	12. 18AUG2011 (177) - 22AUG2011 (181)
	13. 19AUG2011 (178) - 19AUG2011 (178)
	14. 22AUG2011 (181) - 22AUG2011 (181)
	15. 22AUG2011 (181) - 23AUG2011 (182)
	16. 22AUG2011 (181) - --------- (.)
	17. 22AUG2011 (181) - --------- (.)
Duration of AE	1. 135
	2. 4
	3. 3
	4. 2
	5. .
	6. 8
	7. 15
	8. 4
	9. 9
	10. 8
	11. 8
	12. 5
	13. 1
	14. 1
	15. 2
	16. .
	17. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140473012

Parameter	Value
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY,OTHER
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 140473012

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. UNCHANGED
	17. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160013012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/49/N.A./FRANCE/YES
Medical history	
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	APROVEL, ATARAX, BROMAZEPAM, CALCIPARINE, CORTANCYL, COUMADINE, ELUDRIL [CHLORHEXIDINE DIGLUCONATE SOL,CHLOROBUTANOL H?MIHYDRAT?,DOCUSATE SODIUM, ENOXAPARIN, IMODIUM, LASILIX, MINIRIN, OFLOCET, OROKEN, ROCEPHINE, SMECTA [I CONFIRM THAT SMECTA DOES CONTAIN SMECTITE + SACCHARIN SODIUM.], TIORFAN, WARFARIN
Adverse Events (AE) Preferred term	1. Tooth infection 2. Tooth abscess 3. Arthralgia 4. Systemic lupus erythematosus 5. Anxiety 6. Retroperitoneal haematoma 7. Haematuria 8. Diarrhoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/YES/YES/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 27DEC2007 (16) - 31DEC2007 (20) 2. 27DEC2007 (16) - 02JAN2008 (22) 3. 19FEB2008 (70) - 17APR2008 (128) 4. 20FEB2008 (71) - --------- (.) 5. 15APR2008 (126) - --JUN2008 (.) 6. 23APR2008 (134) - 06MAY2008 (147) 7. 23APR2008 (134) - 27APR2008 (138) 8. 26APR2008 (137) - 09MAY2008 (150)
Duration of AE	1. 5 2. 7 3. 59 4. . 5. . 6. 14 7. 5 8. 14
Dose on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013012

Parameter	Value
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED AND RESTARTED
	7. NONE
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160013021/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/74/N.A./FRANCE/YES
Medical history	Humerus fracture, Hypertension, Musculoskeletal pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CLAMOXYL [AMOXICILLIN], DAFALGAN, ENOXAPARIN, IXPRIM, LOXEN, TRIFLUCAN, WARFARIN
Adverse Events (AE) Preferred term	1. Haematuria 2. Lung disorder 3. Urinary tract infection fungal
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 11FEB2008 (4) - 14FEB2008 (7) 2. 12FEB2008 (5) - 22FEB2008 (15) 3. 15FEB2008 (8) - 28FEB2008 (21)
Duration of AE	1. 4 2. 11 3. 14
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160013023/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/81/N.A./FRANCE/YES
Medical history	Angina pectoris, Osteoarthritis, Diverticulum intestinal, Cardiac disorder, Hiatus hernia, Hypercholesterolaemia, Hypertension, Insomnia, Lumbar spinal stenosis, Pulmonary tuberculosis, Rheumatoid arthritis, Back pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	COVERSYL [PERINDOPRIL ALONE], DOLIPRANE, ENOXAPARIN, IMOVANE, INIPOMP, IXPRIM, MEDROL, NOVATREX [METHOTREXATE], TAHOR, TENORMINE, WARFARIN, ZALDIAR
Adverse Events (AE) Preferred term	1. Back pain 2. Ecchymosis 3. Eye haemorrhage 4. Osteoarthritis 5. Osteoarthritis 6. Haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/YES/YES/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 16MAY2008 (86) - --------- (.) 2. 24JUN2008 (125) - --JUL2008 (.) 3. 11JUL2008 (142) - 10SEP2008 (203) 4. 21AUG2008 (183) - --------- (.) 5. 21AUG2008 (183) - --------- (.) 6. 04SEP2008 (197) - --------- (.)
Duration of AE	1. . 2. . 3. 62 4. . 5. . 6. .
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013023

Parameter	Value
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. UNCHANGED
	6. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013031

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160013031/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/72/N.A./FRANCE/YES
Medical history	Depression, Hypertension, Obesity, Lung infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARIXTRA, AUGMENTIN, EFFERALGAN, EFFEXOR, FUROSEMIDE, SEROPLEX
Adverse Events (AE) Preferred term	1. Vulval disorder
	2. Vulval disorder
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 02JUL2008 (26) - 05NOV2008 (152)
	2. 05NOV2008 (152) - 12NOV2008 (159)
Duration of AE	1. 127
	2. 8
Dose on AE onset	1. 20 mg
	2. 20 mg
Dose status on AE onset	1. .
	2. I
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED
	2. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. WORSENED
	2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013063

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160013063/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/84/N.A./FRANCE/YES
Medical history	Constipation, Hypercholesterolaemia, Hypertension, Myocardial infarction, Lung infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOR, ATROPINE, CLAMOXYL, CORVASAL, DAFALGAN, DOLIPRANE, DUPHALAC [LACTULOSE], EFFERALGAN, ELISOR, INFLUVAC, KARDEGIC, MONOALGIC, MOVICOL, SPASFON, TEMERIT, TOPALGIC [TRAMADOL], TRIMEBUTINE, UNFRACTIONATED HEPARIN
Adverse Events (AE) Preferred term	1. Haemoptysis 2. Cough 3. Chest pain 4. Presyncope 5. Constipation 6. Chest pain 7. Rib fracture
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 28MAY2009 (7) - 04JUN2009 (14) 2. 29MAY2009 (8) - 23JUN2009 (33) 3. 30MAY2009 (9) - 31MAY2009 (10) 4. 31MAY2009 (10) - 31MAY2009 (10) 5. 04JUN2009 (14) - 04JUN2009 (14) 6. 04JUN2009 (14) - 04JUN2009 (14) 7. 30JUL2009 (70) - 09AUG2009 (80)
Duration of AE	1. 8 2. 26 3. 2 4. 1 5. 1 6. 1 7. 11
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 15 mg 6. 15 mg 7. 20 mg
Dose status on AE onset	1. . 2. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013063

Parameter	Value
	3. .
	4. .
	5. .
	6. .
	7. .
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013071

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160013071/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/90/N.A./FRANCE/YES
Medical history	Dementia Alzheimer's type, Appendicectomy, Benign breast neoplasm, Arrhythmia, Hypercholesterolaemia, Renal failure chronic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, DAFALGAN, EBIXA, ELISOR, OSTRAM D3, XARELTO
Adverse Events (AE) Preferred term	1. Osteoarthritis 2. Fall 3. Back pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 12AUG2009 (34) - --------- (.) 2. 12AUG2009 (34) - 12AUG2009 (34) 3. 13AUG2009 (35) - 21AUG2009 (43)
Duration of AE	1. . 2. 1 3. 9
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. I
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013078

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160013078/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/51/N.A./FRANCE/YES
Medical history	Epilepsy, Hypothyroidism, Ruptured cerebral aneurysm, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	FORLAX, LEVOTHYROX, NEURONTIN, NICOPATCH, NICORETTE, URBANYL, XYZALL
Adverse Events (AE) Preferred term	1. Constipation 2. Pruritus 3. Influenza like illness 4. Oral herpes 5. Rectal haemorrhage 6. Epilepsy
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 14JAN2010 (1) - 04DEC2010 (325) 2. 15JAN2010 (2) - 19JAN2010 (6) 3. 26JAN2010 (13) - 28JAN2010 (15) 4. 29JAN2010 (16) - 04FEB2010 (22) 5. 14JUN2010 (152) - 14JUN2010 (152) 6. 22JUN2010 (160) - 30JUN2010 (168)
Duration of AE	1. 325 2. 5 3. 3 4. 7 5. 1 6. 9
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013078

Parameter	Value
	4. NONE
	5. NONE
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013088

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160013088/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/56/N.A./FRANCE/YES
Medical history	Eczema, Joint injury, Knee operation, Procedural pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, BIPROFENID, DOLIPRANE, ENOXAPARIN, ENOXAPARINE, EUPANTOL, IXPRIM, NAROPIN, PARACETAMOL, TRAMADOL, WARFARIN
Adverse Events (AE) Preferred term	1. Joint stiffness 2. Post procedural haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/YES/NO/YES
Start/stop date of event with relative date	1. 25APR2010 (26) - 03JUN2010 (65) 2. 04JUN2010 (66) - --------- (.)
Duration of AE	1. 40 2. .
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 2. OTHER
Outcome of event	1. RESOLVED 2. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160013088[1)]	RIGHT KNEE STIFFNESS（PT：関節硬直） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、合併症（右膝の関節硬直）によるものであり、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013092

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160013092/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/87/N.A./FRANCE/YES
Medical history	Diabetes mellitus, Epilepsy, Gout, Prostate cancer, Renal failure, Peripheral arterial occlusive disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANDROCUR (CYPROTÉRONE), DAONIL (GLIBENCLAMIDE), ENOXAPARIN, ISUPREL, KARDEGIC(ACÉTYLSALICYLATE DE DL- LYSINE, METFORMINE, MOPRAL (OMEPRAZOLE), TEGRETOL LP (CARBAMAZÉPINE), TRIVASTAL (PIRIBÉDIL), URBANYL (CLOBAZAM), WARFARIN, XATRAL LP, ZYLORIC (ALLOPURINOL)
Adverse Events (AE) Preferred term	1. Dizziness 2. Atrioventricular block
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 31JUL2010 (2) - 31JUL2010 (2) 2. 04AUG2010 (6) - 05AUG2010 (7)
Duration of AE	1. 1 2. 2
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013093

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160013093/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/18/N.A./FRANCE/YES
Medical history	Drug hypersensitivity, Urinary tract infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, DOXY, ENOXAPARIN, EUPANTOL, GAVISCON, IXPRIM, METEOXAN, NOROXINE, OROPERIDIS, WARFARIN
Adverse Events (AE) Preferred term	1. Acne 2. Chest pain 3. Anxiety 4. Gastroenteritis 5. Toothache 6. Gingivitis 7. Gastritis 8. Tooth infection 9. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/YES/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 10AUG2010 (8) - --------- (.) 2. 06SEP2010 (35) - 28SEP2010 (57) 3. 06SEP2010 (35) - 28SEP2010 (57) 4. 20SEP2010 (49) - 23SEP2010 (52) 5. 10OCT2010 (69) - 13JAN2011 (164) 6. 30OCT2010 (89) - --------- (.) 7. 24DEC2010 (144) - 06JAN2011 (157) 8. 15JAN2011 (166) - 24JAN2011 (175) 9. 29JAN2011 (180) - 04FEB2011 (186)
Duration of AE	1. . 2. 23 3. 23 4. 4 5. 96 6. . 7. 14 8. 10 9. 7
Dose on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013093

Parameter	Value
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. OTHER
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. OTHER
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160013107

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160013107/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/82/N.A./FRANCE/YES
Medical history	Anxiety, Dyspnoea, Hysterectomy, Inguinal hernia, Insomnia, Kyphoscoliosis, Renal failure, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADRENALINE, ATARAX, AUGMENTIN, CETORNAM, LIPANTHYL, OXYGENE, STILNOX, STRESSAM
Adverse Events (AE) Preferred term	1. Lung infection 2. Aspartate aminotransferase increased 3. Pulmonary embolism
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/NO/YES 3. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 15MAR2011 (6) - 28MAR2011 (19) 2. 12APR2011 (34) - --------- (.) 3. 14APR2011 (36) - 14APR2011 (36)
Duration of AE	1. 14 2. . 3. 1
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. UNCHANGED 3. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160013107[4)]	FATAL RECURRENT PULMONARY EMBOLISM（PT：肺塞栓症） 治験担当医はリバーロキサバンと報告事象との関連性があると判断した。弊社は、本試験のエンドポイントであり、有害事象よりむしろ薬効欠如と考えられるため、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

被験者番号：11702-160013107

死亡に至るまでの経過

被験者は 82 歳、女性。2011 年 3 月 8 日に肺塞栓症と診断され、2011 年 3 月 10 日にリバーロキサバン（30mg）の投与を開始した。

2011 年 4 月 14 日、被験者は肺塞栓症（報告用語：致死的な再発性肺塞栓症、以下同様）を発現した。本事象は、死亡に至り重大な医学的事象と考えられたため、重篤とされた。治験責任（分担）医師は、本事象の重症度は高度で、かつ治験薬との因果関係は「あり」と判断した。2011 年 4 月 14 日、被験者は呼吸窮迫症候群を発現、その後心肺停止に陥った。救急医療班により心臓マッサージが行われ、epinephrine が投与されたが、本事象により同日死亡に至った。剖検は実施されなかった。

独立中央判定委員会（CIAC）は、死亡原因は不明であり肺塞栓症である可能性は否定できないとした。

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
Platelets	Local: 150-400 giga/L	09 Mar 2011	**434 giga/L (H)**				
Alkaline Phosphatase	Central: 36-118 U/L	10 Mar 2011	41 U/L	28 Mar 2011	52 U/L	12 Apr 2011	52 U/L
Amylase	Central: 28-100 U/L	10 Mar 2011	45 U/L				
Bilirubin, Direct	Central: 0.10-0.32 mg/dL	10 Mar 2011	0.27 mg/dL	28 Mar 2011	**0.44 mg/dL (H)**	12 Apr 2011	**0.51 mg/dL (H)**
Bilirubin, Total	Central: 0.22-1.28 mg/dL	10 Mar 2011	0.39 mg/dL	28 Mar 2011	0.77 mg/dL	12 Apr 2011	0.78 mg/dL
SGOT/AST	Central: 11-37 U/L	10 Mar 2011	28 U/L	28 Mar 2011	19 U/L	12 Apr 2011	**82 U/L (H)**
SGPT/ALT	Central: 8-43 U/L [a] Local: 0-45 U/L	09 Mar 2011	25 U/L [a]	28 Mar 2011	15 U/L		
		10 Mar 2011	26 U/L	12 Apr 2011	**45 U/L (H)**		
PICT Seconds	Central: 24.80-36.40 S	10 Mar 2011	**77.20 S (H)**	28 Mar 2011	<34.80 S	28 Mar 2011	<34.80 S
Prothrombin Time (PT)	Central: 11.80-15.50 S	10 Mar 2011	15.00 S	28 Mar 2011	**18.20 S (H)**	28 Mar 2011	**29.20 S (H)**
PT Ratio	Central: 0.70-1.20 %	10 Mar 2011	0.74 %	28 Mar 2011	**0.53 % (L)**	28 Mar 2011	**0.27 % (L)**
PT, INR	Central: 0.9-1.2	10 Mar 2011	1.2	28 Mar 2011	**1.6 (H)**	28 Mar 2011	**2.9 (H)**

Subject ID: 160023005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160023005/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/52/N.A./FRANCE/YES
Medical history	Ankylosing spondylitis, Pemphigoid, Diabetes mellitus, Hypercholesterolaemia, Hypertension, Nephrolithiasis, Sinusitis, Sinusitis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBROXOL, AUGMENTIN, DOLIPRANE, ENOXAPARIN, KENZEN, MONOTILDIEM LP, MOPRAL, NAPROSYNE, REMICADE, STAGID, TAHOR
Adverse Events (AE) Preferred term	1. Umbilical hernia 2. Haematoma 3. Road traffic accident 4. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/YES/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 08FEB2008 (73) - --------- (.) 2. 22MAY2008 (177) - 23JUN2008 (209) 3. 22MAY2008 (177) - 22MAY2008 (177) 4. 18SEP2008 (296) - 25SEP2008 (303)
Duration of AE	1. . 2. 33 3. 1 4. 8
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED 3. NONE 4. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160023005

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160023013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160023013/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/72/N.A./FRANCE/YES
Medical history	Angina pectoris, Appendicectomy, Diabetes mellitus, Hypertension, Hysterectomy, Lymphoedema, Obesity, Rheumatoid arthritis, Sleep disorder, Gastrointestinal disorder, Intervertebral disc protrusion, Depression
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMAREL, AMLOR, ATHYMIL, DI ANTALVIC, EFFERALGAN, ESBERIVEN, FORLAX, KARDEGIC, MOXYDAR, NORMACOL, OGAST, SPASFON, STAGID, SULFATE DE MAGNESIUM, TAHOR, VOLTARENE, VOLTARENE EMULGEL, ZOLPIDEM
Adverse Events (AE) Preferred term	1. Ligament sprain 2. Depression 3. Osteoarthritis 4. Rib fracture
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 22OCT2008 (142) - --------- (.) 2. 22MAR2009 (293) - --------- (.) 3. 28APR2009 (330) - 29MAY2009 (361) 4. 19MAY2009 (351) - --------- (.)
Duration of AE	1. . 2. . 3. 32 4. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. UNCHANGED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160023013

Parameter	Value
	4. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160023018

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160023018/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/70/N.A./FRANCE/YES
Medical history	Angioplasty, Appendicectomy, Depression, Hypercholesterolaemia, Hypertension, Hysterectomy, Mitral valve replacement, Obesity, Respiratory tract infection, Bladder prolapse, Back pain, Congestive cardiomyopathy, Aortic bypass, Mitral valve repair
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACÉTYLCYSTÉINE, AMLOR, ATACAND [CANDESARTAN CILEXETIL], ATROVENT, AUGMENTIN, AUGMENTION, AZANTAC, CIFLOX, DAFALGAN, DOBUTAMINE, ENOXAPARIN, FORLAX, FRESH FROZEN PLASMA, GELOX, INSULIN, LASILIX, NICARDIPINE, PERFALGAN, PERINDOPRIL, PLATELET CONCENTRATE, PROZAC, STILNOX, TOPALGIC [TRAMADOL], UNFRACTIONATED HEPARIN, WARFARIN, XANAX, ZALDIAR
Adverse Events (AE) Preferred term	1. Constipation 2. Urinary tract infection 3. Cardiac valve replacement complication 4. Cardiac valve replacement complication 5. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 18MAY2009 (5) - 27MAY2009 (14) 2. 20MAY2009 (7) - 27MAY2009 (14) 3. 01OCT2009 (141) - 02OCT2009 (142) 4. 21OCT2009 (161) - 12DEC2009 (213) 5. 23MAR2010 (314) - 30MAR2010 (321)
Duration of AE	1. 10 2. 8 3. 2 4. 53 5. 8
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160023018

Parameter	Value
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160023020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160023020/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/92/N.A./FRANCE/YES
Medical history	Cataract, Hiatus hernia, Lower limb fracture, Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, AMLOR, CEFAZOLINE, COLÉCALCIFÉROL, DIPRIVAN, EFFERALGAN CODÉINÉ, ENOXAPARIN, GAVISCON, IXPRIM, MOPRAL, PARACETAMOL, RIVOTRIL DROPS, SUFENTHANYL, TOPALGIC [TRAMADOL HYDROCHLORIDE], ZOLÉDRONIQUE ACID
Adverse Events (AE) Preferred term	1. Hypertension 2. Subcutaneous haematoma 3. Upper limb fracture 4. Upper limb fracture
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 09JUL2009 (14) - --------- (.) 2. 01SEP2009 (68) - 21OCT2009 (118) 3. 25SEP2009 (92) - --------- (.) 4. 28SEP2009 (95) - 07OCT2009 (104)
Duration of AE	1. . 2. 51 3. . 4. 10
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. I
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. NONE 4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. IMPROVED 2. RESOLVED 3. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160023020

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160023023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160023023/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/61/N.A./FRANCE/YES
Medical history	Osteoarthritis, Mammoplasty, Headache, Hiatus hernia, Hypertension, Hysterectomy, Obesity, Drug hypersensitivity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, AMLOR, AVLOCARDYL, CELOCURINE, COVERSYL, DIFFU K, ENOXAPARIN, ESIDREX, FORLAX, INEXIUM, LASILIX, MIDAZOLAM, MORPHINE, PARACETAMOL, PERFALGAN, PROFENID, PROPOFOL, PÉRINDOPRIL ARGININE, INDAPAMIDE, SOLUPRED, SUFENTANYL, WARFARIN, ZINNAT
Adverse Events (AE) Preferred term	1. Constipation 2. Pruritus 3. Ear infection 4. Fatigue 5. Haematuria 6. Haematuria 7. Nephrolithiasis 8. Constipation
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MODERATE/YES/NO/YES 7. SEVERE/NO/YES/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 14JAN2010 (4) - 18JAN2010 (8) 2. 16JAN2010 (6) - 18JAN2010 (8) 3. 26JAN2010 (16) - 08FEB2010 (29) 4. 26JAN2010 (16) - 08FEB2010 (29) 5. 28JAN2010 (18) - 28JAN2010 (18) 6. 30JAN2010 (20) - 08FEB2010 (29) 7. 30JAN2010 (20) - 11FEB2010 (32) 8. 03FEB2010 (24) - 04FEB2010 (25)
Duration of AE	1. 5 2. 3 3. 14 4. 14 5. 1 6. 10 7. 13 8. 2
Dose on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160023023

Parameter	Value
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED
	6. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	7. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160023029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160023029/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/63/N.A./FRANCE/YES
Medical history	Arrhythmia, Constipation, Diabetes mellitus, Hypertension, Menopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOR, AMOXICILLINE, ACIDE CLAVULANIQUE, COVERSYL, DOLIPRANE, ENOXAPARIN, FLECAINE, FORLAX, KARDEGIC, MICROLAX [SORBITOL, CITRATE AND LAURYLSULFOACETATE OF SODIUM], OXOMÉMAZINE, WARFARIN
Adverse Events (AE) Preferred term	1. Haematuria 2. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 09OCT2010 (16) - 14OCT2010 (21) 2. 25DEC2010 (93) - 05JAN2011 (104)
Duration of AE	1. 6 2. 12
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160033008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160033008/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/58/N.A./FRANCE/YES
Medical history	Alcoholism, Drug dependence, Duodenal ulcer perforation, Epilepsy, Glomerulonephritis, Insomnia, Liver abscess, Depression
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTONE [SPIRONOLACTONE], ATARAX, CALCIPARINE, CARDENSIEL, COVERSYL, DEPAKINE, ENOXAPARIN, ENOXEPARINE, IMOVANE, KARDEGIC, LASILIX, LOVENOX, MOPRAL, NOZINAN, PLAVIX, RISORDAN, STILNOX, TAVANIC, UNFRACTIONNED HEPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Myocardial ischaemia 2. International normalised ratio increased 3. Epistaxis 4. Epistaxis 5. Epistaxis 6. Rectal haemorrhage 7. Rectal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 16SEP2009 (21) - --------- (.) 2. 02NOV2009 (68) - 24NOV2009 (90) 3. 01DEC2009 (97) - --DEC2009 (.) 4. 11JAN2010 (138) - 12JAN2010 (139) 5. 01FEB2010 (159) - 17FEB2010 (175) 6. 01FEB2010 (159) - 17FEB2010 (175) 7. 05JUN2010 (283) - 07JUN2010 (285)
Duration of AE	1. . 2. 23 3. . 4. 2 5. 17 6. 17 7. 3
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160033008

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
	2. NONE
	3. OTHER
	4. NONE
	5. NONE
	6. NONE
	7. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160033013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160033013/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/60/N.A./FRANCE/YES
Medical history	Appendicectomy, Cardiac arrest, Gastroduodenal ulcer, Hypercholesterolaemia, Hypertension, Insomnia, Menopause, Syncope, Peripheral arterial occlusive disease, Chronic obstructive pulmonary disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOR, CATAPRESAN, CRESTOR, DUPHALAC [GALACTOSE + LACTULOSE + LACTOSE], FORLAX, KARDEGIC, MOPRAL, TORENTAL, UNFRACTIONATED HEPARIN, ZANIDIP, ZOLPIDEM
Adverse Events (AE) Preferred term	1. Constipation 2. Malaise 3. Chest pain 4. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 24FEB2010 (2) - 25FEB2010 (3) 2. 26FEB2010 (4) - 08MAR2010 (14) 3. 04MAR2010 (10) - 04MAR2010 (10) 4. 12APR2010 (49) - --------- (.)
Duration of AE	1. 2 2. 11 3. 1 4. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg
Dose status on AE onset	1. . 2. . 3. F 4. F
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED PERMANENTLY 3. NONE 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160033013

Parameter	Value
	4. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160053004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160053004/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/18/N.A./FRANCE/YES
Medical history	Anaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, DUPHALAC [ONLY LACTULOSE], LANSOYL, PARACETAMOL, PERFALGAN, TOPALGIC [TRAMADOL HYDROCHLORIDE]
Adverse Events (AE) Preferred term	1. Chest pain 2. Haemothorax
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/NO/YES 2. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 10JUL2008 (44) - 28JUL2008 (62) 2. 10JUL2008 (44) - 28JUL2008 (62)
Duration of AE	1. 19 2. 19
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160053006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160053006/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/95/N.A./FRANCE/YES
Medical history	Anxiety, Constipation, Hypertension, Neuropathy peripheral, Obesity, Osteoarthritis, Pyelonephritis, Subacute endocarditis, Varicose vein operation, Renal failure chronic, Eschar
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOR, COVERAM, DAFALGAN, ECONAZOLE, ENOXAPARIN, FORLAX, LANSOYL, NEURONTIN, OFLOCET, ORELOX, RIVOTRIL, ROCEPHINE, SPASFON, TRAMADOL, WARFARIN, XANAX
Adverse Events (AE) Preferred term	1. Cystitis 2. Arthralgia 3. Diarrhoea 4. Vomiting
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 29SEP2009 (14) - 03OCT2009 (18) 2. 03MAR2010 (169) - 12MAR2010 (178) 3. 04MAR2010 (170) - 04MAR2010 (170) 4. 08MAR2010 (174) - 08MAR2010 (174)
Duration of AE	1. 5 2. 10 3. 1 4. 1
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. NONE 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160053006

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160053008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160053008/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/18/N.A./FRANCE/YES
Medical history	Appendicectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	INEXIUM, MONURIL, MUCOMYST, PARACETAMOL, PROFENID
Adverse Events (AE) Preferred term	1. Non-cardiac chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 24NOV2009 (5) - 27NOV2009 (8)
Duration of AE	1. 4
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160053009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160053009/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/70/N.A./FRANCE/YES
Medical history	Femur fracture, Obesity, Cerebrovascular accident, Venous insufficiency, Peripheral arterial occlusive disease, Chronic obstructive pulmonary disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	XYZALL
Adverse Events (AE) Preferred term	1. Pruritus 2. Anaemia 3. Lung adenocarcinoma 4. Nausea 5. Oedema peripheral 6. Pulmonary hypertension 7. Hiatus hernia 8. Oesophagitis 9. Bronchial haemorrhage 10. Cerebellar tumour 11. Central nervous system lesion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 12FEB2010 (15) - 15FEB2010 (18) 2. 31MAR2010 (62) - --------- (.) 3. 31MAR2010 (62) - 22JUL2010 (175) 4. 08APR2010 (70) - 08APR2010 (70) 5. 22APR2010 (84) - --APR2010 (.) 6. 26APR2010 (88) - --------- (.) 7. 26APR2010 (88) - --------- (.) 8. 26APR2010 (88) - --------- (.) 9. 28APR2010 (90) - 28APR2010 (90) 10. 11MAY2010 (103) - --------- (.) 11. 11MAY2010 (103) - --------- (.)
Duration of AE	1. 4 2. . 3. 114 4. 1 5. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160053009

Parameter	Value
	6. .
	7. .
	8. .
	9. 1
	10. .
	11. .
Dose on AE onset	1. 15 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. I
	10. .
	11. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. OTHER
	3. OTHER
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. STUDY DRUG DISCONTINUED AND RESTARTED
	10. NONE
	11. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. DEATH
	4. RESOLVED
	5. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160053009

Parameter	Value
	6. UNCHANGED
	7. UNCHANGED
	8. UNCHANGED
	9. RESOLVED
	10. UNCHANGED
	11. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160063002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160063002/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/92/N.A./FRANCE/YES
Medical history	Appendicectomy, Arrhythmia, Cardiac pacemaker insertion, Depression, Hiatus hernia, Hypercholesterolaemia, Hypertension, Osteoarthritis, Syncope, Lower limb fracture, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLINE, ATARAX [HYDROXYSINE], CALCIPARINE, CORDARONE, DIFFU K, ENOXAPARIN, INIPOMP, LASILIX, LEXOMIL, MIANSERINE, MOTILIUM, PARIET, TAHOR, TAREG, WARFARIN
Adverse Events (AE) Preferred term	1. Cholelithiasis 2. Bronchitis 3. Spinal fracture 4. Fall
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/NO 4. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 11FEB2008 (46) - 14FEB2008 (49) 2. 26MAR2008 (90) - 04APR2008 (99) 3. 02MAY2008 (127) - --------- (.) 4. 02MAY2008 (127) - --------- (.)
Duration of AE	1. 4 2. 10 3. . 4. .
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 2. REMEDIAL DRUG THERAPY 3. NONE 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160063002

Parameter	Value
	4. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160063004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160063004/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/69/N.A./FRANCE/YES
Medical history	Chronic obstructive pulmonary disease, Depression, Gastric ulcer, Myalgia, Pericarditis, Pneumothorax, Pruritus, Inguinal hernia, Asthenia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BRICANYL, CIFLOX, CONTRAMAL, DEXERYL CREAM, DIANTALVIC, ENOXAPARIN, FORTUM, HEC CREAM [EPISTAXIS.HAMAMELIS+TANNIC ACID+PHENAZONE+LANOLINE+GLYCEROLBEHENATE+P, HEPARINE, INIPOMP, INNOHEP, IXPRIM, MAG 2, PARACETAMOL, SERETIDE, SPIRIVA, TAHOR, TEMESTA, TIORFAN, TRANXENE, TRIDESONIT, WARFARIN
Adverse Events (AE) Preferred term	1. Back pain 2. Transient ischaemic attack 3. Epistaxis 4. Hypercholesterolaemia 5. Epistaxis 6. Haemoptysis 7. Diarrhoea 8. Bronchitis 9. Subcutaneous haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MODERATE/YES/YES/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MILD/YES/NO/YES
Start/stop date of event with relative date	1. --APR2008 (.) - --------- (.) 2. 25FEB2008 (6) - 25FEB2008 (6) 3. 24MAR2008 (34) - 26MAR2008 (36) 4. 08APR2008 (49) - --------- (.) 5. 14APR2008 (55) - 16APR2008 (57) 6. 07MAY2008 (78) - 23MAY2008 (94) 7. 10MAY2008 (81) - 22MAY2008 (93) 8. 16MAY2008 (87) - 23MAY2008 (94) 9. 07JUL2008 (139) - 18AUG2008 (181)
Duration of AE	1. . 2. 1 3. 3 4. . 5. 3 6. 17 7. 13

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160063004

Parameter	Value
	8. 8
	9. 43
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
	2. NONE
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. STUDY DRUG DISCONTINUED AND RESTARTED
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
Outcome of event	1. IMPROVED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160063004

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160063006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160063006/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/56/N.A./FRANCE/YES
Medical history	Myocardial ischaemia, Cardiac failure chronic, Renal failure chronic, Hypertension, Bundle branch block left, Congestive cardiomyopathy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTONE [ALDACTONE IS SPIRONOLACTONE], BISOPROLOL, DIGOXINE, ENALAPRIL, FUROSEMIDE, UNFRACTIONATED HEPARIN
Adverse Events (AE) Preferred term	1. Oedema 2. Cardiac failure 3. Cardiac failure
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 04JUL2008 (16) - 18AUG2008 (61) 2. 17JUL2008 (29) - 22JUL2008 (34) 3. 15DEC2008 (180) - 19DEC2008 (184)
Duration of AE	1. 46 2. 6 3. 5
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY,OTHER 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160063010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160063010/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/82/N.A./FRANCE/YES
Medical history	Colon cancer, Anxiety, Cholelithiasis, Bronchitis chronic, Goitre, Hiatus hernia, Hypertension, Hysterectomy, Colectomy, Lung neoplasm malignant, Uterine leiomyoma, Lung neoplasm malignant
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTISKENAN IF NEED, ACUPAN, ALPRAZOLAM, APRANAX, APROVEL, ATHYMIL, AVLOCARDYL, AVLOCARDYLL, BIPROFENID, CITALOPRAM, COAPROVEL, CONTRAMAL LP, CORTANCYL, DEROXAT, DI ANTALVIC, DIFFU K, DOLIPRANE, ESIDREX, FORLAX, INIPOMP, ISOPTINE, KARDEGIC, LANOSYL, LANSOYL IF NEED, LAROXYL, LEXOMIL, LYRICA, MOTILIUM, NEOMERCAZOLE, OXYGEN, PAMIDRONATE, PRORACYL, SERETIDE, SPIRIVA, THIOCOLCHICOSIDE IF NEED
Adverse Events (AE) Preferred term	1. Depression 2. Ischaemic stroke 3. Metastases to spine 4. Lung cancer metastatic 5. Abdominal pain upper 6. Metastases to spine 7. Pneumonia 8. Cardiac failure acute 9. Coma
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. SEVERE/NO/YES/YES 4. SEVERE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. SEVERE/NO/YES/YES 7. SEVERE/NO/YES/NO 8. SEVERE/NO/YES/NO 9. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. --JAN2009 (.) - --------- (.) 2. 13NOV2008 (11) - --DEC2008 (.) 3. 17DEC2008 (45) - 22APR2009 (171) 4. 17DEC2008 (45) - --------- (.) 5. 09JAN2009 (68) - 20MAY2009 (199) 6. 22APR2009 (171) - --------- (.) 7. 12MAY2009 (191) - --------- (.) 8. 12MAY2009 (191) - --------- (.) 9. 18MAY2009 (197) - 20MAY2009 (199)
Duration of AE	1. . 2. . 3. 127 4. . 5. 132 6. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160063010

Parameter	Value
	7. .
	8. .
	9. 3
Dose on AE onset	1.
	2. 15 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. F
	8. F
	9. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. OTHER
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. WORSENED
	4. UNCHANGED
	5. RESOLVED
	6. WORSENED
	7. UNCHANGED
	8. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160063010

Parameter	Value
	9. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160063014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160063014/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/81/N.A./FRANCE/YES
Medical history	Aortic aneurysm, Appendicectomy, Carpal tunnel decompression, Intervertebral disc degeneration, Hypercholesterolaemia, Hypothyroidism, Stent-graft endoleak
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, CONTRAMAL, CRESTOR, IXPRIM, KARDEGIC, LEVOTHYROX, MYOLASTAN, PARACETAMOL, PYOSTACINE, XATRAL
Adverse Events (AE) Preferred term	1. Benign prostatic hyperplasia 2. Intervertebral disc disorder 3. Intervertebral discitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 22MAR2009 (2) - --------- (.) 2. 19JUN2009 (91) - 08JUL2009 (110) 3. 29JUN2009 (101) - 08JUL2009 (110)
Duration of AE	1. . 2. 20 3. 10
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160063018

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160063018/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/39/N.A./FRANCE/YES
Medical history	Rhinitis allergic, Appendicectomy, Hypertension, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, AMOXICILLINE, APROVEL, CONTRAMAL, EFFERALGAN CODEINE, ENOXAPARIN, IXPRIM, UNFRACTIONATED HEPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Pleural effusion 2. Tonsillitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 16JUL2009 (4) - 20JUL2009 (8) 2. 04SEP2009 (54) - 10SEP2009 (60)
Duration of AE	1. 5 2. 7
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160063030

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160063030/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/62/N.A./FRANCE/YES
Medical history	Hiatus hernia, Hip arthroplasty, Hip arthroplasty, Hypertension, Osteonecrosis, Renal colic, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CONTRAMAL, ENOXAPARIN, INEXIUM, IXPRIM, RASILEZ, TAHOR, WARFARIN
Adverse Events (AE) Preferred term	1. Subcutaneous haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 18JAN2011 (6) - 11FEB2011 (30)
Duration of AE	1. 25
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083003/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/25/N.A./FRANCE/YES
Medical history	Abdominal pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, AUGMENTIN, CLAMOXYL, DI-ANTALVIC, LEXOMIL, PERFALGAN, SOLUMEDROL, SOLUPRED, SPECIAFOLDINE, TEMGESIC
Adverse Events (AE) Preferred term	1. Anxiety 2. Pleuritic pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 11FEB2008 (4) - 12FEB2008 (5) 2. 12FEB2008 (5) - 15FEB2008 (8)
Duration of AE	1. 2 2. 4
Dose on AE onset	1. 15 mg 2. 15 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/27/N.A./FRANCE/YES
Medical history	Hand fracture, Psychotic disorder, Renal colic, Meningitis viral, Alcohol detoxification
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, BI-PROFENID, DI-ANTALVIC, DOLIPRANE, EQUANIL, PERFALGAN, SOLUPRED, TERCIAN, TRANXÈNE, VIT B1 B6
Adverse Events (AE) Preferred term	1. Psychotic disorder 2. Dyspnoea 3. Chest pain 4. Tachycardia 5. Traumatic fracture
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 05MAR2008 (3) - --------- (.) 2. 21MAR2008 (19) - --------- (.) 3. 21MAR2008 (19) - --------- (.) 4. 21MAR2008 (19) - --------- (.) 5. 11JUN2008 (101) - 19JUN2008 (109)
Duration of AE	1. . 2. . 3. . 4. . 5. 9
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5.
Dose status on AE onset	1. . 2. . 3. . 4. . 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. NONE 4. NONE 5. OTHER
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. INSUFFICIENT FOLLOW-UP 3. INSUFFICIENT FOLLOW-UP

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083004

Parameter	Value
	4. INSUFFICIENT FOLLOW-UP
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/85/N.A./FRANCE/YES
Medical history	Hypertension, Cholecystectomy, Thyroid disorder, Hypercholesterolaemia, Hypothyroidism, Obesity, Phlebitis, Renal abscess, Atrial tachycardia, Varicose vein, Pain, Dyslipidaemia, Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPEGIC, AVLOCARDYL, CLAMOXYL, CORDARONE, DIFFU-K, DOLIPRANE, ENOXAPARIN, FLECAINE, HEMIGOXINE, LASILIX, LEVOTHYROX, PROPRANOLOL, SECTRAL, STRIADYNE, WARFARIN
Adverse Events (AE) Preferred term	1. Tachycardia 2. Urinary tract infection 3. Tachycardia 4. Tachycardia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 07MAR2008 (2) - 09MAR2008 (4) 2. 09MAR2008 (4) - 13MAR2008 (8) 3. 07APR2008 (33) - 08APR2008 (34) 4. 13MAY2008 (69) - 14MAY2008 (70)
Duration of AE	1. 3 2. 5 3. 2 4. 2
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083005

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083010/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/81/N.A./FRANCE/YES
Medical history	Rhinitis allergic, Cerebrovascular accident, Cerebrovascular accident, Chronic obstructive pulmonary disease, Epilepsy, Inguinal hernia repair, Lung neoplasm malignant, Prostate cancer, Subdural haematoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT, BRICANYL, COMBIVENT, CYCLO 3 FORT, DI-HYDAN, FLUIMUCIL, FORLAX, LOVENOX, SPIRIVA, SYMBICORT, VASTAREL
Adverse Events (AE) Preferred term	1. Epilepsy 2. Cerebral haemorrhage traumatic
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 23APR2008 (14) - 25APR2008 (16) 2. 28JUL2008 (110) - 02AUG2008 (115)
Duration of AE	1. 3 2. 6
Dose on AE onset	1. 15 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. RESOLVED 2. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号：11702-160083010

死亡に至るまでの経過

被験者は 81 歳、男性。2008 年 4 月 10 日に肺塞栓症と診断され、同日リバーロキサバン（30mg）の投与を開始した。

2008 年 4 月 23 日、被験者はてんかん〔てんかん悪化（推定）〕を発現した。本事象により入院に至ったため、重篤とされた。治験責任（分担）医師は、本事象の重症度は軽度で、かつ治験薬との因果関係は「なし」と判断した。被験者はてんかんの病歴を有していた。被験者は 5 分間意識を消失した。この症状は、肺塞栓症発現前に複数回起こっていた。2008 年 4 月 23 日に実施したドプラスキャンでは深部静脈血栓は認められず。2008 年 4 月 24 日に実施した EEG（脳波）、2008 年 4 月 25 日に実施した頭部 CT スキャンのいずれでも異常所見は認められなかった。本事象により治験薬は変更されなかった。本事象に対する治療として、すでに併用薬として投与していた phenytoin を増量した。2008 年 4 月 25 日、本事象は消失し、被験者は同日退院した。

2008 年 7 月 28 日、被験者は外傷性脳出血（出血：致死的な高度外傷後脳内血腫）を発現した。本事象により死亡に至ったため重篤と判定された。被験者の治験も中止された。治験責任（分担）医師は、本事象の重症度は高度で、かつ治験薬との因果関係を否定できない事象と判断した。被験者は過去に硬膜下血腫と脳血管発作を発現していた（1998 年、2005 年）。被験者は、本事象発現前に自宅で複数回転倒していた。本事象により、2008 年 8 月 2 日に治験薬の投与は中止され、同日、被験者は死亡に至った。剖検は実施されなかった。

CIAC は、外傷性脳出血（出血：致死的な高度外傷後脳内血腫）を「重大な出血事象」とみなし、死亡原因を出血と判定した。

Laboratory Parameter	**Normal Range**	**Date**	**Result**	**Date**	**Result**	**Date**	**Result**
Hemoglobin	Local: 13.9-16.1 g/dL	10 Apr 2008	15.9 g/dL				
Platelets	Local: 150-400 giga/L	10 Apr 2008	163 giga/L				
Alkaline Phosphatase	Central: 35-123 U/L	10 Apr 2008	115 U/L	09 May 2008	106 U/L	09 Jul 2008	99 U/L
		24 Apr 2008	106 U/L	13 Jun 2008	110 U/L		
Amylase	Central: 28-100 U/L	10 Apr 2008	70 U/L				
Bilirubin, Direct	Central: 0.10-0.32 mg/dL	10 Apr 2008	0.14 mg/dL	09 Jul 2008	**<0.10 mg/dL (L)**		
Bilirubin, Total	Central: 0.22-1.28 mg/dL	10 Apr 2008	0.50 mg/dL	13 Jun 2008	0.39 mg/dL		
		24 Apr 2008	0.50 mg/dL	09 Jul 2008	0.28 mg/dL		
SGOT/AST	Central: 11-39 U/L	10 Apr 2008	21 U/L	09 May 2008	35 U/L	09 Jul 2008	34 U/L
		24 Apr 2008	25 U/L	13 Jun 2008	31 U/L		

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
SGPT/ALT	Central: 8-45 U/L	10 Apr 2008	32 U/L	09 May 2008	38 U/L	09 Jul 2008	27 U/L
		24 Apr 2008	19 U/L	13 Jun 2008	24 U/L		
PICT Seconds	Central: 24.80-36.40 S	10 Apr 2008	**75.50 S (H)**	13 Jun 2008	<33.60 S		
		24 Apr 2008	<33.60 S	09 Jul 2008	<33.60 S		
Prothrombin Time (PT)	Central: 11.80-15.50 S	10 Apr 2008	**16.70 S (H)**	13 Jun 2008	**17.00 S (H)**		
		24 Apr 2008	**28.20 S (H)**	09 Jul 2008	**28.10 S (H)**		
PT Ratio	Central: 0.70-1.20 %	10 Apr 2008	**0.65 % (L)**	13 Jun 2008	**0.62 % (L)**		
		24 Apr 2008	**0.31 % (L)**	09 Jul 2008	**0.30 % (L)**		
PT, INR	Central: 0.9-1.2	10 Apr 2008	**1.4 (H)**	13 Jun 2008	**1.4 (H)**		
		24 Apr 2008	**2.6 (H)**	09 Jul 2008	**2.7 (H)**		

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083025

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083025/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/76/N.A./FRANCE/YES
Medical history	Arrhythmia supraventricular, Prostate cancer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CORDARONE, ENOXAPARIN, TAVANIC, WARFARIN
Adverse Events (AE) Preferred term	1. Haematuria
	2. Prostatic adenoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 18DEC2008 (77) - 19DEC2008 (78)
	2. 04MAR2009 (153) - 10MAR2009 (159)
Duration of AE	1. 2
	2. 7
Dose on AE onset	1.
	2.
Dose status on AE onset	1.
	2.
Action taken	1. NONE
	2. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083030

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083030/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/87/N.A./FRANCE/YES
Medical history	Atrial fibrillation, Hypertension, Breast cancer, Oesophageal carcinoma, Cataract, Cholecystectomy, Colectomy, Depression, Diabetes mellitus, Diverticulum, Hiatus hernia, Temporal arteritis, Polyp, Monoclonal gammopathy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, AMIODARONE, CORDARONE, CORTANCYL, COVERSYL, DEBRIDAT, DOLIPRANE, ENOXAPARIN, INEXIUM, INIPOMP, LAMALINE [PARACETAMOL, OPIUM, MORPHINE, CAFEINE. INDICATION: PAIN], MOPRAL, NOVOMIX 30, NOVORAPID, TARDYFERON, WARFARIN, ZYLORIC
Adverse Events (AE) Preferred term	1. Anaemia 2. Blood blister 3. Gastroenteritis 4. Death
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 12NOV2008 (3) - 06MAR2009 (117) 2. 12NOV2008 (3) - 23JAN2009 (75) 3. 02JAN2009 (54) - 23JAN2009 (75) 4. 06MAR2009 (117) - 06MAR2009 (117)
Duration of AE	1. 115 2. 73 3. 22 4. 1
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. DOSE OF STUDY DRUG REDUCED 3. NONE 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083030

Parameter	Value
	4. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160083030[2)]	DEATH（UNKNOWN CAUSE）（PT：死亡） 治験担当医はワルファリンと報告事象との関連性があると判断した。弊社は、患者は既往の結腸癌、食道癌、乳癌、不整脈、高血圧を有しており高齢でもあることから、ワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

被験者番号：11702-160083030

死亡に至るまでの経過

被験者は 87 歳、女性。2008 年 11 月 9 日、肺塞栓症と診断され、翌日エノキサパリン（1.60mL）／用量調節ワルファリンの投与を開始した。

2008 年 11 月 12 日、被験者は血性水疱（出血：腕の皮膚の出血性小水疱）及び貧血（貧血）を発現し、いずれも非重篤な有害事象として報告された。

2009 年 3 月 6 日、被験者は死亡した〔死亡（特定不能の死亡）〕。本事象は重篤な有害事象とされた。治験責任（分担）医師は、本事象の重症度は高度で、治験薬との因果関係は「あり」と判断した。被験者は、高血圧、乳癌、食道癌、結腸部分切除、胆嚢摘出、心房細動、心不整脈／心房細動の病歴を有していた。2009 年 1 月 2 日、被験者は胃腸炎（胃腸炎）を発現した（非重篤な有害事象として報告）。本事象発現前の最終臨床検査値は、ヘモグロビン 11.6g/dL、クレアチニン 0.96mg/dL（いずれも 2008 年 11 月 9 日）、プロトロンビナーゼ誘導凝固時間 98.80 秒、プロトロンビン時間（PT）16.60 秒、PT 比 0.67%、PT-INR 1.3（いずれも 2008 年 11 月 10 日）、直接ビリルビン 0.10mg/dL（2008 年 12 月 12 日）であった。本事象により治験薬（ワルファリン）は変更されなかった。本事象に対する治療は行われなかった。2009 年 3 月 6 日、本事象により被験者は死亡に至った。剖検は実施されなかった。

CIAC は血性水疱（出血：腕の皮膚の出血性小水疱）を「軽微な出血事象」、貧血（貧血）をそれに関連した事象と判定した。死亡原因は不明であり肺塞栓症である可能性は否定できないとした。

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
Hemoglobin	Local: 11.9-14.5 g/dL	09 Nov 2008	**11.6 g/dL (L)**				
Platelets	Local: 150-400 giga/L	09 Nov 2008	159 giga/L				
Alkaline Phosphatase	Central: 36-118 U/L	10 Nov 2008	46 U/L	12 Dec 2008	42 U/L		
		24 Nov 2008	**33 U/L (L)**	23 Jan 2009	65 U/L		
Amylase	Central: 28-100 U/L	10 Nov 2008	44 U/L				
Bilirubin, Direct	Central: 0.10-0.32 mg/dL	10 Nov 2008	0.27 mg/dL	24 Nov 2008	0.14 mg/dL	12 Dec 2008	**<0.10 mg/dL (L)**
Bilirubin, Total	Central: 0.22-1.28 mg/dL	10 Nov 2008	0.70 mg/dL	12 Dec 2008	0.34 mg/dL		
		24 Nov 2008	0.37 mg/dL	23 Jan 2009	0.47 mg/dL		
Creatinine	Local: 0.41-0.90 mg/dL	09 Nov 2008	**0.96 mg/dL (H)**				
SGOT/AST	Central: 11-37 U/L	10 Nov 2008	21 U/L	24 Nov 2008	14 U/L	12 Dec 2008	18 U/L

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
SGPT/ALT	Central: 8-43 U/L [a] Local: 10-31 U/L	09 Nov 2008	24 U/L [a]	24 Nov 2008	21 U/L		
		10 Nov 2008	19 U/L	12 Dec 2008	21 U/L		
PICT Seconds	Central: 24.80-36.40 S	10 Nov 2008	**98.80 S (H)**				
Prothrombin Time (PT)	Central: 11.80-15.50 S	10 Nov 2008	**16.60 S (H)**				
PT Ratio	Central: 0.70-1.20 %	10 Nov 2008	**0.67 % (L)**				
PT, INR	Central: 0.9-1.2	10 Nov 2008	**1.3 (H)**				

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083034

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083034/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/78/N.A./FRANCE/YES
Medical history	Hypertension, Chronic obstructive pulmonary disease, Constipation, Diabetes mellitus, Dyspnoea, Respiratory failure, Angiopathy, Dyslipidaemia, Prostatectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, ALDACTONE [SPIRONOLACTONE], ALDALIX, DAONIL, DIAMICRON, FORLAX, GLUCOPHAGE, ISKEDYL, LASILIX, LIPANTHYL, LOGIMAX, NOVONIX, OXYGEN, TRACLEER
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Dyspnoea 3. Hyperglycaemia 4. Diabetes mellitus 5. Respiratory failure 6. Hypertension 7. Diarrhoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES 7. MODERATE/YES/NO/YES
Start/stop date of event with relative date	1. 23DEC2008 (17) - 31DEC2008 (25) 2. 31DEC2008 (25) - 04JAN2009 (29) 3. 03JAN2009 (28) - 03JAN2009 (28) 4. 04JAN2009 (29) - 20JAN2009 (45) 5. 20FEB2009 (76) - 21FEB2009 (77) 6. 21FEB2009 (77) - 21FEB2009 (77) 7. 20MAR2009 (104) - 28AUG2009 (265)
Duration of AE	1. 9 2. 5 3. 1 4. 17 5. 2 6. 1 7. 162
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg
Dose status on AE onset	1. . 2. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083034

Parameter	Value
	3. .
	4. .
	5. .
	6. .
	7. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083038

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083038/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/76/N.A./FRANCE/YES
Medical history	Hypertension, Prostatic adenoma, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, CIFLOX, CORDARONE, ECAZIDE, ELISOR, FORLAX, VASTEN, ZOCOR
Adverse Events (AE) Preferred term	1. Constipation
	2. Insomnia
	3. Arrhythmia
	4. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/YES/YES
	4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 01JAN2009 (2) - 01JAN2009 (2)
	2. 02JAN2009 (3) - 03JAN2009 (4)
	3. 02JAN2009 (3) - 02JAN2009 (3)
	4. 23JAN2009 (24) - 01FEB2009 (33)
Duration of AE	1. 1
	2. 2
	3. 1
	4. 10
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083038

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083040

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083040/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/75/N.A./FRANCE/YES
Medical history	Anxiety, Spinal fracture, Knee arthroplasty, Osteoporosis, Pulmonary fibrosis, Spinal fusion surgery
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADRENALINE, ATROPINE, DIPRIVAN, DOLIPRANE, ENOXAPARIN, EPHÉDRINE, INEXIUM, INIPOMP, OSTRAM, OXYGEN, SERETIDE, SOLUPRED, TEMESTA, WARFARIN
Adverse Events (AE) Preferred term	1. Blood creatinine increased 2. Respiratory failure
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 12JAN2009 (1) - 08MAR2009 (56) 2. 08MAR2009 (56) - 09MAR2009 (57)
Duration of AE	1. 56 2. 2
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083042

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083042/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/72/N.A./FRANCE/YES
Medical history	Alcohol poisoning, Hypertension, Hypothyroidism, Insomnia, Obesity, Glucose tolerance impaired, Respiratory failure
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DIFFU-K, ENOXAPARIN, INNOHEP, KARDEGIC, LEVOTHYROX, NOCTRAN, SOLUDACTONE, TIORFAN, WARFARIN
Adverse Events (AE) Preferred term	1. International normalised ratio increased 2. Hypokalaemia 3. Diarrhoea
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 27MAR2009 (66) - 27MAR2009 (66) 2. 27MAR2009 (66) - 31MAR2009 (70) 3. 28MAR2009 (67) - 07APR2009 (77)
Duration of AE	1. 1 2. 5 3. 11
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083043

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083043/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/76/N.A./FRANCE/YES
Medical history	Benign prostatic hyperplasia, Chronic obstructive pulmonary disease, Pneumothorax, Pulmonary fibrosis, Tachycardia, Tuberculosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, ATROVENT, CELESTENE, CIFLOX, CORDARONE, DAFALGAN, DIGOXINE, ENOXAPARIN, FORLAX, HYDRO-CORTISONE, SPIRIVA, VENTOLINE, WARFARIN
Adverse Events (AE) Preferred term	1. Tachycardia 2. Respiratory failure 3. Constipation 4. Anxiety
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 30JAN2009 (2) - 02FEB2009 (5) 2. 01FEB2009 (4) - 03FEB2009 (6) 3. 01FEB2009 (4) - 01FEB2009 (4) 4. 02FEB2009 (5) - 02FEB2009 (5)
Duration of AE	1. 4 2. 3 3. 1 4. 1
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. DEATH 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083043

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083053

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083053/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/73/N.A./FRANCE/YES
Medical history	Depression, Myocardial infarction, Renal colic, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPEGIC, CELECTOL, PLAVIX, TAHOR
Adverse Events (AE) Preferred term	1. Ankle fracture
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 18JUN2009 (99) - 24JUN2009 (105)
Duration of AE	1. 7
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083056

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083056/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/68/N.A./FRANCE/YES
Medical history	Asthma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT, BRICANYL, FLORADIL, PULMICORT, SOLUPRED, SPIRIVA
Adverse Events (AE) Preferred term	1. Ankle fracture
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 20JUL2009 (97) - 28JUL2009 (105)
Duration of AE	1. 9
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083059

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083059/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/79/N.A./FRANCE/YES
Medical history	Benign prostatic hyperplasia, Humerus fracture, Inguinal hernia repair, Periphlebitis, Inner ear disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, CORDARONE, DAFLON [DIOSMIN + HESPERIDIN + FLAVONOIDES], JOSIR, PERFALGAN, SOLUPRED, TITANOREINE [LIDOCAINE + CARRAGH?NATES + ZINC OXYDE + TITANE DIOXYDE], TOPALGIC [TRAMADOL CHLORHYDRATE], XATRAL
Adverse Events (AE) Preferred term	1. Tachycardia 2. Rectal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 28APR2009 (2) - 28APR2009 (2) 2. 24AUG2009 (120) - 04SEP2009 (131)
Duration of AE	1. 1 2. 12
Dose on AE onset	1. 15 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083061

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083061/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/54/N.A./FRANCE/YES
Medical history	Cholecystectomy, Hypercholesterolaemia, Lower limb fracture, Affective disorder, Tympanoplasty
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ANAFRANIL, ATHYMIL, DOLIPRANE, EFFEXOR, ELISOR, ENOXAPARIN, STILNOX, SULFARLEM, TRANXENE, VASOBRAL, VASTEN, XANAX
Adverse Events (AE) Preferred term	1. International normalised ratio increased 2. Bipolar I disorder 3. Depression
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/NO/YES 2. SEVERE/NO/YES/YES 3. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 03JUN2009 (28) - --------- (.) 2. 14AUG2009 (100) - 03SEP2009 (120) 3. 12OCT2009 (159) - 16NOV2009 (194)
Duration of AE	1. . 2. 21 3. 36
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083083

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083083/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/80/N.A./FRANCE/YES
Medical history	Anxiety, Hypertension, Diabetes mellitus, Pyrexia, Hepatitis A, Herpes zoster, Pleuritic pain, Rheumatoid arthritis, Postmenopause, Dyspnoea
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOR, ATRAPID, AUGMENTIN, CORTANCYL, DAFALGAN, DIFFU-K, DOLIPRANE, ENOXAPARIN, INEXIUM, LAMALINE [PARACETAMOL, OPIUM, CAFEINE], METFORMINE, METHOTREXATE, MOPRAL, MOTILIUM, PERFALGAN, PRIMPERAN, SOLUMEDROL, TEMESTA, WARFARIN, ZELITREX
Adverse Events (AE) Preferred term	1. Vitamin D deficiency 2. Nausea 3. Nausea 4. Hypertension 5. Chest pain 6. Herpes dermatitis 7. Back pain 8. Urinary tract infection 9. Pleural effusion
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/YES/NO 8. MODERATE/NO/NO/NO 9. MILD/NO/NO/NO
Start/stop date of event with relative date	1. -----2010 (.) - --APR2010 (.) 2. -----2010 (.) - --MAY2010 (.) 3. 30SEP2009 (1) - 04OCT2009 (5) 4. 01OCT2009 (2) - --------- (.) 5. 07OCT2009 (8) - 16OCT2009 (17) 6. 12NOV2009 (44) - 20NOV2009 (52) 7. 29MAR2010 (181) - 15MAY2010 (228) 8. 12APR2010 (195) - 18APR2010 (201) 9. 14APR2010 (197) - 09JUL2010 (283)
Duration of AE	1. . 2. . 3. 5 4. . 5. 10 6. 9 7. 48 8. 7

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083083

Parameter	Value
	9. 87
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083083

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083084

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083084/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/80/N.A./FRANCE/YES
Medical history	Osteoarthritis, Breast cancer, Gout, Knee arthroplasty, Obesity, Phlebitis, Phlebitis, Phlebitis, Lung infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALOPURINOL, AUGMENTIN, CLAMOXYL, FEMARA, FORLAX
Adverse Events (AE) Preferred term	1. Breast cancer recurrent 2. Breast cancer recurrent
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 09OCT2009 (1) - 09NOV2009 (32) 2. 20JAN2010 (104) - 24JAN2010 (108)
Duration of AE	1. 32 2. 5
Dose on AE onset	1. 15 mg 2. 20 mg
Dose status on AE onset	1. . 2. I
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083086

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083086/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/68/N.A./FRANCE/YES
Medical history	Appendicectomy, Sciatica, Prostate cancer, Intervertebral disc protrusion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BIPROFENID, CONTRAMAL, DAFALGAN, DOLIPRANE, FORLAX, INEXIUM, LEXOMIL, MOPRAL, MORPHINE, PERFALGAN, RIVOTRIL, XATRAL
Adverse Events (AE) Preferred term	1. Anxiety 2. Dyspnoea 3. Abdominal pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 03NOV2009 (5) - 04NOV2009 (6) 2. 03NOV2009 (5) - 04NOV2009 (6) 3. 27DEC2009 (59) - --------- (.)
Duration of AE	1. 2 2. 2 3. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083088

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083088/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/60/N.A./FRANCE/YES
Medical history	Alanine aminotransferase increased, Delusion, Obesity, Pneumonia legionella, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	EQUANIL, LOVENOX, OFLOCET, TAHOR, VITAMINE B1B6
Adverse Events (AE) Preferred term	1. Delusion 2. Alanine aminotransferase increased
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 02DEC2009 (23) - 28DEC2009 (49) 2. 11DEC2009 (32) - --------- (.)
Duration of AE	1. 27 2. .
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. F
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 2. NONE
Outcome of event	1. RESOLVED 2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083091

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083091/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/72/N.A./FRANCE/YES
Medical history	Glaucoma, Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CRESTOR
Adverse Events (AE) Preferred term	1. Haemorrhoidal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/YES/YES
Start/stop date of event with relative date	1. 12MAR2010 (105) - 19MAR2010 (112)
Duration of AE	1. 8
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. NONE
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083125

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083125/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/N.A./FRANCE/YES
Medical history	Anaemia, Anxiety, Appendicectomy, Cataract, Cholecystectomy, Hysterectomy, Myelodysplastic syndrome, Pleural effusion, Sciatica, Bladder prolapse, Hernial eventration, Pulmonary arterial hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTISKENAN, AUGMENTIN, BICARBONATE SODIUM, DAFALGAN, DIFFU-K, DOLIPRANE, DUROGESIC, ENOXAPARIN, FORLAX, IMODIUM, INEXIUM, LASILIX, LYRICA, MOTILIUM, OXYCONTIN, OXYNORM, PARACETAMOL, PARIET, PERFALGAN, SERESTA, SEROPRAM, SOLUDACTONE, SOLUMEDROL, SOLUPRED, SPASFON, WARFARIN
Adverse Events (AE) Preferred term	1. Abdominal pain 2. Lung infection 3. Pulmonary arterial hypertension 4. Anaemia 5. Myelodysplastic syndrome 6. Hypertension
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/YES/YES 5. SEVERE/NO/YES/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 24MAY2010 (1) - 02JUN2010 (10) 2. 24MAY2010 (1) - 02JUN2010 (10) 3. 25MAY2010 (2) - 01JUN2010 (9) 4. 26MAY2010 (3) - 08JUN2010 (16) 5. 05JUN2010 (13) - 10JUN2010 (18) 6. 06JUN2010 (14) - 07JUN2010 (15)
Duration of AE	1. 10 2. 10 3. 8 4. 14 5. 6 6. 2
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083125

Parameter	Value
	6.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. OTHER
	5. REMEDIAL DRUG THERAPY
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. DEATH
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160083125[1),1)]	WORSENING OF ANEMIA（PT：貧血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、合併症（骨髄異形成症候群）によるものであり、エノキサパリンとの因果関係は否定できると考える。 WORSENING OF MYELODYSPLASIA（PT：骨髄異形成症候群） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、合併症（骨髄異形成症候群）によるものであり、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083130

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083130/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/68/N.A./FRANCE/YES
Medical history	Inguinal hernia repair, Neoplasm malignant, Prostatectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN
Adverse Events (AE) Preferred term	1. Haematuria
	2. Renal cancer
	3. Pyrexia
	4. Prostatitis
	5. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. SEVERE/NO/YES/NO
	3. MILD/NO/NO/NO
	4. MILD/NO/NO/NO
	5. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 09JUN2010 (1) - 27AUG2010 (80)
	2. 02JUL2010 (24) - 21SEP2010 (105)
	3. 16SEP2010 (100) - 21SEP2010 (105)
	4. 16SEP2010 (100) - 06OCT2010 (120)
	5. 16SEP2010 (100) - 06OCT2010 (120)
Duration of AE	1. 80
	2. 82
	3. 6
	4. 21
	5. 21
Dose on AE onset	1.
	2.
	3.
	4.
	5.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
Action taken	1. NONE
	2. DOSE OF STUDY DRUG REDUCED,OTHER
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083130

Parameter	Value
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160083136

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160083136/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/85/N.A./FRANCE/YES
Medical history	Benign prostatic hyperplasia, Hypertension, Cataract, Dementia, Depression, Diabetes mellitus, Faecal incontinence, Gout, Osteoporosis, Inguinal hernia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, ADENURIC, APROVEL, AUGMENTIN, CHIBROPROSCAR, COVERSYL, CRESTOR, DOLIPRANE, ENOXAPARIN, FORLAX, GLUCOR, KARDEGIC, LACRYFLUID, LASILIX, LEXOMIL, NOVONORM, OFLOCET, PERFALGAN, PREVISCAN, SERESTA, SEROPRAM, SOLUMÉDROL, TAMUSOLINE, TRIATEC, VIT A, WARFARIN
Adverse Events (AE) Preferred term	1. Osteoarthritis 2. Peripheral arterial occlusive disease 3. Lung disorder
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --DEC2010 (.) - --------- (.) 2. --NOV2010 (.) - --------- (.) 3. 18NOV2010 (45) - 21JAN2011 (109)
Duration of AE	1. . 2. . 3. 65
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. UNCHANGED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160103012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160103012/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/70/N.A./FRANCE/YES
Medical history	Neoplasm prostate, Sleep apnoea syndrome, Cyclopia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANDROCUR, CALTRATE [CALTRATE CONTAINS CALCIUM CARBONATE + VITAMIN D3], OMEPRAZOLE, OMNEXEL, PERFALGAN, SOLUMEDROL, TAREG
Adverse Events (AE) Preferred term	1. Brain neoplasm 2. Hypertension 3. Tumour haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 16MAY2008 (2) - 04JUN2008 (21) 2. 16MAY2008 (2) - 29MAY2008 (15) 3. 30MAY2008 (16) - 04JUN2008 (21)
Duration of AE	1. 20 2. 14 3. 6
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg
Dose status on AE onset	1. . 2. . 3. F
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY 2. REMEDIAL DRUG THERAPY 3. NONE
Outcome of event	1. DEATH 2. RESOLVED 3. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160103021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160103021/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/82/N.A./FRANCE/YES
Medical history	Atrioventricular block, Depression, Head injury, Hip arthroplasty, Hypertension, Skin neoplasm excision, Obesity, Neoplasm prostate, Transurethral prostatectomy, Transurethral prostatectomy, Constipation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASASANTINE LP200, COZAAR, FLUOXETINE, FORLAX 10G, FUROSEMIDE, KARDEGIC, LOVENOX, LYSANXIA, TAHOR, UNFRACTIONATED HEPARIN, UNFRACTIONATED HEPARINE, XATRAL LP10
Adverse Events (AE) Preferred term	1. Chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 09APR2009 (21) - 11APR2009 (23)
Duration of AE	1. 3
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. I
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160103024

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160103024/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/48/N.A./FRANCE/YES
Medical history	Appendicectomy, Phlebectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTISKENAN, ACUPAN, CELESTENE, MERCILON, MORPHINE, PERFALGAN, PLASMALYTE 4G, ZOPHREN
Adverse Events (AE) Preferred term	1. Ovarian germ cell teratoma benign
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 12JAN2010 (113) - 12JAN2010 (113)
Duration of AE	1. 1
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. I
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160103026

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160103026/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/80/N.A./FRANCE/YES
Medical history	Brucellosis, Carotid artery stenosis, Carotid endarterectomy, Carotid endarterectomy, Herpes zoster, Hydrocele, Hypertension, Cerebrovascular accident, Tinnitus, Left ventricular hypertrophy, Dyslipidaemia, Varicose vein operation, Renal failure chronic, Carotid artery stent insertion, Cough
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, ATORVASTATIN, ATROVENT, AUGMENTIN, BIPRETERAX (PERINDOPRIL ARGININ+INDAPAMID), BISOPROLOL, BRICANIL, CALCIPARINE, CIFLOX, CORDARONE (AMIODARONE), DEBRIDAT, DIGOXINE, FORLAX, FUCIDINE, FUROSEMID, FUROSEMIDE, GLUCOSE 5%, IMODIUM, INEXIUM, KARDEGIC, LANTHUS, MAGNESIUM, MOTILIUM, OFLOCET, PANTOPRAZOL, PARACETAMOL, PERFALGAN, PLASMALYTE, POTASSIUM, PREVISCAN, PULMICORT, ROCEPHINE, SPECIAFOLDINE, TAVANIC, TEMESTA, UNFRACTIONATED HEPARIN, UNFRACTIONNATED HEPARIN, VENTOLINE
Adverse Events (AE) Preferred term	1. Headache 2. Folliculitis 3. Bronchitis 4. Oedema 5. Tachycardia 6. Hyperglycaemia 7. Gastrointestinal disorder
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 05OCT2010 (2) - 05OCT2010 (2) 2. 09OCT2010 (6) - 21OCT2010 (18) 3. 06DEC2010 (64) - 11JAN2011 (100) 4. 07DEC2010 (65) - 07DEC2010 (65) 5. 16DEC2010 (74) - 20DEC2010 (78) 6. 20DEC2010 (78) - 11JAN2011 (100) 7. 28MAR2011 (176) - 08APR2011 (187)
Duration of AE	1. 1 2. 13 3. 37 4. 1 5. 5 6. 23 7. 12
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160103026

Parameter	Value
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	4. OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160113001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160113001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/70/N.A./FRANCE/YES
Medical history	Adrenal insufficiency, Asthma, Hypertension, Breast cancer, Depression, Diabetes mellitus, Drug hypersensitivity, VIIth nerve paralysis, Gastric ulcer, Goitre, Cardiac disorder, Mastectomy, Menopause, Obesity, Oedema peripheral, Osteoporosis, Respiratory failure, Sleep apnoea syndrome, Tuberculosis, Osteoarthritis, Lung disorder, Gastrointestinal disorder, Bronchopulmonary aspergillosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTONE [SPIRONOLACTONE], ATARAX, ATROVENT, AUGMENTIN, BRICANYL, CALCI D3, CALCIDOSE, CORTANCYL, DAFALGAN, DEBRIDAT, DIFFU K, DOLIPRANE, ENOXAPARIN, FEMARA, FORLAX, FOSAMAX, FRAXIPARINE, FUNGIZONE, HYDROCORTISONE, INEXIUM, INIPOMP, IXPRIM, MOTILIUM, NOVOMIX, OXYGEN, PREVISCAN, PROZAC, SPASFON, SPIRIVA, SYMBICORT, TAREG, TOPALGIC [I CONFIRM TRAMADOL HYDROCHLORIDE], VITAMIN D, WARFARIN, XANAX
Adverse Events (AE) Preferred term	1. Venous injury 2. Obesity 3. Abdominal pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 10MAR2008 (63) - 10MAR2008 (63) 2. 31MAR2008 (84) - 21APR2008 (105) 3. 18MAY2008 (132) - 13JUN2008 (158)
Duration of AE	1. 1 2. 22 3. 27
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. NONE 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160113001

Parameter	Value
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160113006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160113006/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/52/N.A./FRANCE/YES
Medical history	Asthma, Hepatitis B, Pertussis, Intervertebral disc protrusion, Iodine allergy, Transaminases increased
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPRAZOLAM, AUGMENTIN, BRICANYL, ENOXAPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Hepatitis
	2. Anxiety
	3. Lung infection
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/NO
	2. MILD/NO/NO/YES
	3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 02APR2009 (1) - 29APR2009 (28)
	2. 03APR2009 (2) - 07APR2009 (6)
	3. 03APR2009 (2) - 08APR2009 (7)
Duration of AE	1. 28
	2. 5
	3. 6
Dose on AE onset	1.
	2.
	3.
Dose status on AE onset	1.
	2.
	3.
Action taken	1. OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160113012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160113012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/37/N.A./FRANCE/YES
Medical history	Alopecia, Chronic sinusitis, Haemorrhoids, Salivary gland calculus, Sciatica, Social phobia, Intervertebral disc protrusion, Lung infection, Body fat disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, DOLIPRANE, DOXYLIS, ENOXAPARIN, LEXOMIL, MOPRAL, PARACETAMOL, PROPECIA, PROZAC, WARFARIN, XANAX
Adverse Events (AE) Preferred term	1. Anxiety 2. Nocturnal dyspnoea 3. Asthenia 4. Pain in extremity 5. Chest discomfort 6. Dermatitis allergic 7. Gastrooesophageal reflux disease 8. Dyspnoea 9. Chest pain 10. Back pain 11. Alanine aminotransferase increased 12. Aspartate aminotransferase increased 13. Chlamydial infection 14. Alanine aminotransferase increased 15. Haematoma 16. Haematoma 17. Laryngeal haemorrhage 18. Headache 19. Pyrexia 20. Diarrhoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/YES/YES 12. MODERATE/NO/NO/YES 13. MILD/NO/NO/YES 14. MODERATE/NO/NO/YES 15. MILD/NO/NO/YES 16. MILD/NO/NO/YES 17. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160113012

Parameter	Value
	18. MILD/NO/NO/YES
	19. MILD/NO/NO/YES
	20. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --MAR2010 (.) - --------- (.)
	2. --APR2010 (.) - --APR2010 (.)
	3. --JUN2010 (.) - --JUL2010 (.)
	4. --MAY2010 (.) - --JUN2010 (.)
	5. --JUL2010 (.) - 18AUG2010 (246)
	6. --JUL2010 (.) - --JUL2010 (.)
	7. --APR2010 (.) - 13SEP2010 (272)
	8. 27DEC2009 (12) - 28DEC2009 (13)
	9. 27DEC2009 (12) - 28DEC2009 (13)
	10. 27DEC2009 (12) - 28DEC2009 (13)
	11. 29DEC2009 (14) - 11JAN2010 (27)
	12. 29DEC2009 (14) - 11JAN2010 (27)
	13. 11JAN2010 (27) - 15FEB2010 (62)
	14. 11JAN2010 (27) - 22MAR2010 (97)
	15. 01JUN2010 (168) - --JUL2010 (.)
	16. 01JUN2010 (168) - --JUL2010 (.)
	17. 07AUG2010 (235) - 30AUG2010 (258)
	18. 13NOV2010 (333) - 14NOV2010 (334)
	19. 03DEC2010 (353) - 03DEC2010 (353)
	20. 03DEC2010 (353) - 10DEC2010 (360)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. 2
	9. 2
	10. 2
	11. 14
	12. 14
	13. 36
	14. 71
	15. .
	16. .
	17. 24
	18. 2
	19. 1
	20. 8
Dose on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160113012

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160113012

Parameter	Value
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. NONE
	16. NONE
	17. OTHER
	18. REMEDIAL DRUG THERAPY
	19. NONE
	20. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED
	20. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160123003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160123003/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/78/N.A./FRANCE/YES
Medical history	Arrhythmia, Hyperthyroidism, Mitral valve incompetence, Bronchitis chronic, Osteoporosis, Prostatic adenoma, Gastrointestinal carcinoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALFUZOSINE CHLORHYDRATE, AMOXICILLINE + ACIDE CLAVULANIQUE, ANTAGONIST OF ANGIOTENSIN II, AUGMENTIN, CALCIPARINE, CELESTENE, COVERSYL, DAFALGAN, DIFFU K, DIGOXINE, FUROSEMIDE, INEXIUM, IPATROPIUM BROMURE, IPRATROPIUM BROMURE, KLEAN-PREP, NITRIDERM, OXYGEN, RISORDAN, ROVAMYCINE, SALBUTAMOL, TERBUTALINE, TERBUTALINE SULFATE, TINZAPARIN, ZOLPIDEM
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Lung infection 3. Cardiac failure 4. Melaena 5. Gastrointestinal dysplasia 6. Gastrointestinal dysplasia 7. Cardiac failure 8. Cardiac failure
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MODERATE/YES/YES/YES 5. MODERATE/NO/YES/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/YES/YES 8. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 03MAR2008 (41) - 13MAR2008 (51) 2. 03MAR2008 (41) - --MAR2008 (.) 3. 03MAR2008 (41) - 13MAR2008 (51) 4. 06MAR2008 (44) - 06MAR2008 (44) 5. 26MAR2008 (64) - 28MAR2008 (66) 6. 29MAR2008 (67) - --------- (.) 7. 11APR2008 (80) - 17APR2008 (86) 8. 05AUG2008 (196) - 05AUG2008 (196)
Duration of AE	1. 11 2. . 3. 11 4. 1 5. 3 6. . 7. 7 8. 1
Dose on AE onset	1. 20 mg 2. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160123003

Parameter	Value
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. I
	5. .
	6. .
	7. .
	8. F
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED
	5. STUDY DRUG DISCONTINUED AND RESTARTED
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. IMPROVED
	6. UNCHANGED
	7. RESOLVED
	8. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160123003[1),1)]	ACUTE DYSPNEA（PT：呼吸困難） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、偶発的な感染症と判断し、リバーロキサバンとの因果関係を否定できると考える。 PULMONARY INFECTION（PT：肺感染） 報告者は報告事象との因果関係評価を行っていない。弊社は、偶発的な感染症と判断し、リバーロキサバンとの因果関係を否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160123005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160123005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/79/N.A./FRANCE/YES
Medical history	Spinal osteoarthritis, Lung disorder, Alcoholism
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT, AUGMENTIN, BRICANYL, DAFALGAN, DIFFU K, ENOXAPARIN, FLAGYL, IMOVANE, MUCOMYST, OFLOCET, PERFALGAN, ROCEPHINE, SERESTA, TAVANIC, VITAMINE B1 B6, VITAMINE B1B6, WARFARIN
Adverse Events (AE) Preferred term	1. Pleurisy 2. Pleurisy
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 09MAY2008 (43) - 15MAY2008 (49) 2. 16MAY2008 (50) - 29MAY2008 (63)
Duration of AE	1. 7 2. 14
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. WORSENED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160123010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160123010/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/82/N.A./FRANCE/YES
Medical history	Appendicectomy, Hypertension, Glaucoma, Cataract, Lymphadenopathy, Cerebrovascular accident, Lung disorder, Myocardial ischaemia, Dyslipidaemia, Skin graft
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AZANTAC, ELISOR, LUMIGAN COLLYRE, NISISCO, PLAVIX, TEMESTA, VASTAREL
Adverse Events (AE) Preferred term	1. Adenocarcinoma 2. Ischaemic stroke 3. Hypercalcaemia 4. Diarrhoea 5. Overdose 6. Haematoma
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/NO 5. ./NO/NO/NO 6. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 18JUN2008 (6) - --------- (.) 2. 23JUN2008 (11) - 02AUG2008 (51) 3. 24JUN2008 (12) - 24JUN2008 (12) 4. 02JUL2008 (20) - 19JUL2008 (37) 5. 19JUL2008 (37) - 19JUL2008 (37) 6. 31JUL2008 (49) - --------- (.)
Duration of AE	1. . 2. 41 3. 1 4. 18 5. 1 6. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 15 mg 6. 15 mg
Dose status on AE onset	1. . 2. . 3. F 4. F 5. F 6. F
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160123010

Parameter	Value
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
Outcome of event	1. UNCHANGED
	2. DEATH
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160123011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160123011/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/67/N.A./FRANCE/YES
Medical history	Osteoarthritis, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, AMOXICILLINE, AUGMENTIN, CHONDROSULF, DAFALGAN, DAFLON [DIOSMIN+HESPERIDIN], ENOXAPARIN, OESCLIM, STILNOX, TAKETIAM, UTROGESTAN, WARFARIN
Adverse Events (AE) Preferred term	1. Sinusitis 2. Oedema peripheral 3. Pericardial haemorrhage 4. Pleural effusion
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/YES/YES/YES 4. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 25AUG2008 (9) - 20SEP2008 (35) 2. 21OCT2008 (66) - 19NOV2008 (95) 3. 13NOV2008 (89) - 16DEC2008 (122) 4. 13NOV2008 (89) - 16DEC2008 (122)
Duration of AE	1. 27 2. 30 3. 34 4. 34
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER 4. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160123011

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160123021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160123021/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/32/N.A./FRANCE/YES
Medical history	Intra-uterine contraceptive device, Obesity, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLINE, AUGMENTIN, BETASERC, CONTRAMAL, DAFALGAN, MOTILIUM, MYOLASTAN, PARACETAMOL, PRIMPERAN, STRESAM, TANGANIL, TOPALGIC [TRAMADOL HYDROCHLORID]
Adverse Events (AE) Preferred term	1. Breast haematoma 2. Vertigo 3. Back pain 4. Vulvovaginal mycotic infection 5. Haematoma 6. Benign oesophageal neoplasm 7. Nasopharyngitis 8. Benign oesophageal neoplasm
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 22SEP2009 (21) - --------- (.) 2. 24SEP2009 (23) - 02DEC2009 (92) 3. 02OCT2009 (31) - --------- (.) 4. 22OCT2009 (51) - 04NOV2009 (64) 5. 02DEC2009 (92) - --------- (.) 6. 03DEC2009 (93) - --------- (.) 7. 11DEC2009 (101) - 18DEC2009 (108) 8. 31MAY2010 (272) - 02JUN2010 (274)
Duration of AE	1. . 2. 70 3. . 4. 14 5. . 6. . 7. 8 8. 3
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160123021

Parameter	Value
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. I
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160123024

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160123024/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/70/N.A./FRANCE/YES
Medical history	Appendicectomy, Osteoarthritis, Asthma, Diarrhoea, Influenza, Gastrooesophageal reflux disease, Haemorrhoids, Osteoporosis, Gastrointestinal disorder, Rectal haemorrhage
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AERIUS, CACITD3, CHONDROSULF, CIFLOX, COLCHIMAX [COLCHICINE + PAPAVER SOMNIFERUM POWDER + TIEMONIUM METHYLSULPHATE], CONTRAMAL, DAFALGAN, FORLAX, INEXIUM, ROCEPHINE
Adverse Events (AE) Preferred term	1. Hiatus hernia 2. Latex allergy 3. Pericarditis 4. Sepsis syndrome 5. Pleural effusion
Intensity/ Relationship to study drug /SAE/TE	1. ./NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. ./NO/NO/YES
Start/stop date of event with relative date	1. --OCT2009 (.) - --------- (.) 2. 15OCT2009 (2) - 15OCT2009 (2) 3. 23OCT2009 (10) - 07NOV2009 (25) 4. 23OCT2009 (10) - 07NOV2009 (25) 5. 23OCT2009 (10) - 07NOV2009 (25)
Duration of AE	1. . 2. 1 3. 16 4. 16 5. 16
Dose on AE onset	1. 2. 15 mg 3. 15 mg 4. 15 mg 5. 15 mg
Dose status on AE onset	1. 2. . 3. . 4. . 5. .
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY 5. NONE
Outcome of event	1. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160123024

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160123025

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160123025/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/64/N.A./FRANCE/YES
Medical history	Prostate cancer, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CETIRIZINE, ENOXAPARIN, HUMEX [BENZALKONIUM CHLORIDE ONLY], PYOSTACINE, UNFRACTIONATED HEPARIN, WARFARIN, XYLOCAINE
Adverse Events (AE) Preferred term	1. Allergic cough 2. Erysipelas 3. Urethral stenosis 4. Urethral stenosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 12MAY2010 (202) - 16JUL2010 (267) 2. 16JUL2010 (267) - 23JUL2010 (274) 3. 21SEP2010 (334) - 19OCT2010 (362) 4. 20OCT2010 (363) - 22OCT2010 (365)
Duration of AE	1. 66 2. 8 3. 29 4. 3
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. WORSENED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160123025

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160133002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160133002/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/74/N.A./FRANCE/YES
Medical history	Hypertension, Obesity, Infectious peritonitis, Prostatomegaly, Alcoholism, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOR, CHIBROPROSCAR, ESIDREX, METFORMINE, RAMIPRIL, TAMSULOSINE
Adverse Events (AE) Preferred term	1. Hypertension 2. Prostate cancer 3. Type 2 diabetes mellitus 4. Atrial fibrillation 5. Sudden death 6. Haematemesis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. SEVERE/YES/YES/YES 6. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 27DEC2007 (12) - --------- (.) 2. 08JAN2008 (24) - --------- (.) 3. 16JUN2008 (184) - --------- (.) 4. 16JUN2008 (184) - --------- (.) 5. 31AUG2008 (260) - 31AUG2008 (260) 6. 31AUG2008 (260) - 31AUG2008 (260)
Duration of AE	1. . 2. . 3. . 4. . 5. 1 6. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. I 3. . 4. . 5. . 6. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY,OTHER 3. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160133002

Parameter	Value
Outcome of event	4. NONE 5. NONE 6. NONE 1. UNCHANGED 2. UNCHANGED 3. UNCHANGED 4. UNCHANGED 5. DEATH 6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160133002[4),5)]	BLACK VOMITING（PT：吐血） 治験担当医は、因果関係は否定できると判断した。弊社は、リバーロキサバンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。 SUDDEN DEATH（PT：突然死） 治験担当医は、「突然死」との関連性はあると判断した。ドイツ本社安全性部門は、リバーロキサバン投与開始時に罹患していた合併症（前立腺癌）によるものと考え、関連性は低いと評価しているが、弊社は、臨床経過、死因等の情報が得られておらず、因果関係の評価は困難と考える。したがって、因果関係については完全には否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

被験者番号：11702-160133002

死亡に至るまでの経過

被験者は74歳、男性。2007年12月14日に肺塞栓症、2007年12月19日に深部静脈血栓症と診断され、2007年12月16日にリバーロキサバン（30mg）の投与を開始した。

2008年1月8日、被験者は前立腺癌（前立腺腺癌）を発現した。本事象は重大な医学的事象と考えられたため、重篤とされた。治験責任（分担）医師は、本事象の重症度は中等度で、かつ治験薬との因果関係は「なし」と判断した。2007年12月14日、頻尿及び前立腺容積増加が認められたが、治験責任（分担）医師はその時点で癌の徴候は認めなかった。2008年1月8日、前立腺癌の診断検査が行われ、前立腺生検の結果、中等度の腺癌（グリーソンスコア 6、被膜浸潤なし）が認められ、前立腺特異抗原（PSA）の増加（8.17mcg/L）がみられた。本事象により治験薬は変更されなかった。前立腺癌の治療として finasteride 及び tamsulosin が投与された。本事象の最終転帰は継続中及び不変と報告された。

2008年8月31日、被験者は吐血（黒色吐血）及び突然死（突然死、原因不明）を発現した。いずれも重大な医学的事象と考えられ、更に吐血（黒色吐血）は生命を脅かす事象と考えられ、突然死（突然死、原因不明）は死亡に至ったため、重篤とされた。治験責任（分担）医師はいずれの事象の重症度も高度と判断した。吐血（黒色吐血）と治験薬との因果関係は「なし」と判断されたが、突然死（突然死、原因不明）と治験薬との因果関係は「あり」と判断された。2008年8月31日、被験者は自宅で疲れを訴え、その後死亡しているのが発見された。蘇生を試みたが功を奏さなかった。吐血（黒色吐血）の転帰は2008年8月31日に消失、突然死（突然死、原因不明）の転帰は同日に死亡と報告された。いずれの事象に対しても治療は行われなかった。剖検は実施されなかった。

CIACは、死亡原因は不明であり肺塞栓症である可能性は否定できないとした。

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
Platelets	Local: 150-450 giga/L	15 Dec 2007	**149 giga/L (L)**				
Alkaline Phosphatase	Central: 35-123 U/L	16 Dec 2007	68 U/L	17 Mar 2008	81 U/L	10 Jul 2008	71 U/L
		27 Dec 2007	74 U/L	14 Apr 2008	84 U/L	18 Aug 2008	74 U/L
		10 Jan 2008	69 U/L	19 May 2008	92 U/L		
		11 Feb 2008	69 U/L	16 Jun 2008	81 U/L		
Amylase	Central: 28-100 U/L	16 Dec 2007	32 U/L	16 Jun 2008	36 U/L		
Bilirubin, Direct	Central: 0.10-0.32 mg/dL	16 Dec 2007	**0.37 mg/dL (H)**	11 Feb 2008	**0.40 mg/dL (H)**	19 May 2008	**0.66 mg/dL (H)**
		27 Dec 2007	**0.48 mg/dL (H)**	17 Mar 2008	**0.43 mg/dL (H)**	10 Jul 2008	**0.55 mg/dL (H)**
		10 Jan 2008	**0.64 mg/dL (H)**	14 Apr 2008	**0.42 mg/dL (H)**	18 Aug 2008	**0.37 mg/dL (H)**

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
Bilirubin, Total	Central: 0.22-1.28 mg/dL	16 Dec 2007	0.94 mg/dL	17 Mar 2008	1.16 mg/dL	10 Jul 2008	**1.43 mg/dL (H)**
		27 Dec 2007	1.03 mg/dL	14 Apr 2008	1.09 mg/dL	18 Aug 2008	1.26 mg/dL
		10 Jan 2008	**1.85 mg/dL (H)**	19 May 2008	**1.63 mg/dL (H)**		
		11 Feb 2008	1.23 mg/dL	16 Jun 2008	1.18 mg/dL		
SGOT/AST	Central: 11-39 U/L	16 Dec 2007	26 U/L	11 Feb 2008	21 U/L	19 May 2008	19 U/L
		27 Dec 2007	22 U/L	17 Mar 2008	19 U/L	10 Jul 2008	18 U/L
		10 Jan 2008	17 U/L	14 Apr 2008	19 U/L	18 Aug 2008	21 U/L
SGPT/ALT	Central: 8-45 U/L [a] Local: 0-45 U/L	15 Dec 2007	44 U/L [a]	11 Feb 2008	26 U/L	10 Jul 2008	21 U/L
		16 Dec 2007	37 U/L	17 Mar 2008	27 U/L	18 Aug 2008	22 U/L
		27 Dec 2007	43 U/L	14 Apr 2008	22 U/L		
		10 Jan 2008	25 U/L	19 May 2008	22 U/L		
PICT Seconds	Central: 24.80-36.40 S	16 Dec 2007	**48.20 S (H)**	27 Dec 2007	34.70 S	16 Jun 2008	<33.60 S
		27 Dec 2007	<32.00 S	17 Mar 2008	<33.60 S		
Prothrombin Time (PT)	Central: 11.80-15.50 S	16 Dec 2007	14.80 S	27 Dec 2007	**26.20 S (H)**	16 Jun 2008	**16.00 S (H)**
		27 Dec 2007	**20.70 S (H)**	17 Mar 2008	**19.80 S (H)**		
PT Ratio	Central: 0.70-1.20 %	16 Dec 2007	0.77 %	27 Dec 2007	**0.35 % (L)**	16 Jun 2008	**0.68 % (L)**
		27 Dec 2007	**0.48 % (L)**	17 Mar 2008	**0.50 % (L)**		
PT, INR	Central: 0.9-1.2	16 Dec 2007	1.2	27 Dec 2007	**2.4 (H)**	16 Jun 2008	**1.3 (H)**
		27 Dec 2007	**1.8 (H)**	17 Mar 2008	**1.7 (H)**		

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160143013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160143013/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/72/N.A./FRANCE/YES
Medical history	Glaucoma, Abdominal hernia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, COLTRAMYL, COVERSYL, FORLAX, LEXOMIL, OFLOCET, PARACETAMOL, PROFENID, TIMOPTOL, ULTRA LEVURE, XALATAN
Adverse Events (AE) Preferred term	1. Lymphadenopathy 2. Parkinsonism 3. Headache 4. Dizziness 5. Hydrocele 6. Neck pain 7. Sciatica 8. Lymphadenopathy 9. Constipation 10. Hypertension
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JUL2009 (.) - 08SEP2009 (218) 2. --SEP2009 (.) - --------- (.) 3. --JUL2009 (.) - 13AUG2009 (192) 4. --JUL2009 (.) - 13AUG2009 (192) 5. --JUL2009 (.) - 08SEP2009 (218) 6. --JUL2009 (.) - 13AUG2009 (192) 7. --SEP2009 (.) - --------- (.) 8. 03FEB2009 (1) - 06FEB2009 (4) 9. 06FEB2009 (4) - 20FEB2009 (18) 10. 03APR2009 (60) - 08SEP2009 (218)
Duration of AE	1. . 2. . 3. . 4. . 5. . 6. . 7. . 8. 4

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160143013

Parameter	Value
	9. 15
	10. 159
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8. 15 mg
	9. 15 mg
	10. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8. .
	9. .
	10. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160143013

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160143020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160143020/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/82/N.A./FRANCE/YES
Medical history	Depression, Diabetes mellitus, Hiatus hernia, Hypercholesterolaemia, Hypertension, Inflammation, Overweight, Iodine allergy, Hysterectomy, Fungal infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOR, APPROVEL, CELIPROLOL, CLOPIDOGREL, CRESTOR, DEROXAT, DOMPERIDONE, ENOXAPARIN, GLUCOR, HYPERUIM, LASILIX, PREVISCAN, SERETIDE, SURMONTIL, VASTAREL, WARFARIN, ZADITEN
Adverse Events (AE) Preferred term	1. Amaurosis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --JUL2009 (.) - 10JUL2009 (32)
Duration of AE	1. .
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. NONE
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160143032

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160143032/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/55/N.A./FRANCE/YES
Medical history	Hypercholesterolaemia, Overweight, Sciatica, Sleep apnoea syndrome, Varicocele, Meniscus lesion, Intervertebral disc protrusion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CONTRAMAL, DERINOX [NAPHAZOLINE NITRATE AND PREDNISOLONE], DEROXAT, DOLIPRANE, DOLPIRANE, FLECTOR, MONOZECLAR, OMEPRAZOLE, PARACETAMOL, PAROXETINE, SOLUPRED
Adverse Events (AE) Preferred term	1. Depression 2. Burning sensation 3. Chest pain 4. Dyspnoea 5. Headache 6. Asthenia 7. Influenza 8. Alanine aminotransferase increased 9. Rib fracture 10. Aspartate aminotransferase increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --MAR2010 (.) - --------- (.) 2. --SEP2010 (.) - --OCT2010 (.) 3. 04JAN2010 (6) - 25JAN2010 (27) 4. 04JAN2010 (6) - 18JAN2010 (20) 5. 08MAR2010 (69) - 12APR2010 (104) 6. 14AUG2010 (228) - --NOV2010 (.) 7. 14SEP2010 (259) - 22NOV2010 (328) 8. 14SEP2010 (259) - 02NOV2010 (308) 9. 21SEP2010 (266) - --------- (.) 10. 05OCT2010 (280) - 02NOV2010 (308)
Duration of AE	1. . 2. . 3. 22 4. 15 5. 36 6. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160143032

Parameter	Value
	7. 70
	8. 50
	9. .
	10. 29
Dose on AE onset	1.
	2.
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. OTHER
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160143032

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160143039

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160143039/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/77/N.A./FRANCE/YES
Medical history	Appendicectomy, Cholecystectomy, Cardiac failure chronic, Chronic obstructive pulmonary disease, Gout, Hypercholesterolaemia, Hypertension, Myocardial infarction, Neoplasm prostate, Sleep apnoea syndrome, Peripheral arterial occlusive disease, Coronary artery bypass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, BRONCHODUAL, CONTRAMAL, FUROSEMIDE, KREDEX, LASILIX, METFORMINE, METFORMNIE, NAFTYDROFURYL, PLAVIX, RAMIRPIL, SERETIDE, TAHOR
Adverse Events (AE) Preferred term	1. Ecchymosis 2. Diabetes mellitus 3. Bronchitis 4. Epistaxis 5. Sudden death
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/YES/NO/YES 5. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 14APR2010 (1) - --------- (.) 2. 16APR2010 (3) - --------- (.) 3. 28MAY2010 (45) - 30JUN2010 (78) 4. 16JUN2010 (64) - 16JUN2010 (64) 5. 11AUG2010 (120) - 11AUG2010 (120)
Duration of AE	1. . 2. . 3. 34 4. 1 5. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. NONE 4. NONE 5. NONE
Outcome of event	1. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160143039

Parameter	Value
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160143040

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160143040/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/83/N.A./FRANCE/YES
Medical history	Cervicobrachial syndrome, Chronic obstructive pulmonary disease, Hiatus hernia, Hypertension, Inguinal hernia, Neoplasm prostate, Upper limb fracture, Lung infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AERIUS, ATACAND [CANDESARTAN CILEXETIL], AUGMENTIN, CIFLOX, GAVISCON, INIPOMP, INNOVAIR, ISOPTINE, LEXOMIL, LORAMIC, MEPRONIZINE, MOTILIUM, OXYGEN, ROCEPHINE, UNFRACTIONATED HEPARIN, VIT B1 B6, XYZALL
Adverse Events (AE) Preferred term	1. Palpitations 2. Abdominal pain 3. Sleep apnoea syndrome 4. Diverticulum oesophageal 5. Hypertension
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/NO 5. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --MAY2010 (.) - -----2010 (.) 2. 02MAY2010 (17) - --------- (.) 3. 29JUL2010 (105) - --------- (.) 4. 25OCT2010 (193) - 26OCT2010 (194) 5. 05NOV2010 (204) - --------- (.)
Duration of AE	1. . 2. . 3. . 4. 2 5. .
Dose on AE onset	1. 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. F 5. F
Action taken	1. NONE 2. NONE 3. NONE 4. NONE 5. NONE
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160143040

Parameter	Value
	2. UNCHANGED
	3. UNCHANGED
	4. RESOLVED
	5. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160143041

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160143041/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/32/N.A./FRANCE/YES
Medical history	Alcoholism, Appendicectomy, Tendon injury, Tonsillectomy, Withdrawal syndrome, Familial risk factor
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, DAFALGAN, DEROXAT, DEXTROPROPOXYPHENE, ENOXAPARIN, N ACETHYLCYSTEINE, PARACETAMOL, TAHOR, TETRAZEPAM, WARFARIN
Adverse Events (AE) Preferred term	1. Chest pain 2. Dyspnoea 3. Hypercholesterolaemia 4. Chest pain 5. Toxicity to various agents 6. Tachycardia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --DEC2010 (.) - --------- (.) 2. --AUG2010 (.) - 27SEP2010 (102) 3. 18JUN2010 (1) - --------- (.) 4. 06OCT2010 (111) - 07OCT2010 (112) 5. 12OCT2010 (117) - 14OCT2010 (119) 6. 19NOV2010 (155) - 21DEC2010 (187)
Duration of AE	1. . 2. . 3. . 4. 2 5. 3 6. 33
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. NONE 2. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160143041

Parameter	Value
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. IMPROVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160153002/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/49/N.A./FRANCE/YES
Medical history	Ankle fracture, Hypercholesterolaemia, Klinefelter's syndrome, Obesity, Osteoporosis, Toxoplasmosis, Wrist fracture, Fractured coccyx, Fractured coccyx
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DI-ANTALVIC, ENOXAPARIN, LOVENOX, MORPHINE, STILNOX, TOPALGIC 100 LP, TOPALGIC 100 [TRAMADOL HYDROCHLORIDE], TOPALGIC 50 LP, VENA CAVAL FILTER, WARFARIN
Adverse Events (AE) Preferred term	1. Oropharyngeal pain 2. Pyrexia 3. Pain in extremity 4. Subcutaneous haematoma 5. Haematuria 6. Kidney rupture 7. Insomnia 8. Gingival bleeding 9. Oedema
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MODERATE/YES/NO/YES 6. MILD/YES/YES/YES 7. MILD/NO/NO/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --APR2008 (.) - --APR2008 (.) 2. --MAR2008 (.) - --MAR2008 (.) 3. --MAR2008 (.) - --MAR2008 (.) 4. 21NOV2007 (1) - -----2008 (.) 5. 30NOV2007 (10) - 06DEC2007 (16) 6. 06DEC2007 (16) - 13DEC2007 (23) 7. 07DEC2007 (17) - 12DEC2007 (22) 8. 20DEC2007 (30) - --------- (.) 9. 21FEB2008 (93) - 20MAR2008 (121)
Duration of AE	1. . 2. . 3. . 4. . 5. 7 6. 8 7. 6 8. . 9. 29
Dose on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153002

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. OTHER
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. WORSENED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160153002[2)]	RUPTURE OF RENAL PELVIS（PT：腎臓破裂） 治験担当医はエノキサパリン及びワルファリンと報告事象との関連性はあると判断した。弊社は、合併症（腎疝痛及び肥満）によるものであり、エノキサパリン及びワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160153015/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/65/N.A./FRANCE/YES
Medical history	Adrenal insufficiency, Decreased appetite, Anxiety, Chronic obstructive pulmonary disease, Coronary artery disease, Bartholin's cyst removal, Rib fracture, Hypercholesterolaemia, Hypertension, Renal colic, Lung disorder, Lung neoplasm, Postmenopause, Vocal cord polypectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, ATARAX, AUGMENTIN, AZACTAM, BRICANYL, CACIT D3, COMBIVENT, DIFFU-K, ENOXAPARIN, FORLAX, GAVISCON, HYDROCORTISONE, INIPOMP, ISOPTINE, LEXOMIL, LOXEN, MOTILIUM, PARACETAMOL, SEROPRAM, SYMBICORT, TOPALGIC 50 LP, TOPALGIC [TRAMADOL], VASTEN, WARFARIN
Adverse Events (AE) Preferred term	1. Nausea 2. International normalised ratio increased 3. Constipation 4. Chronic obstructive pulmonary disease 5. International normalised ratio increased 6. Haemoglobin decreased 7. Melaena 8. Diabetes mellitus 9. Oedema 10. Septic shock 11. Rash 12. Constipation 13. Bradycardia 14. Hypokalaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MODERATE/YES/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/YES/YES/YES 8. MILD/NO/NO/NO 9. MILD/NO/NO/NO 10. MODERATE/NO/NO/NO 11. MILD/NO/NO/NO 12. MILD/NO/NO/NO 13. MODERATE/NO/NO/NO 14. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 27MAR2008 (3) - 08APR2008 (15) 2. 01APR2008 (8) - 03APR2008 (10) 3. 04APR2008 (11) - 06APR2008 (13) 4. 08APR2008 (15) - 01MAY2008 (38) 5. 08APR2008 (15) - 11APR2008 (18) 6. 08APR2008 (15) - 01MAY2008 (38)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153015

Parameter	Value
	7. 10APR2008 (17) - 11APR2008 (18)
	8. 15APR2008 (22) - --------- (.)
	9. 18APR2008 (25) - 20APR2008 (27)
	10. 22APR2008 (29) - 24APR2008 (31)
	11. 26APR2008 (33) - 26APR2008 (33)
	12. 26APR2008 (33) - 26APR2008 (33)
	13. 30APR2008 (37) - 30APR2008 (37)
	14. 01MAY2008 (38) - 01MAY2008 (38)
Duration of AE	1. 13
	2. 3
	3. 3
	4. 24
	5. 4
	6. 24
	7. 2
	8. .
	9. 3
	10. 3
	11. 1
	12. 1
	13. 1
	14. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153015

Parameter	Value
	9.
	10.
	11.
	12.
	13.
	14.
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY,OTHER
	5. STUDY DRUG DISCONTINUED PERMANENTLY
	6. NONE
	7. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. DEATH
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153030

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160153030/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/80/N.A./FRANCE/YES
Medical history	Anxiety, Asthma, Skin neoplasm excision, Eczema, Gastrooesophageal reflux disease, Hiatus hernia, Hypercholesterolaemia, Hypertension, Skin neoplasm excision, Osteoporosis, Venous insufficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, BRONCHODUAL, LASILIX, LEXOMIL, LIPANTHYL, MONOTILDIEM, SERETIDE, VASTAREL, ZALDIAR
Adverse Events (AE) Preferred term	1. Mitral valve incompetence 2. Epistaxis 3. Mitral valve incompetence 4. Pericardial haemorrhage 5. Cardiogenic shock
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/YES/YES 4. SEVERE/NO/YES/NO 5. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 19JAN2009 (127) - 05SEP2009 (356) 2. 05JUN2009 (264) - 08JUN2009 (267) 3. 06SEP2009 (357) - --------- (.) 4. 07SEP2009 (358) - --------- (.) 5. 07SEP2009 (358) - 07SEP2009 (358)
Duration of AE	1. 230 2. 4 3. . 4. . 5. 1
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. F 4. F 5. F
Action taken	1. NONE 2. NONE 3. NONE 4. OTHER 5. NONE
Outcome of event	1. WORSENED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153030

Parameter	Value
	3. UNCHANGED
	4. UNCHANGED
	5. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153034

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160153034/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/82/N.A./FRANCE/YES
Medical history	Hypothyroidism
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, AUGMENTIN, BRICANYL, DAFALGAN, DIFFU K, FORLAX, HEPARINE, IMODIUM, IMOVANE, INNOHEP, KETAMINE, LASILIX, LEVOTHYROX, MOPRAL, MORPHINE, PERFALGAN, STILNOX, TOPALGIC [TRAMADOL HYDROCHLORIDE]
Adverse Events (AE) Preferred term	1. Bronchitis 2. Rhinorrhoea 3. Insomnia 4. Lung infection 5. Cough 6. Dyspepsia 7. Lung adenocarcinoma 8. Pneumonia aspiration 9. Constipation 10. Insomnia 11. Diarrhoea 12. Procedural pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. SEVERE/NO/YES/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --FEB2009 (.) - --FEB2009 (.) 2. --MAY2009 (.) - --MAY2009 (.) 3. 02NOV2008 (0) - 17MAR2009 (135) 4. 04NOV2008 (2) - 11NOV2008 (9) 5. 14NOV2008 (12) - 22DEC2008 (50) 6. 15NOV2008 (13) - --DEC2008 (.) 7. 22DEC2008 (50) - --------- (.) 8. 21MAR2009 (139) - 27MAR2009 (145) 9. 21MAR2009 (139) - 24MAR2009 (142) 10. 22MAR2009 (140) - 26MAR2009 (144) 11. 24MAR2009 (142) - 28MAR2009 (146) 12. 03APR2009 (152) - 27MAY2009 (206)
Duration of AE	1. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153034

Parameter	Value
	2. .
	3. 136
	4. 8
	5. 39
	6. .
	7. .
	8. 7
	9. 4
	10. 5
	11. 5
	12. 55
Dose on AE onset	1.
	2.
	3.
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4. .
	5. .
	6. .
	7. .
	8. I
	9. I
	10. I
	11. I
	12. .
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153034

Parameter	Value
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. IMPROVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153040

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160153040/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/63/N.A./FRANCE/YES
Medical history	Renal cell carcinoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDARA, AUGMENTIN, DI ANTALVIC, LOVENOX, VENA CAVA FILTER
Adverse Events (AE) Preferred term	1. Rotator cuff syndrome
	2. Renal cell carcinoma
	3. Kidney infection
	4. Skin lesion
	5. Basal cell carcinoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MODERATE/NO/YES/YES
	3. MILD/NO/NO/YES
	4. MILD/NO/NO/YES
	5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --FEB2009 (.) - --MAR2009 (.)
	2. 09MAR2009 (82) - --------- (.)
	3. 17MAR2009 (90) - 26MAR2009 (99)
	4. 25MAY2009 (159) - --------- (.)
	5. 09JUN2009 (174) - 09JUN2009 (174)
Duration of AE	1. .
	2. .
	3. 10
	4. .
	5. 1
Dose on AE onset	1.
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
Dose status on AE onset	1.
	2. .
	3. I
	4. .
	5. I
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. RESOLVED
	2. IMPROVED
	3. RESOLVED
	4. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153040

Parameter	Value
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153043

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160153043/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/77/N.A./FRANCE/YES
Medical history	Anxiety, Hiatus hernia, Temporal arteritis, Hypercholesterolaemia, Hypertension, Hypothyroidism, Alopecia scarring
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CACIT, CITALOPRAM, CORTANCYL, ENOXAPARIN, EUPANTHOL, LEVOTHYROX, LOVENOX, LOXEN LP, PRAVASTATINE, TRIATEC, WARFARIN
Adverse Events (AE) Preferred term	1. Temporal arteritis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 11MAY2009 (95) - 18MAY2009 (102)
Duration of AE	1. 8
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153053

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160153053/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/83/N.A./FRANCE/YES
Medical history	Anxiety, Colon cancer, Diarrhoea, Uterine cancer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPEGIC, ATHYMIL, AUGMENTIN, CALCIPARINE, CARDENSIEL, CORDARONE, COVERSYL, DIFFU K, ENOXAPARIN, HEPARIN, IMODIUM, INEXIUM, INSPRA, KARDEGIC, LASILIX FAIBLE, LOVENOX, PARIET, QUESTRAN, TEMESTA, TIORFAN, VITAMINE B12, WARFARIN
Adverse Events (AE) Preferred term	1. Asthenia 2. Fall 3. Pelvic fracture 4. Myocarditis 5. Viral myocarditis 6. Cardiac failure congestive 7. Hypokalaemia 8. Diarrhoea 9. Blood alkaline phosphatase increased 10. International normalised ratio increased 11. Transient ischaemic attack
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/YES/NO/YES 11. MILD/NO/YES/YES
Start/stop date of event with relative date	1. --JUL2009 (.) - --AUG2009 (.) 2. 23JUN2009 (28) - 23JUN2009 (28) 3. 23JUN2009 (28) - 23JUN2009 (28) 4. 09OCT2009 (136) - 13NOV2009 (171) 5. 09OCT2009 (136) - 16OCT2009 (143) 6. 09OCT2009 (136) - 22OCT2009 (149) 7. 10OCT2009 (137) - --------- (.) 8. 11OCT2009 (138) - --------- (.) 9. 27NOV2009 (185) - --------- (.) 10. 27NOV2009 (185) - 27NOV2009 (185) 11. 06APR2010 (315) - 14APR2010 (323)
Duration of AE	1. . 2. 1 3. 1 4. 36

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153053

Parameter	Value
	5. 8
	6. 14
	7. .
	8. .
	9. .
	10. 1
	11. 9
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY,OTHER
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. STUDY DRUG DISCONTINUED AND RESTARTED
	11. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153053

Parameter	Value
	5. RESOLVED
	6. RESOLVED
	7. IMPROVED
	8. IMPROVED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153062

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160153062/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/73/N.A./FRANCE/YES
Medical history	Gastritis, Hypercholesterolaemia, Sciatica, Uterine leiomyoma, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CELEBREX, DOLIPRANE, INIPOMP, LIPANTHYL, VACCINE H1N1 FLU
Adverse Events (AE) Preferred term	1. Asthenia 2. Muscle spasms 3. Chest pain 4. Dyspnoea 5. Asthenia 6. Transaminases increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/YES/YES/YES
Start/stop date of event with relative date	1. --APR2010 (.) - --JUN2010 (.) 2. --FEB2010 (.) - --FEB2010 (.) 3. 05DEC2009 (22) - 17DEC2009 (34) 4. 05DEC2009 (22) - 17DEC2009 (34) 5. 05DEC2009 (22) - 17DEC2009 (34) 6. 12MAY2010 (180) - 30JUN2010 (229)
Duration of AE	1. . 2. . 3. 13 4. 13 5. 13 6. 50
Dose on AE onset	1. 2. 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. 2. 3. . 4. . 5. . 6. .
Action taken	1. NONE 2. NONE 3. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153062

Parameter	Value
	4. NONE
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153065

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160153065/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/78/N.A./FRANCE/YES
Medical history	Depression, Hypertension, Myocardial infarction, Urinary incontinence, Postmenopause, Parkinson's disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DITROPAN, DIVARIUS, INIPOMP, KARDEGIC, LOXEN, SINEMET, SINEMET LP
Adverse Events (AE) Preferred term	1. Hypotension
	2. Transient ischaemic attack
	3. Parkinson's disease
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. SEVERE/NO/YES/YES
	3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --MAY2010 (.) - 08JUN2010 (200)
	2. 23JAN2010 (64) - 30JAN2010 (71)
	3. 17FEB2010 (89) - 19FEB2010 (91)
Duration of AE	1. .
	2. 8
	3. 3
Dose on AE onset	1.
	2. 20 mg
	3. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153077

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160153077/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/53/N.A./FRANCE/YES
Medical history	Depression, Obesity, Alcoholism, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	EFFEXOR, ENOXAPARIN, NICOBION, NOZINAN, SERESTA, VALIUM, VITAMIN B1B6, WARFARIN, ZYPREXA
Adverse Events (AE) Preferred term	1. Varicose vein 2. Haematoma 3. Depression 4. Depression 5. Epistaxis 6. Rectal haemorrhage 7. Weight increased 8. Dyspnoea 9. Alcohol abuse
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/YES/YES 5. MILD/YES/NO/YES 6. MILD/YES/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/YES/YES
Start/stop date of event with relative date	1. --OCT2010 (.) - --------- (.) 2. 24FEB2010 (1) - 20APR2010 (56) 3. 07APR2010 (43) - 03MAY2010 (69) 4. 14JUN2010 (111) - 08JUL2010 (135) 5. 01OCT2010 (220) - --DEC2010 (.) 6. 01OCT2010 (220) - --DEC2010 (.) 7. 16NOV2010 (266) - --------- (.) 8. 16NOV2010 (266) - 14DEC2010 (294) 9. 06JAN2011 (317) - 20JAN2011 (331)
Duration of AE	1. . 2. 56 3. 27 4. 25 5. . 6. . 7. . 8. 29 9. 15
Dose on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153077

Parameter	Value
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160153089

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160153089/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/68/N.A./FRANCE/YES
Medical history	Acute pulmonary oedema, Atrial fibrillation, Inguinal hernia, Central nervous system stimulation, Parkinson's disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	18F-FLUORODESOXYGLUCOSE, COMTAN, ENOXAPARIN, INNOHEP, ISOPTINE, SINEMET, TOPALGIC LP, WARFARIN
Adverse Events (AE) Preferred term	1. VIIth nerve paralysis 2. Dysphagia 3. VIIth nerve paralysis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 05NOV2010 (54) - 08NOV2010 (57) 2. 06NOV2010 (55) - 13DEC2010 (92) 3. 08NOV2010 (57) - 22NOV2010 (71)
Duration of AE	1. 4 2. 38 3. 15
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. NONE 3. NONE
Outcome of event	1. WORSENED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173002/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/77/N.A./FRANCE/YES
Medical history	Hypertension, Tachycardia, Angina unstable, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CIFLOX, CORDARONE, DITROPAN, KARDEGIC, NITRIDERM, TAHOR
Adverse Events (AE) Preferred term	1. Conjunctival haemorrhage
	2. Haematuria
	3. Haematuria
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES
	2. MODERATE/YES/YES/YES
	3. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 17NOV2007 (15) - 19NOV2007 (17)
	2. 11DEC2007 (39) - 16DEC2007 (44)
	3. 19DEC2007 (47) - 24DEC2007 (52)
Duration of AE	1. 3
	2. 6
	3. 6
Dose on AE onset	1. 15 mg
	2. 20 mg
	3. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
Action taken	1. NONE
	2. OTHER
	3. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173006/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/N.A./FRANCE/YES
Medical history	Asthma, Breast cancer, Diverticulum intestinal, Hypertension, Osteoporosis, Venous insufficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTONEL, BECOTIDE, CACIT VITAMIN D3, COTAREG, ENOXAPARIN, HEPARINE, PARACETAMOL, PRIMPERAN, VENTOLINE, VIT K, WARFARIN
Adverse Events (AE) Preferred term	1. Intra-abdominal haematoma 2. Anaemia 3. Hypovolaemia 4. Renal failure acute 5. Hyperglycaemia 6. Anaemia 7. Urinary tract infection 8. Constipation 9. Fall 10. Intra-abdominal haematoma 11. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. SEVERE/YES/YES/YES 3. SEVERE/YES/YES/YES 4. SEVERE/YES/YES/YES 5. MILD/NO/NO/YES 6. MILD/YES/NO/NO 7. MODERATE/NO/NO/NO 8. MILD/NO/NO/NO 9. MILD/NO/NO/NO 10. MODERATE/YES/NO/NO 11. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 04DEC2007 (7) - 07JAN2008 (41) 2. 05DEC2007 (8) - 08DEC2007 (11) 3. 05DEC2007 (8) - 05DEC2007 (8) 4. 05DEC2007 (8) - 09DEC2007 (12) 5. 05DEC2007 (8) - 10DEC2007 (13) 6. 08DEC2007 (11) - 21JAN2008 (55) 7. 12DEC2007 (15) - 17DEC2007 (20) 8. 15DEC2007 (18) - --------- (.) 9. 20DEC2007 (23) - 20DEC2007 (23) 10. 07JAN2008 (41) - --------- (.) 11. 07FEB2008 (72) - 20FEB2008 (85)
Duration of AE	1. 35 2. 4 3. 1 4. 5 5. 6

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173006

Parameter	Value
	6. 45
	7. 6
	8. .
	9. 1
	10. .
	11. 14
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	2. OTHER
	3. REMEDIAL DRUG THERAPY
	4. OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. IMPROVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173006

Parameter	Value
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED
	10. IMPROVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173013/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/75/N.A./FRANCE/YES
Medical history	Amyotrophic lateral sclerosis, Diabetes mellitus, Drug hypersensitivity, Obesity, Chronic obstructive pulmonary disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT, DANTRIUM, FLIXOTIDE, LANTUS, NORDAZ, OMEPRAZOLE, PARACETAMOL, TERBUTALINE, TOCO
Adverse Events (AE) Preferred term	1. Amyotrophic lateral sclerosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/NO
Start/stop date of event with relative date	1. 11SEP2008 (210) - 16SEP2008 (215)
Duration of AE	1. 6
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. F
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173014/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/49/N.A./FRANCE/YES
Medical history	Depression, Hypertension, Intervertebral disc protrusion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AERIUS, AMODEX, COUMADINE, FUMAFER, HYZAAR, IZILOX, LAROXYL, LÉVONORGESTREL, PAROXETINE, PREDNISONE, PYOSTACINE, QVAR AUTOHALERTM, SOLUPRED, TARDYFERON B9, VENTOLINE, XYZALL
Adverse Events (AE) Preferred term	1. Muscle contracture 2. Menorrhagia 3. Anaemia 4. Bronchitis 5. Asthma 6. Rib fracture 7. Bronchitis 8. Sinusitis 9. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/YES/YES 3. MODERATE/YES/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/YES/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JUN2008 (.) - --JUL2008 (.) 2. 10MAY2008 (58) - 21MAY2008 (69) 3. 19MAY2008 (67) - 30JUL2008 (139) 4. 26JUN2008 (105) - 11JUL2008 (120) 5. 11JUL2008 (120) - --------- (.) 6. 04AUG2008 (144) - --SEP2008 (.) 7. 08OCT2008 (209) - 15OCT2008 (216) 8. 09DEC2008 (271) - 17DEC2008 (279) 9. 05JAN2009 (298) - 12JAN2009 (305)
Duration of AE	1. . 2. 12 3. 73 4. 16 5. . 6. . 7. 8 8. 9 9. 8
Dose on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173014

Parameter	Value
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173015/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/75/N.A./FRANCE/YES
Medical history	Benign prostatic hyperplasia, Arrhythmia, Finger amputation, Hypercholesterolaemia, Hypertension, Hyperuricaemia, Insomnia, Sleep apnoea syndrome, Vascular purpura, Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, ALLOPURINOL, ART 50, ATARAX, AUGMENTIN, AVODART, CALCIPARINE, CARBOSYMAG, CASODEX, CIFLOX, CLAFORAN, CONTRAMAL, DIANTALVIC, DITROPAN, ENOXAPARIN, EUPANTOL, FLAGYL, FORLAX, LANSOYL, LOVENOX, MICROLAX [SODIUM CITRATE + SORBITOL], MORPHINE, NEBCINE, NEURONTIN, NITRIDERM, NORMACOL, PARACETAMOL, PARAPSYLLIUM, PCA MORPHINE, PERFALGAN, PROCTOLOG, RECTOGESIC, SEDORRHOIDE VEINOTONIQUE, SMECTA [SMECTITE + VANILLIN + SACCHARIN SODIUM + GLUCOSE MONOHYDRATE], SPASFON, STILNOX, TAREG, TICARCILLINE, TITANOREINE [CHONDRUS CRISPUS EXTRACT,TITANIUM DIOXIDE,ZINC OXIDE], TRANSIPEG [MACROGOL3350,POTASSIUM CHLORID,NA BICARB,NA CHLORID,NA SULFAT ANHYDR], VERCYTE, VITAMIN K, WARFARIN, XATRAL LP 10, ZOLADEX
Adverse Events (AE) Preferred term	1. Eyelid oedema 2. Constipation 3. Prostate cancer 4. Haematuria 5. Anuria 6. Prostate cancer 7. Appendiceal abscess 8. Subcutaneous haematoma 9. Anal fissure 10. Diarrhoea 11. Pain in extremity 12. Oedema peripheral 13. Sciatica
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MODERATE/YES/YES/YES 5. MODERATE/NO/YES/YES 6. SEVERE/NO/YES/YES 7. SEVERE/NO/YES/YES 8. MODERATE/YES/NO/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MODERATE/NO/NO/YES 13. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --APR2009 (.) - --------- (.) 2. 02APR2008 (2) - --------- (.) 3. 07APR2008 (7) - 09APR2008 (9)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173015

Parameter	Value
	4. 09APR2008 (9) - 14APR2008 (14)
	5. 09APR2008 (9) - 14APR2008 (14)
	6. 14APR2008 (14) - --------- (.)
	7. 24MAY2008 (54) - 09JUN2008 (70)
	8. 30MAY2008 (60) - --JUL2008 (.)
	9. 22JUL2008 (113) - --------- (.)
	10. 01SEP2008 (154) - --------- (.)
	11. 23MAR2009 (357) - 24MAR2009 (358)
	12. 23MAR2009 (357) - 06APR2009 (371)
	13. 24MAR2009 (358) - --------- (.)
Duration of AE	1. .
	2. .
	3. 3
	4. 6
	5. 6
	6. .
	7. 17
	8. .
	9. .
	10. .
	11. 2
	12. 15
	13. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173015

Parameter	Value
	9.
	10.
	11.
	12.
	13.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	4. DOSE OF STUDY DRUG REDUCED,STUDY DRUG DISCONTINUED AND RESTARTED,INFUSION RATE OF STUDY DRUG REDUCED
	5. REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. OTHER
	13. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED
	9. IMPROVED
	10. UNCHANGED
	11. RESOLVED
	12. RESOLVED
	13. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173029/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/84/N.A./FRANCE/YES
Medical history	Aortic valve incompetence, Depression, Dyskinesia, Hip arthroplasty, Knee arthroplasty, Obesity, Prostatic adenoma, Sleep disorder, Cerebrovascular accident, Cerebrovascular accident, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPRAZOLAM, ARTANE, BACTRIM, DAFALGAN, ENOXAPARIN, EXACYL, GAVISCON, HEPARINE, INIPOMP, INNOHEP, KARDEGIC, LOVENOX, PLAVIX, STILNOX, TARDYFERON, VASTAREL, VITAMIN B6, VITAMINE PP, WARFARIN, XANAX, XATRAL
Adverse Events (AE) Preferred term	1. Prostate infection 2. Haematuria 3. International normalised ratio increased 4. Haematuria 5. Aortic thrombosis 6. Pain in extremity 7. Aortic aneurysm 8. Abdominal pain 9. Haematuria 10. Haemoptysis 11. Lung squamous cell carcinoma stage unspecified 12. Arterial haemorrhage 13. Constipation 14. Dizziness 15. Haematuria
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/YES/NO/YES 3. MILD/YES/NO/YES 4. MILD/YES/NO/YES 5. SEVERE/NO/YES/YES 6. MILD/NO/NO/YES 7. SEVERE/NO/YES/YES 8. SEVERE/YES/NO/YES 9. MILD/YES/NO/YES 10. SEVERE/YES/YES/YES 11. SEVERE/NO/YES/YES 12. MILD/YES/YES/NO 13. MILD/NO/NO/NO 14. MILD/NO/NO/NO 15. MILD/YES/NO/NO
Start/stop date of event with relative date	1. 14DEC2008 (18) - 15JAN2009 (50) 2. 03FEB2009 (69) - --FEB2009 (.) 3. 10MAR2009 (104) - 24MAR2009 (118) 4. 15MAR2009 (109) - --APR2009 (.) 5. 28APR2009 (153) - 13MAY2009 (168) 6. 28APR2009 (153) - 05MAY2009 (160)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173029

Parameter	Value
	7. 28APR2009 (153) - 13MAY2009 (168)
	8. 28APR2009 (153) - 05MAY2009 (160)
	9. 01JUN2009 (187) - --JUN2009 (.)
	10. 15JUL2009 (231) - 21JUL2009 (237)
	11. 20JUL2009 (236) - --------- (.)
	12. 24JUL2009 (240) - 27JUL2009 (243)
	13. 24JUL2009 (240) - 25JUL2009 (241)
	14. 22SEP2009 (300) - --SEP2009 (.)
	15. 22SEP2009 (300) - --SEP2009 (.)
Duration of AE	1. 33
	2. .
	3. 15
	4. .
	5. 16
	6. 8
	7. 16
	8. 8
	9. .
	10. 7
	11. .
	12. 4
	13. 2
	14. .
	15. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173029

Parameter	Value
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	6. NONE
	7. OTHER
	8. STUDY DRUG DISCONTINUED AND RESTARTED
	9. NONE
	10. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	11. OTHER
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. UNCHANGED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173029

Parameter	Value
	15. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173033

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173033/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/71/N.A./FRANCE/YES
Medical history	Pyelonephritis acute, Cholecystectomy, Depression, Hypercholesterolaemia, Hypertension, Hyperuricaemia, Prostate cancer, Prostatectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, ATORVASTATINE, DILTIAZEM, FLUDEX LP, IMOVANE, RAMIPRIL, SEROPLEX, TRANSIPEG [MACROGOL 3350], UVEDOSE
Adverse Events (AE) Preferred term	1. Chest pain 2. Epistaxis 3. Lymphocele 4. Hypertension
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --FEB2009 (.) - 24MAR2009 (62) 2. 30JAN2009 (9) - 30JAN2009 (9) 3. 06FEB2009 (16) - 28APR2009 (97) 4. 06MAR2009 (44) - --------- (.)
Duration of AE	1. . 2. 1 3. 82 4. .
Dose on AE onset	1. 2. 15 mg 3. 15 mg 4. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. .
Action taken	1. NONE 2. OTHER 3. NONE 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173033

Parameter	Value
	4. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173042

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173042/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/21/N.A./FRANCE/YES
Medical history	Ligament injury
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTISKENAN, ACUPAN, AMPICILLIN, AUGMENTIN, DIANTALVIC, DOLIPRANE, ENOXAPARIN, JASMINE, LEVOFLOXACIN, PROSED/DS, WARFARIN
Adverse Events (AE) Preferred term	1. Pneumonia 2. Urinary tract infection 3. Laryngitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 14MAY2009 (9) - 25MAY2009 (20) 2. 01JUL2009 (57) - 23JUL2009 (79) 3. 01DEC2009 (210) - --------- (.)
Duration of AE	1. 12 2. 23 3. .
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173043

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173043/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/77/N.A./FRANCE/YES
Medical history	Osteoarthritis, Gastrooesophageal reflux disease, Hypercholesterolaemia, Hypertension, Osteoporosis, Prostate cancer, Vertigo, Depression
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CASODEX, CELIPROLOL, COTAREG, ENOXAPARIN, EXFORGE 160 / 5 MG, FLUDEX LP, INIPOMP, LOXEN, OROCAL D3, PERIDYS, PIASCLEDINE, SULPIRIDE, TANAKAN, VASTEN, WARFARIN
Adverse Events (AE) Preferred term	1. Hypertension
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 01OCT2009 (148) - 03OCT2009 (150)
Duration of AE	1. 3
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173045

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173045/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/72/N.A./FRANCE/YES
Medical history	Atrial fibrillation, Bronchiectasis, Bronchopulmonary aspergillosis allergic, Chronic obstructive pulmonary disease, Emphysema, Prostate cancer, Tendonitis, Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMIKLIN, ATROVENT, AUGMENTIN, AZITHROMYCINE, BRICANYL, CACIT D3, CIFLOX, CIPRALAN, COLIMYCINE, DOLIPRANE, EUPANTOL, FORTUM, FOSFOMYCINE, FUNGIZONE, IZILOX, LASILIX, NASONEX, NORMACOL, OMEXEL, OXYGEN THERAPY, PERMIXON, PROTOLOG, RULID, SERETIDE, SINGULAIR, SOLUPRED, TAZOCILLINE, TIENAM, VANCOMYCINE, VENTILASTIN
Adverse Events (AE) Preferred term	1. Haemoptysis 2. Bronchitis 3. Bronchitis 4. Acute respiratory failure 5. Rectal haemorrhage 6. Bronchitis 7. Bronchitis 8. Bronchitis 9. Acute respiratory failure 10. Acute respiratory failure
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/YES/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/YES/YES 10. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 27JUL2009 (38) - 27JUL2009 (38) 2. 27JUL2009 (38) - 05AUG2009 (47) 3. 29AUG2009 (71) - 11SEP2009 (84) 4. 04OCT2009 (107) - 17OCT2009 (120) 5. 04NOV2009 (138) - --------- (.) 6. 14NOV2009 (148) - 28NOV2009 (162) 7. 14JAN2010 (209) - 23JAN2010 (218) 8. 11MAR2010 (265) - 21MAR2010 (275) 9. 06APR2010 (291) - 14APR2010 (299) 10. 28APR2010 (313) - 25MAY2010 (340)
Duration of AE	1. 1 2. 10 3. 14 4. 14

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173045

Parameter	Value
	5. .
	6. 15
	7. 10
	8. 11
	9. 9
	10. 28
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173045

Parameter	Value
	9. RESOLVED
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173047

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173047/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/32/N.A./FRANCE/YES
Medical history	Tendon rupture, Tendon rupture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLINE, BACTRIM, IXPRIM, LOVENOX, MORPHINE, OFLOCET, RIFADINE
Adverse Events (AE) Preferred term	1. Joint injury 2. Skin haemorrhage 3. Wound infection staphylococcal
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/YES/NO/YES 3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 14NOV2009 (69) - 20NOV2009 (75) 2. 22NOV2009 (77) - 30NOV2009 (85) 3. 25NOV2009 (80) - 31DEC2009 (116)
Duration of AE	1. 7 2. 9 3. 37
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. I
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173057

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173057/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/87/N.A./FRANCE/YES
Medical history	Asthenia, Skin cancer, Renal failure chronic, Depression, Gastrooesophageal reflux disease, Hypercholesterolaemia, Hypertension, Hypothyroidism, Iron deficiency anaemia, Syncope, Urinary incontinence
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATHYMIL, AUGMENTIN, FUNGIZONE, HYDROCORTISONE, LEVOTHYROX, MEDIATENSYL, NISIS, OMEPRAZOLE, SIMVASTATINE, TARDYFERON, VENOFER
Adverse Events (AE) Preferred term	1. Lung infection 2. Anaemia 3. Diarrhoea
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 27SEP2010 (181) - 11OCT2010 (195) 2. 28SEP2010 (182) - 28APR2011 (394) 3. 27NOV2010 (242) - 28NOV2010 (243)
Duration of AE	1. 15 2. 213 3. 2
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173058

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173058/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/71/N.A./FRANCE/YES
Medical history	Urinary retention, Appendicectomy, Constipation, Cystocele, Depression, Diabetes mellitus, Erysipelas, Erysipelas, Folate deficiency, Humerus fracture, Haemorrhoids, Humerus fracture, Hypercholesterolaemia, Hypertension, Insomnia, Nephrolithiasis, Knee arthroplasty, Lymphoedema, Obesity, Tuberculosis, Pyelonephritis, Raynaud's phenomenon, Sleep apnoea syndrome, Varicose ulceration, Fibromyalgia, Eschar, Venous insufficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, BACTRIM FORTE, ELISOR, FUNGIZONZE, FUROSEMIDE, GENTALLINE, HUMALOG, LASILIX, NEBCINE, NOCTRAN, NOROXINE, OROKEN, RIVOTRIL, ROCEPHINE, ROCÉPHINE, SPECIAFOLDINE, TEMESTA, TIENAM, TITANOREINE [CHONDRUS CRISPUS EXTRACT,TITANIUM DIOXIDE,ZINC OXIDE], TRIATEC
Adverse Events (AE) Preferred term	1. Skin haemorrhage 2. Skin haemorrhage 3. Urinary tract infection 4. Pyelonephritis 5. Urinary tract infection 6. Rectal haemorrhage 7. Orthopnoea 8. Candidiasis 9. Rectal haemorrhage 10. Urinary tract infection 11. Subcutaneous haematoma 12. Urinary tract infection 13. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/NO 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MILD/YES/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/YES/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 20JUN2010 (1) - 23JUN2010 (4) 2. 26JUN2010 (7) - 27JUN2010 (8) 3. 10JUL2010 (21) - 13JUL2010 (24) 4. 07AUG2010 (49) - 16AUG2010 (58) 5. 28SEP2010 (101) - 09OCT2010 (112) 6. 05NOV2010 (139) - 08NOV2010 (142)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173058

Parameter	Value
	7. 26JAN2011 (221) - --------- (.)
	8. 02FEB2011 (228) - 26FEB2011 (252)
	9. 03MAR2011 (257) - 07APR2011 (292)
	10. 25MAR2011 (279) - 05APR2011 (290)
	11. 07APR2011 (292) - --MAY2011 (.)
	12. 25APR2011 (310) - 29APR2011 (314)
	13. 23MAY2011 (338) - 03JUN2011 (349)
Duration of AE	1. 4
	2. 2
	3. 4
	4. 10
	5. 12
	6. 4
	7. .
	8. 25
	9. 36
	10. 12
	11. .
	12. 5
	13. 12
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173058

Parameter	Value
	12. .
	13. .
Action taken	1. OTHER
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173061

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173061/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/64/N.A./FRANCE/YES
Medical history	Anaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	TARDYFERON
Adverse Events (AE) Preferred term	1. Anaemia 2. Colorectal cancer
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 28SEP2010 (35) - 14OCT2010 (51) 2. 05OCT2010 (42) - --------- (.)
Duration of AE	1. 17 2. .
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY 2. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
Outcome of event	1. RESOLVED 2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173063

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160173063/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/60/N.A./FRANCE/YES
Medical history	Gout, Insomnia, Hip arthroplasty, Arthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, COLCHIMAX [COLCHICINE + PAPAVER SOMNIFERUM POWDER + TIEMONIUM METHYLSULPHATE], IMOVANE, PARACETAMOL
Adverse Events (AE) Preferred term	1. Epistaxis 2. Haemoptysis 3. Panic attack 4. Haemoptysis 5. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 01NOV2010 (3) - 03NOV2010 (5) 2. 02NOV2010 (4) - 02NOV2010 (4) 3. 22NOV2010 (24) - 23NOV2010 (25) 4. 22NOV2010 (24) - 22NOV2010 (24) 5. 20JAN2011 (83) - 22JAN2011 (85)
Duration of AE	1. 3 2. 1 3. 2 4. 1 5. 3
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. OTHER 2. NONE 3. NONE 4. NONE 5. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160173063

Parameter	Value
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160183005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160183005/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/63/N.A./FRANCE/YES
Medical history	Diabetes mellitus, Hypertension, Pseudomonas infection, Asthma, Postmenopause, Ex-tobacco user
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, AMLOR, ATROVENT, AUGMENTIN, BRICANYL, CACIT VIT D3, CORTANCYL, DEROXAT, DI ANTALVIC, DIDRONEL [ETIDRONATE DISODIUM], DUPHALAC [LACTULOSE], FLIXONASE, LASILIX, OXYGEN, PULMICORT, SERETIDE, SERUM [NACL 9/1000 IN STERILE WATER FOR INJECTION], SPIRIVA, UNFRACTIONATED HEPARIN, VITAMIN K, ZOLPIDEM
Adverse Events (AE) Preferred term	1. Depression 2. Asthma 3. Hepatitis acute 4. Cardiac failure
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/YES/YES/YES 4. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 05JAN2008 (9) - --------- (.) 2. 12JAN2008 (16) - 14JAN2008 (18) 3. 14JAN2008 (18) - --------- (.) 4. 17JAN2008 (21) - 22JAN2008 (26)
Duration of AE	1. . 2. 3 3. . 4. 6
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg
Dose status on AE onset	1. . 2. . 3. . 4. F
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED 2. RESOLVED 3. WORSENED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160183005

Parameter	Value
	4. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160183005[5)]	SEVERE ACUTE HEPATITIS（PT：急性肝炎） 治験担当医はリバーロキサバンと報告事象との関連性があると判断した。しかしながら、ドイツ本社安全性部門は、本事象は心不全から併発した肺塞栓が肝および腎の低酸素状態を惹起し、肝酵素の上昇をもたらしたと考えられ、因果関係は否定できると評価している。弊社もリバーロキサバンが関与した可能性は低いと考えるが、報告事象とリバーロキサバンとの因果関係は完全には否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160193002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160193002/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/82/N.A./FRANCE/YES
Medical history	Anxiety, Appendicectomy, Arterial disorder, Bronchitis chronic, Hypertension, Type 2 diabetes mellitus, Obesity, Sleep apnoea syndrome, Prostate cancer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CASODEX, CERIS, ENANTONE, ENOXAPARIN, FUROSEMIDE, GLUCOR, INNOHEP, LANTUS, LOVENOX, NAFTIDROFURYL, NOVONORM, WARFARIN
Adverse Events (AE) Preferred term	1. Prostate cancer 2. Prostate cancer 3. Cataract
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 06FEB2008 (36) - 07FEB2008 (37) 2. 07FEB2008 (37) - --------- (.) 3. 26JUN2008 (177) - 28JUN2008 (179)
Duration of AE	1. 2 2. . 3. 3
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED 2. REMEDIAL DRUG THERAPY 3. OTHER
Outcome of event	1. IMPROVED 2. IMPROVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160193004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160193004/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/73/N.A./FRANCE/YES
Medical history	Osteoarthritis, Breast cyst, Bronchitis, Hypertension, Hysterectomy, Idiopathic thrombocytopenic purpura, Obesity, Osteoporosis, Splenectomy, Cognitive disorder, Depression
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTONEL, ART, CALCIUM SANDOZ, CHONDROSULF, COAPROVEL, CONTRAMAL, DAFALGAN, ESIDREX, EUPRESSYL, FIXICAL D3, MEDIATENSYL, MUCOMYST, SERESTA, SEROPLEX, TANAKAN
Adverse Events (AE) Preferred term	1. Bronchitis 2. Haemoptysis 3. Haematoma 4. Haematuria 5. Fracture 6. Pleural haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/YES/YES/YES 3. MILD/YES/NO/YES 4. MODERATE/YES/NO/YES 5. MILD/NO/NO/NO 6. MILD/YES/NO/NO
Start/stop date of event with relative date	1. 07APR2008 (89) - 07MAY2008 (119) 2. 11APR2008 (93) - 11APR2008 (93) 3. 24JUN2008 (167) - 31JUL2008 (204) 4. 27NOV2008 (323) - 29NOV2008 (325) 5. 08JAN2009 (365) - --------- (.) 6. 16JAN2009 (373) - 30JAN2009 (387)
Duration of AE	1. 31 2. 1 3. 38 4. 3 5. . 6. 15
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. F 6. F

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160193004

Parameter	Value
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. IMPROVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160193009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160193009/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/57/N.A./FRANCE/YES
Medical history	Anxiety, Asthma, Hypertension, Hypothyroidism, Menopause, Obesity, Sciatica, Food allergy, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTAZINE, BETARSEC, CLARYTINE, DAFLON [DIOSMIN + HESPERIDIN], DI ANTALVIC, DIANTALVIC, ENOXAPARIN, INIPOMP, KARDÉGIC, LEVOTHYROX, LIPANTHYL, LYSANXIA, ORELOX, POLARAMINE, SOLUPRED, SURBRONC, TANGANIL, TEGRETOL, VENTOLINE, WARFARIN, XYZALL
Adverse Events (AE) Preferred term	1. Bone pain 2. Haemorrhoids 3. Vaginal haemorrhage 4. Neuralgia 5. Back pain 6. Non-cardiac chest pain 7. Bronchitis 8. Vertigo 9. Angioedema
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 20FEB2008 (15) - 03MAR2008 (27) 2. 14MAR2008 (38) - 21MAR2008 (45) 3. 19APR2008 (74) - 19APR2008 (74) 4. 20APR2008 (75) - 01MAY2008 (86) 5. 09MAY2008 (94) - 09MAY2008 (94) 6. 09MAY2008 (94) - 09MAY2008 (94) 7. 09MAY2008 (94) - 17MAY2008 (102) 8. 02JUN2008 (118) - 04JUN2008 (120) 9. 27JUN2008 (143) - 28JUN2008 (144)
Duration of AE	1. 13 2. 8 3. 1 4. 12 5. 1 6. 1 7. 9 8. 3 9. 2

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160193009

Parameter	Value
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. OTHER
	6. OTHER
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160193009

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160193014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160193014/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/85/N.A./FRANCE/YES
Medical history	Atrial fibrillation, Cardiac failure, Hiatus hernia, Hip arthroplasty, Mitral valve incompetence, Transurethral prostatectomy, Renal colic, Osteoarthritis, Urethrotomy, Sciatica, Duodenitis, Intestinal congestion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLIN, BRONCHOKOD, CARDENSIEL, DAFALGAN, ENOXAPARIN, INIPOMP, KETODERM, LASILIX, OMEPRAZOLE, ROXITHROMYCINE, VITAMINE K, WARFARIN
Adverse Events (AE) Preferred term	1. Haematuria 2. Rash 3. Bronchitis 4. Overdose 5. Conjunctival haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/YES/YES 5. MODERATE/YES/NO/YES
Start/stop date of event with relative date	1. 07APR2008 (5) - 13APR2008 (11) 2. 08APR2008 (6) - 09APR2008 (7) 3. 25APR2008 (23) - 04MAY2008 (32) 4. 02MAY2008 (30) - 02MAY2008 (30) 5. 24AUG2008 (144) - 27AUG2008 (147)
Duration of AE	1. 7 2. 2 3. 10 4. 1 5. 4
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. DOSE OF STUDY DRUG REDUCED,REMEDIAL DRUG THERAPY 5. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160193014

Parameter	Value
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160193032

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160193032/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/73/N.A./FRANCE/YES
Medical history	Appendicectomy, B-cell lymphoma stage III, Inguinal hernia repair, Neck pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BROCHOKOD, ENOXAPARIN, INEXIUM, NECYRANE, PANENZA, WARFARIN
Adverse Events (AE) Preferred term	1. Epistaxis
	2. Influenza
	3. Abdominal pain upper
	4. Pain in extremity
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/YES/YES
	4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 31AUG2009 (180) - 02SEP2009 (182)
	2. 15NOV2009 (256) - 27NOV2009 (268)
	3. 07FEB2010 (340) - 08FEB2010 (341)
	4. 07FEB2010 (340) - 08FEB2010 (341)
Duration of AE	1. 3
	2. 13
	3. 2
	4. 2
Dose on AE onset	1.
	2.
	3.
	4.
Dose status on AE onset	1.
	2.
	3.
	4.
Action taken	1. DOSE OF STUDY DRUG REDUCED
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160193032

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160193035

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160193035/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/56/N.A./FRANCE/YES
Medical history	Head injury, Hemiplegia, Prostatism, Cerebrovascular accident, Subdural haematoma evacuation, Intervertebral disc protrusion, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CIPROFLOXACINE, CRESTOR, JOSIR LP, KEPPRA, LIORESAL, NEUROTIN, PARACETAMOL, SPASFON LYOC
Adverse Events (AE) Preferred term	1. Malignant melanoma 2. Malignant melanoma 3. Wound haemorrhage 4. Haematuria 5. Urinary retention 6. Urinary tract infection 7. Malignant melanoma
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/YES/YES 3. MILD/YES/NO/YES 4. MILD/YES/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 25JUN2009 (6) - 10AUG2009 (52) 2. 10AUG2009 (52) - 14AUG2009 (56) 3. 11AUG2009 (53) - 12AUG2009 (54) 4. 12AUG2009 (54) - 15AUG2009 (57) 5. 12AUG2009 (54) - 15AUG2009 (57) 6. 24SEP2009 (97) - 15OCT2009 (118) 7. 28SEP2009 (101) - 29SEP2009 (102)
Duration of AE	1. 47 2. 5 3. 2 4. 4 5. 4 6. 22 7. 2
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg
Dose status on AE onset	1. . 2. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160193035

Parameter	Value
	3. .
	4. .
	5. .
	6. .
	7. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY,OTHER
	3. OTHER
	4. OTHER
	5. OTHER
	6. REMEDIAL DRUG THERAPY
	7. OTHER
Outcome of event	1. WORSENED
	2. IMPROVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160193042

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160193042/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/47/N.A./FRANCE/YES
Medical history	Dental caries, Hepatitis C, Insomnia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, AMOXICILLINE, DOLIPRANE, ENOXAPARIN, ENOXAPARINE, WARFARIN
Adverse Events (AE) Preferred term	1. Pharyngeal cyst
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 31MAR2010 (112) - 02APR2010 (114)
Duration of AE	1. 3
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160193042[1)]	RIGHT VALLECULAR CYST（PT：咽頭嚢腫） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリンの関与を示す情報がないため、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160193048

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160193048/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/20/N.A./FRANCE/YES
Medical history	Migraine
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CONTRAMAL, ENOXAPARIN, LUTERAN, WARFARIN
Adverse Events (AE) Preferred term	1. Haemothorax
	2. Alopecia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
	2. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 28APR2010 (14) - 04MAY2010 (20)
	2. 02SEP2010 (141) - --------- (.)
Duration of AE	1. 7
	2. .
Dose on AE onset	1.
	2.
Dose status on AE onset	1.
	2.
Action taken	1. OTHER
	2. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160193048[4),3)]	HEMORRHAGIC PLEURAL EFFUSION（PT：血胸） 治験担当医は、ワルファリンとの因果関係について否定できると判断した。弊社は、ワルファリンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。 治験担当医はエノキサパリンと報告事象との因果関係評価を行っていない。弊社は、エノキサパリンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160203003/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/71/N.A./FRANCE/YES
Medical history	Angina pectoris, Decreased appetite, Anxiety, Aortic stenosis, Hypertension, Retinal vein occlusion, Hypothyroidism, Knee arthroplasty, Macular oedema, Myocardial infarction, Tachycardia, Depressive symptom, Dyslipidaemia, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACULAR 0.5, APROVEL, DIAFUSOR, DIFFU K, FORADIL, FUROSEMIDE, LAROXYL, LESCOL, LEVOTHYROX, NATISPRAY, NITRENDIPINE, OMEPRAZOLE, PRAVADUAL [PRAVADUAL INGREDIENTS ARE ASPIRIN (81MG) AND PRAVASTATIN SODIUM (40MG, RYTHMODAN LP, SEROPLEX, TRANXENE, XALATAN 0.005
Adverse Events (AE) Preferred term	1. Depressive symptom 2. Dry mouth 3. Lip dry 4. Depressive symptom 5. Epistaxis 6. Bronchitis 7. Chest pain 8. Acute left ventricular failure 9. Angina pectoris 10. Angina unstable 11. Epistaxis 12. Haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/YES/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. SEVERE/NO/YES/YES 9. MILD/NO/NO/YES 10. SEVERE/NO/YES/NO 11. MILD/NO/NO/NO 12. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --JUL2008 (.) - --SEP2008 (.) 2. 12DEC2007 (1) - 15DEC2007 (4) 3. 12DEC2007 (1) - 15DEC2007 (4) 4. 14FEB2008 (65) - --APR2008 (.) 5. 27MAR2008 (107) - 06APR2008 (117) 6. 27MAR2008 (107) - 12APR2008 (123) 7. 07JUN2008 (179) - 07JUN2008 (179) 8. 20AUG2008 (253) - 21AUG2008 (254) 9. 20AUG2008 (253) - 20AUG2008 (253) 10. 26SEP2008 (290) - 27SEP2008 (291)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203003

Parameter	Value
	11. 19OCT2008 (313) - 19OCT2008 (313)
	12. 01NOV2008 (326) - --------- (.)
Duration of AE	1. .
	2. 4
	3. 4
	4. .
	5. 11
	6. 17
	7. 1
	8. 2
	9. 1
	10. 2
	11. 1
	12. .
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. F
	11. F
	12. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203003

Parameter	Value
	7. NONE
	8. REMEDIAL DRUG THERAPY,OTHER
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160203006/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/77/N.A./FRANCE/YES
Medical history	Anaemia, Arthralgia, Cholecystectomy, Epilepsy, Hypercholesterolaemia, Phlebitis superficial
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLIN, ANTIGRIPPE VACCINE, APAROXAL, DAFALGAN, LIPANOR, MACULA Z [LUTEINE,ZEAXANTHINE,CUIVRE,ZINC,VIT E,ACID ASCORBIC,POLYNSAT ACID RICH, PARACETAMOL, PARIET, TEGRETOL, ZECLAR
Adverse Events (AE) Preferred term	1. Dyspnoea exertional 2. Asthenia 3. Pain in extremity 4. Abdominal pain upper 5. Extranodal marginal zone B-cell lymphoma (MALT type) 6. Helicobacter infection 7. Hepatitis C 8. Ovarian cyst 9. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JUN2008 (.) - --DEC2008 (.) 2. --JUL2008 (.) - --AUG2008 (.) 3. 05MAY2008 (25) - 06MAY2008 (26) 4. 02JUL2008 (83) - 17JUL2008 (98) 5. 22JUL2008 (103) - --------- (.) 6. 22JUL2008 (103) - --SEP2008 (.) 7. 07AUG2008 (119) - --------- (.) 8. 08SEP2008 (151) - --------- (.) 9. 17FEB2009 (313) - 27FEB2009 (323)
Duration of AE	1. . 2. . 3. 2 4. 16 5. . 6. . 7. . 8. . 9. 11
Dose on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203006

Parameter	Value
	2.
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY,OTHER
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. IMPROVED
	6. RESOLVED
	7. INSUFFICIENT FOLLOW-UP
	8. INSUFFICIENT FOLLOW-UP
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160203009/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/82/N.A./FRANCE/YES
Medical history	Dysuria, Peripheral arterial occlusive disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, HEPARINE IVSE, PARACETAMOL, SMECTA [SMECTITE+ VANILLIN + SACCHARIN SODIUM+ GLUCOSE MONOHYDRATE], SPECIAFOLDINE, WARFARIN
Adverse Events (AE) Preferred term	1. Folate deficiency 2. Diarrhoea 3. Ileus
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 29JUL2008 (1) - --------- (.) 2. 30JUL2008 (2) - 30JUL2008 (2) 3. 01AUG2008 (4) - --------- (.)
Duration of AE	1. . 2. 1 3. .
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. RESOLVED 3. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160203010/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/66/N.A./FRANCE/YES
Medical history	Appendicectomy, Benign breast lump removal, Bronchopneumonia, Cholecystectomy, Constipation, Gastric ulcer, Hiatus hernia, Hypertension, Lumbar spinal stenosis, Menopause, Drug hypersensitivity, Sciatica, Urticaria, Varicose vein operation, Upper limb fracture, Cystocele repair
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, DAFALGAN, DICETEL, ENOXAPARIN, FORTZAAR, INEXIUM, ISOPTINE LP, IXPRIM, KETAMINE, LAROXYL, LYRICA, METEOXANE, MONOCRIXO, MOTILIUM, RIFAMYCINE, RIVOTRIL, STILNOX, TRANSIPEG [MACROGOL 3350, SODIUM CHLORIDE, SODIUM SULFATE ANHYDROUS , POTASSIUM, WARFARIN
Adverse Events (AE) Preferred term	1. Chest pain 2. Eye infection 3. Complex regional pain syndrome 4. Complex regional pain syndrome 5. Complex regional pain syndrome
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 07AUG2008 (3) - 07AUG2008 (3) 2. 08AUG2008 (4) - 15AUG2008 (11) 3. 25SEP2008 (52) - 13OCT2008 (70) 4. 13OCT2008 (70) - 05DEC2008 (123) 5. 06DEC2008 (124) - --------- (.)
Duration of AE	1. 1 2. 8 3. 19 4. 54 5. .
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203010

Parameter	Value
Outcome of event	5. NONE 1. RESOLVED 2. RESOLVED 3. WORSENED 4. RESOLVED 5. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160203012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/86/N.A./FRANCE/YES
Medical history	Atrial fibrillation, Constipation, Hypertension, Osteoarthritis, Dyslipidaemia, Heart valve replacement
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTISKENAN, ACUPAN, AMOXICILLINE, ART, CALCIPARINE, CARBOCYSTEINE, CARDENSIEL, CLAMOXYL, CORDARONE, COVERSYL, DOLIPRANE, ENOXAPARIN, ERYTHROMYCINE, FLAGYL, FORLAX, GENTAMICINE, HEMIGOXINE, HEPARINE, INEXIUM, INFLUVAC, INNOHEP, KARDEGIC, KASKADIL, LANSOYL, LASILIX, LOVENOX, PARACETAMOL, PERFALGAN, PRIMPERAN, ROCEPHINE, SIMVASTATINE, SOLUPRED, SPASFON, TOPALGIC [THE INGREDIENT IS TRAMADOL HYDROCHLORIDE], VIT K, WARFARIN
Adverse Events (AE) Preferred term	1. Melaena 2. Transfusion-related immunomodulation reaction 3. Atrial fibrillation 4. Cardiac failure 5. Back pain 6. Nausea 7. Bronchitis 8. Muscle haemorrhage 9. Pain in extremity 10. Constipation 11. Dyspnoea 12. Bronchopneumonia 13. International normalised ratio increased 14. Asthenia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. SEVERE/YES/YES/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. SEVERE/NO/YES/YES 13. MILD/YES/NO/YES 14. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 05JAN2009 (42) - 06JAN2009 (43) 2. 05JAN2009 (42) - 05JAN2009 (42) 3. 06JAN2009 (43) - --------- (.) 4. 06JAN2009 (43) - --------- (.) 5. 07JAN2009 (44) - 09JAN2009 (46) 6. 09JAN2009 (46) - 09JAN2009 (46)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203012

Parameter	Value
	7. 16FEB2009 (84) - 24FEB2009 (92)
	8. 27FEB2009 (95) - 06MAR2009 (102)
	9. 28FEB2009 (96) - --MAR2009 (.)
	10. 03MAR2009 (99) - 06MAR2009 (102)
	11. 20MAY2009 (177) - 20MAY2009 (177)
	12. 15JUN2009 (203) - 25JUN2009 (213)
	13. 15JUN2009 (203) - 23JUN2009 (211)
	14. 06NOV2009 (347) - 19NOV2009 (360)
Duration of AE	1. 2
	2. 1
	3. .
	4. .
	5. 3
	6. 1
	7. 9
	8. 8
	9. .
	10. 4
	11. 1
	12. 11
	13. 9
	14. 14
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203012

Parameter	Value
	9.
	10.
	11.
	12.
	13.
	14.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. STUDY DRUG DISCONTINUED AND RESTARTED
	14. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160203012[2),1)]	HEMATOMA PSOAS（PT：筋肉内出血） 治験担当医はエノキサパリンと報告事象との関連性があると判断した。弊社は、エノキサパリン投与終了約 3 か月後の発現であり、時間的関連性がないため、因果関係は否定できると考える。 MELENA（PT：メレナ） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリン投与終了約 5 週間後の発現のため、時間的関連性がないことから、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203019

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160203019/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/67/N.A./FRANCE/YES
Medical history	Anaemia, Hypercholesterolaemia, Hypertension, Hysterectomy, Drug hypersensitivity, Phlebitis, Type 2 diabetes mellitus, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, FLAGYL, HEPARINE, INEXIUM, LASILIX, OFLOCET, PARACETAMOL, PERFALGAN, ROCEPHINE, TARDYFERON, VITAMINE K
Adverse Events (AE) Preferred term	1. Gastritis 2. Hyperthermia 3. Sepsis 4. Adrenal mass 5. Goitre 6. Haematuria 7. Rectal haemorrhage 8. Rectal cancer 9. Tumour pain 10. Diabetes mellitus 11. Prothrombin level decreased 12. Procedural pain 13. Hypertension 14. Vomiting
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. SEVERE/NO/YES/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/NO 11. MILD/NO/NO/NO 12. MODERATE/NO/NO/NO 13. MILD/NO/NO/NO 14. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 12MAY2009 (1) - --------- (.) 2. 14MAY2009 (3) - 17MAY2009 (6) 3. 15MAY2009 (4) - 18MAY2009 (7) 4. 15MAY2009 (4) - --------- (.) 5. 15MAY2009 (4) - --------- (.) 6. 16MAY2009 (5) - 11JUN2009 (31) 7. 18MAY2009 (7) - 27MAY2009 (16) 8. 18MAY2009 (7) - 27MAY2009 (16) 9. 18MAY2009 (7) - 25MAY2009 (14)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203019

Parameter	Value
	10. 24MAY2009 (13) - 30MAY2009 (19)
	11. 25MAY2009 (14) - 26MAY2009 (15)
	12. 27MAY2009 (16) - --------- (.)
	13. 28MAY2009 (17) - 03JUN2009 (23)
	14. 03JUN2009 (23) - 03JUN2009 (23)
Duration of AE	1. .
	2. 4
	3. 4
	4. .
	5. .
	6. 27
	7. 10
	8. 10
	9. 8
	10. 7
	11. 2
	12. .
	13. 7
	14. 1
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 15 mg
	12. 15 mg
	13. 15 mg
	14. 15 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. F
	11. F

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203019

Parameter	Value
	12. F
	13. F
	14. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY,OTHER
	7. REMEDIAL DRUG THERAPY,OTHER
	8. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. NONE
Outcome of event	1. INSUFFICIENT FOLLOW-UP
	2. RESOLVED
	3. RESOLVED
	4. INSUFFICIENT FOLLOW-UP
	5. INSUFFICIENT FOLLOW-UP
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. INSUFFICIENT FOLLOW-UP
	13. RESOLVED
	14. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203024

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160203024/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/80/N.A./FRANCE/YES
Medical history	Prostate cancer, Hypertension, Inguinal hernia repair, Prostatectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPINE, ENOXAPARIN, ESTRACYT, EXFORGE, TAREG, WARFARIN, ZOLADEX
Adverse Events (AE) Preferred term	1. Prostate cancer recurrent
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 15MAR2010 (76) - --------- (.)
Duration of AE	1. .
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203026

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160203026/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/76/N.A./FRANCE/YES
Medical history	Drug hypersensitivity, Appendicectomy, Benign prostatic hyperplasia, Hypertension, Constipation, Coronary artery disease, Drug hypersensitivity, Drug hypersensitivity, Hiatus hernia, Osteoporosis, Angina unstable, Intervertebral disc compression, Myocardial ischaemia, Venous insufficiency, Dyslipidaemia, Drug intolerance, Peripheral arterial occlusive disease, Cataract operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, AMLOR, AUGMENTIN, CEFAZOLINE, CISATRACURIUM, COUMADINE, DEXERYL [GLYCEROL, PARAFFIN LIQUID , WHITE SOFT PARAFFIN], EDUCTYL, FORLAX, MOLSIDOMINE, OMEPRAZOLE, OROCAL D3, PARACETAMOL, PERFALGAN, PERMIXON, PRAVASTATINE, PROPOFOL, RIVOTRIL, SUFENTANYL, TEMERIT, TOPALGIC [TRAMADOL CHLORHYDRATE], ZALDIAR
Adverse Events (AE) Preferred term	1. Dry skin 2. Memory impairment 3. Somnolence 4. Balance disorder 5. Back pain 6. Inguinal hernia 7. Inguinal hernia 8. Neuralgia 9. Neuralgia 10. International normalised ratio increased 11. International normalised ratio increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/YES/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/NO 11. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --MAY2010 (.) - --------- (.) 2. --AUG2010 (.) - --------- (.) 3. --AUG2010 (.) - 18SEP2010 (191) 4. --SEP2010 (.) - --------- (.) 5. 26MAR2010 (15) - 14JUL2010 (125) 6. 28MAY2010 (78) - 16JUN2010 (97) 7. 17JUN2010 (98) - 20JUN2010 (101) 8. 21JUN2010 (102) - --------- (.) 9. 21JUN2010 (102) - --------- (.) 10. 13SEP2010 (186) - 16SEP2010 (189)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203026

Parameter	Value
	11. 24SEP2010 (197) - 24SEP2010 (197)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. 111
	6. 20
	7. 4
	8. .
	9. .
	10. 4
	11. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5. 15 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4.
	5. .
	6. .
	7. I
	8. .
	9. .
	10. F
	11. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203026

Parameter	Value
Outcome of event	11. OTHER
	1. INSUFFICIENT FOLLOW-UP
	2. UNCHANGED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. WORSENED
	7. RESOLVED
	8. IMPROVED
	9. IMPROVED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203028

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160203028/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/36/N.A./FRANCE/YES
Medical history	Anxiety, Depression, Adenomatous polyposis coli, Conversion disorder, Insomnia, Pain in jaw, Meningioma, Neoplasm, Osteoma, Osteoma, Photosensitivity reaction, Suicide attempt, Suicide attempt, Thyroid neoplasm, Colectomy total, Female sterilisation, Malnutrition, Iodine allergy, Gastrointestinal neoplasm, Adrenalectomy, Fallopian tube operation, Volvulus of small bowel, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTISKENAN, ACUPAN, ARIXTRA, ATARAX, AUGMENTIN, AZANTAC, BETNEVAL, CALCIDOSE, CEFPODOXIME, CELOCURINE, CHLORURE SODIIUM, CONTRAMAL, CYNOMEL, DIFFU K, DOLIPRANE, DUPHALAC [LACTULOSE ALONE], ENOXAPARIN, FORLAX, GAVISCON, HEMISUCCINATE HYDROCORTISONE, INNOHEP, LEVOTHYROX, LEXOMIL, LOVENOX, MORPHINE, NORMACOL, OMEPRAZOLE, PERFALGAN, PHOSPHONEUROS, PROFENID, PROPOFOL, RADIOACTIVE IODINE, RAPIFEN, SEVOFLURANE, SKENAN LP, SOLUMEDROL, STILNOX, SULFENTANYL, TRACRIUM, UN ALPHA, VITAMIN C, WARFARIN
Adverse Events (AE) Preferred term	1. Pain in jaw 2. Asthenia 3. Salivary gland enlargement 4. Breast pain 5. Chest pain 6. Cough 7. Dyspnoea exertional 8. Sputum discoloured 9. International normalised ratio increased 10. Odynophagia 11. Dyspepsia 12. Nausea 13. Metrorrhagia 14. International normalised ratio increased 15. Chest pain 16. Chest pain 17. Pain in extremity 18. Thyroid cancer 19. Thyroid cancer 20. Hypocalcaemia 21. Respiratory tract congestion 22. Hypothyroidism 23. Thyroid cancer 24. Diarrhoea 25. Vomiting 26. Nausea 27. Somnolence 28. Metrorrhagia 29. Hypercalcaemia 30. Hypercalcaemia

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203028

Parameter	Value
	31. International normalised ratio increased
	32. Headache
	33. Dehydration
	34. Hypokalaemia
	35. Hypophosphataemia
	36. Abdominal pain
	37. Back pain
	38. Rash papular
	39. Thyroid cancer
	40. Hypotension
	41. Metrorrhagia
	42. Melaena
	43. Metrorrhagia
	44. Sinusitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/NO/YES
	4. MILD/NO/NO/YES
	5. MILD/NO/NO/YES
	6. MILD/NO/NO/YES
	7. MILD/NO/NO/YES
	8. MILD/NO/NO/YES
	9. MILD/YES/NO/YES
	10. MILD/NO/NO/YES
	11. MILD/NO/NO/YES
	12. MILD/NO/NO/YES
	13. MILD/YES/NO/YES
	14. MILD/YES/NO/YES
	15. MILD/NO/NO/YES
	16. MODERATE/NO/YES/YES
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. SEVERE/NO/YES/YES
	20. MODERATE/NO/NO/YES
	21. MILD/NO/NO/YES
	22. MILD/NO/NO/YES
	23. MILD/NO/NO/YES
	24. MILD/NO/NO/YES
	25. MILD/NO/NO/YES
	26. MILD/NO/NO/YES
	27. MILD/NO/NO/YES
	28. MILD/YES/NO/YES
	29. MODERATE/NO/NO/YES
	30. SEVERE/NO/YES/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203028

Parameter	Value
	31. MILD/YES/NO/YES
	32. MILD/NO/NO/YES
	33. MILD/NO/NO/YES
	34. MILD/NO/NO/YES
	35. MILD/NO/NO/YES
	36. MILD/NO/NO/YES
	37. MILD/NO/NO/YES
	38. MILD/NO/NO/YES
	39. MILD/NO/YES/YES
	40. MILD/NO/NO/YES
	41. MILD/YES/NO/YES
	42. MILD/YES/NO/YES
	43. MILD/YES/NO/YES
	44. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --APR2011 (.) - 01JUN2011 (281)
	2. 25AUG2010 (1) - 28APR2011 (247)
	3. 27AUG2010 (3) - 31AUG2010 (7)
	4. 04SEP2010 (11) - 04SEP2010 (11)
	5. 04SEP2010 (11) - --SEP2010 (.)
	6. 04SEP2010 (11) - 08SEP2010 (15)
	7. 04SEP2010 (11) - 29SEP2010 (36)
	8. 06SEP2010 (13) - --JAN2011 (.)
	9. 06SEP2010 (13) - 07SEP2010 (14)
	10. 13SEP2010 (20) - 26NOV2010 (94)
	11. 13SEP2010 (20) - 26NOV2010 (94)
	12. 27SEP2010 (34) - 27SEP2010 (34)
	13. 13OCT2010 (50) - 17OCT2010 (54)
	14. 22OCT2010 (59) - 18NOV2010 (86)
	15. 04NOV2010 (72) - 18NOV2010 (86)
	16. 18NOV2010 (86) - 23NOV2010 (91)
	17. 24NOV2010 (92) - 25NOV2010 (93)
	18. 07FEB2011 (167) - 14FEB2011 (174)
	19. 15FEB2011 (175) - 19FEB2011 (179)
	20. 17FEB2011 (177) - 27FEB2011 (187)
	21. 17FEB2011 (177) - 17FEB2011 (177)
	22. 17FEB2011 (177) - --------- (.)
	23. 20FEB2011 (180) - 03APR2011 (222)
	24. 25FEB2011 (185) - 03MAR2011 (191)
	25. 25FEB2011 (185) - 02MAR2011 (190)
	26. 25FEB2011 (185) - 03MAR2011 (191)
	27. 25FEB2011 (185) - 03MAR2011 (191)
	28. 27FEB2011 (187) - 04MAR2011 (192)
	29. 28FEB2011 (188) - 01MAR2011 (189)
	30. 02MAR2011 (190) - 04MAR2011 (192)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203028

Parameter	Value
	31. 02MAR2011 (190) - 07MAR2011 (195)
	32. 02MAR2011 (190) - 03MAR2011 (191)
	33. 02MAR2011 (190) - 04MAR2011 (192)
	34. 03MAR2011 (191) - 03MAR2011 (191)
	35. 03MAR2011 (191) - 03MAR2011 (191)
	36. 03MAR2011 (191) - 03MAR2011 (191)
	37. 03MAR2011 (191) - 03MAR2011 (191)
	38. 24MAR2011 (212) - 01JUN2011 (281)
	39. 04APR2011 (223) - 07APR2011 (226)
	40. 04APR2011 (223) - 28APR2011 (247)
	41. 06MAY2011 (255) - 07MAY2011 (256)
	42. 06MAY2011 (255) - 07MAY2011 (256)
	43. 23MAY2011 (272) - 28MAY2011 (277)
	44. 18SEP2011 (390) - --------- (.)
Duration of AE	1. .
	2. 247
	3. 5
	4. 1
	5. .
	6. 5
	7. 26
	8. .
	9. 2
	10. 75
	11. 75
	12. 1
	13. 5
	14. 28
	15. 15
	16. 6
	17. 2
	18. 8
	19. 5
	20. 11
	21. 1
	22. .
	23. 43
	24. 7
	25. 6
	26. 7
	27. 7
	28. 6
	29. 2
	30. 3

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203028

Parameter	Value
	31. 6
	32. 2
	33. 3
	34. 1
	35. 1
	36. 1
	37. 1
	38. 70
	39. 4
	40. 25
	41. 2
	42. 2
	43. 6
	44. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
	27.
	28.
	29.
	30.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203028

Parameter	Value
	31.
	32.
	33.
	34.
	35.
	36.
	37.
	38.
	39.
	40.
	41.
	42.
	43.
	44.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
	27.
	28.
	29.
	30.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203028

Parameter	Value
	31.
	32.
	33.
	34.
	35.
	36.
	37.
	38.
	39.
	40.
	41.
	42.
	43.
	44.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. STUDY DRUG DISCONTINUED AND RESTARTED
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. NONE
	14. STUDY DRUG DISCONTINUED AND RESTARTED
	15. NONE
	16. NONE
	17. NONE
	18. NONE
	19. OTHER
	20. REMEDIAL DRUG THERAPY
	21. REMEDIAL DRUG THERAPY
	22. REMEDIAL DRUG THERAPY
	23. NONE
	24. NONE
	25. NONE
	26. NONE
	27. NONE
	28. NONE
	29. NONE
	30. REMEDIAL DRUG THERAPY,OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203028

Parameter	Value
	31. STUDY DRUG DISCONTINUED AND RESTARTED
	32. NONE
	33. OTHER
	34. REMEDIAL DRUG THERAPY
	35. REMEDIAL DRUG THERAPY
	36. REMEDIAL DRUG THERAPY
	37. REMEDIAL DRUG THERAPY
	38. REMEDIAL DRUG THERAPY
	39. REMEDIAL DRUG THERAPY,OTHER
	40. NONE
	41. NONE
	42. NONE
	43. STUDY DRUG DISCONTINUED AND RESTARTED
	44. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. UNCHANGED
	23. RESOLVED
	24. RESOLVED
	25. RESOLVED
	26. RESOLVED
	27. RESOLVED
	28. RESOLVED
	29. WORSENED
	30. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160203028

Parameter	Value
	31. RESOLVED
	32. RESOLVED
	33. RESOLVED
	34. RESOLVED
	35. RESOLVED
	36. RESOLVED
	37. RESOLVED
	38. RESOLVED
	39. RESOLVED
	40. RESOLVED
	41. RESOLVED
	42. RESOLVED
	43. RESOLVED
	44. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160213006/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/93/N.A./FRANCE/YES
Medical history	Aortic valve incompetence, Asthma, Atrial fibrillation, Cardiac failure, Cholecystectomy, Bronchitis chronic, Meniere's disease, Menopause, Tibia fracture, Skin ulcer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADANCOR, ATROVENT, AUGMENTIN, CARDENSIEL, COUMADINE, DIFFU K, ENOXAPARIN, ESIDREX, LASILIX, PEVARYL, PULMICORT, RENITEC, SPECIAFOLDINE, WARFARIN, XATRAL LP
Adverse Events (AE) Preferred term	1. Skin irritation 2. Dyspnoea 3. Bladder dilatation 4. Haematuria 5. Urinary tract infection 6. Cardiac failure 7. Wound haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 04FEB2008 (5) - --------- (.) 2. 11FEB2008 (12) - 13FEB2008 (14) 3. 13FEB2008 (14) - 06MAR2008 (36) 4. 15FEB2008 (16) - 17FEB2008 (18) 5. 15FEB2008 (16) - 21FEB2008 (22) 6. 15FEB2008 (16) - 22FEB2008 (23) 7. 30JUN2008 (152) - 30JUN2008 (152)
Duration of AE	1. . 2. 3 3. 23 4. 3 5. 7 6. 8 7. 1
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213006

Parameter	Value
	3.
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY,OTHER
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY,OTHER
	7. NONE
Outcome of event	1. IMPROVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160213008/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/74/N.A./FRANCE/YES
Medical history	Anaemia, Ligament sprain, Arthroscopy, Depression, Diarrhoea, Haemorrhoid operation, Hypertension, Mastoiditis, Menopause, Obesity, Uterine polypectomy, Dyslipidaemia, Breast haematoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	APROVEL, ATHYMIL, COUMADINE, CRESTOR, ENOXAPARIN, ESIDREX, LOVENOX, NEBILOX, SPECIAFOLDINE, STABLON, WARFARIN, XANAX, ZOLPIDEM
Adverse Events (AE) Preferred term	1. Anorectal disorder 2. Anaemia 3. Pleural effusion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. SEVERE/YES/YES/NO 3. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 01MAY2008 (73) - 05MAY2008 (77) 2. 13SEP2008 (208) - 06OCT2008 (231) 3. 13SEP2008 (208) - --------- (.)
Duration of AE	1. 5 2. 24 3. .
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED 2. OTHER 3. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160213014/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/79/N.A./FRANCE/YES
Medical history	Haemangioma, Appendicectomy, Hypertension, Seborrhoeic dermatitis, Coronary artery bypass, Stent placement, Myocardial ischaemia, Dyslipidaemia, Age-related macular degeneration
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPEGIC, CONTRAMAL, CORVASAL, COZAAR, DIFFU K, DOLIPRANE, DUROGESIC, ENOXAPARIN, ESIDREX, FORLAX, JAMYLÈNE, KARDEGIC, LIPANTHYL, LOVENOX, MONOTILDIEM, OXYCONTIN, OXYNORM, PRIMPERAN, VASTAREL, VITAMIN K1, WARFARIN, XANAX, ZOCOR
Adverse Events (AE) Preferred term	1. Hypokalaemia 2. Pain 3. Constipation 4. Nausea 5. Hypokalaemia 6. Anxiety 7. Bladder neoplasm 8. Traumatic haematoma 9. Joint dislocation 10. Anaemia 11. Rib fracture
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/NO 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/YES/YES 8. MODERATE/YES/NO/YES 9. SEVERE/NO/YES/YES 10. MODERATE/NO/NO/YES 11. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 27JUN2008 (1) - 30JUN2008 (4) 2. 27JUN2008 (1) - 14JUL2008 (18) 3. 03JUL2008 (7) - 18JUL2008 (22) 4. 07JUL2008 (11) - 08JUL2008 (12) 5. 07JUL2008 (11) - 11JUL2008 (15) 6. 13JUL2008 (17) - --------- (.) 7. 22SEP2008 (88) - 25SEP2008 (91) 8. 10OCT2008 (106) - 27OCT2008 (123) 9. 10OCT2008 (106) - 27OCT2008 (123) 10. 10OCT2008 (106) - 20OCT2008 (116) 11. 10OCT2008 (106) - 27OCT2008 (123)
Duration of AE	1. 4 2. 18

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213014

Parameter	Value
	3. 16
	4. 2
	5. 5
	6. .
	7. 4
	8. 18
	9. 18
	10. 11
	11. 18
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	8. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	9. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	10. REMEDIAL DRUG THERAPY
	11. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213014

Parameter	Value
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160213021/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/89/N.A./FRANCE/YES
Medical history	Atrial fibrillation, Diverticulum intestinal, Gastrooesophageal reflux disease, Restless legs syndrome, Urinary incontinence
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT, AUGMENTIN, COLCHIMAX [COLCHICINE + PAPAVER SOMNIFERUM POWDER + TIEMONIUM METHYLSULPHATE], CORDARONE, DAFALGAN, DEXERYL [GLYCEROL,PARAFFIN, LIQUID,WHITE SOFT PARAFFIN.], DIFFU K, ECONAZOL, ENOXAPARIN, ENOXAPARIN PREVENTIVE DOSE, FLAGYL, HEMIGOXINE, IMODIUM, INEXIUM, INIPOMP, KALEORID, LASILIX, PEVARYL, PULMICORT, ROCEPHINE, SMECTA [SMECTITE + SACCHARIN SODIUM + GLUCOSE MONOHYDRATE], SOLUDACTONE, SOLUMEDROL, UNFRACTIONATED HEPARIN, UNFRACTIONNED HEPARIN, VITAMINE K, WARFARIN
Adverse Events (AE) Preferred term	1. Haemoptysis 2. Lung infection 3. Overdose 4. Diarrhoea 5. Weight decreased 6. Hyperthyroidism 7. Fungal infection 8. Epistaxis 9. Hypokalaemia 10. Fungal skin infection 11. Asthenia 12. Decreased appetite 13. Cardiac failure 14. Gait disturbance 15. Hyperthyroidism 16. Nausea 17. Muscular weakness
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/NO/YES 3. MODERATE/YES/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/YES/NO/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MODERATE/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MODERATE/NO/NO/YES 15. MODERATE/NO/YES/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213021

Parameter	Value
	16. MILD/NO/NO/YES
	17. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 23DEC2008 (4) - 23DEC2008 (4)
	2. 23DEC2008 (4) - 07JAN2009 (19)
	3. 27DEC2008 (8) - 01JAN2009 (13)
	4. 31DEC2008 (12) - 02JAN2009 (14)
	5. 02JAN2009 (14) - 16APR2009 (118)
	6. 16JAN2009 (28) - 26MAR2009 (97)
	7. 04FEB2009 (47) - 05APR2009 (107)
	8. 15FEB2009 (58) - --------- (.)
	9. 19FEB2009 (62) - --------- (.)
	10. 19FEB2009 (62) - --------- (.)
	11. 19FEB2009 (62) - --------- (.)
	12. 19FEB2009 (62) - --------- (.)
	13. 19FEB2009 (62) - --------- (.)
	14. 19FEB2009 (62) - --------- (.)
	15. 26MAR2009 (97) - --------- (.)
	16. 26MAR2009 (97) - --------- (.)
	17. 02APR2009 (104) - --------- (.)
Duration of AE	1. 1
	2. 16
	3. 6
	4. 3
	5. 105
	6. 70
	7. 61
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213021

Parameter	Value
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. OTHER
	7. REMEDIAL DRUG THERAPY
	8. STUDY DRUG DISCONTINUED AND RESTARTED
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. OTHER
	12. OTHER
	13. REMEDIAL DRUG THERAPY
	14. OTHER
	15. OTHER
	16. NONE
	17. NONE
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213021

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. WORSENED
	7. RESOLVED
	8. UNCHANGED
	9. UNCHANGED
	10. UNCHANGED
	11. UNCHANGED
	12. UNCHANGED
	13. UNCHANGED
	14. UNCHANGED
	15. IMPROVED
	16. UNCHANGED
	17. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160213029/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/40/N.A./FRANCE/YES
Medical history	Anxiety, Haemoptysis, Peptic ulcer, Hepatic steatosis, Alcohol use
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALFENTANIL, AUGMENTIN, COLCHICINE, CONTRAMAL, CONTRAMAL LP, DOLIPRANE, ENOXAPARIN, FORLAX, HEMISUCCINATE D'HYDOCORTISONE, HEMISUCCINATE D'HYDROCORTISONE, HYDROXYZINE, HYPNOVEL, IMOVANE, INEXIUM, INNOHEP, MICROLAX [SODIUM CITRATE + SODIUM LAURYL SULFOACETATE + SORBITOL], NICOPATCH, PERFALGAN, PROFENID, PROPOFOL, SEROPLEX, SPASFON, STILNOX, TAVANIC, TOPALGIC [TRAMADOL HYDROCHLORIDE], VALIUM, VITAMINE B1-B6, WARFARIN
Adverse Events (AE) Preferred term	1. Constipation 2. Pyrexia 3. Back pain 4. C-reactive protein increased 5. Haemoptysis 6. Tachycardia 7. Pyrexia 8. Back pain 9. Pain 10. Haematoma 11. Vomiting 12. Pregnancy 13. Dyspnoea 14. Phlebitis 15. Flank pain 16. Abortion induced 17. Nasopharyngitis 18. Menorrhagia 19. Asthma 20. Depression
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/YES/NO/YES 11. MILD/NO/NO/YES 12. SEVERE/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213029

Parameter	Value
	15. MILD/NO/NO/YES
	16. MODERATE/NO/YES/YES
	17. MILD/NO/NO/YES
	18. MILD/YES/NO/YES
	19. MILD/NO/NO/YES
	20. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 18JUN2009 (1) - 24JUN2009 (7)
	2. 21JUN2009 (4) - 22JUN2009 (5)
	3. 21JUN2009 (4) - 21JUN2009 (4)
	4. 21JUN2009 (4) - 20AUG2009 (64)
	5. 22JUN2009 (5) - 22JUN2009 (5)
	6. 22JUN2009 (5) - 22JUN2009 (5)
	7. 24JUN2009 (7) - 25JUN2009 (8)
	8. 25JUN2009 (8) - 25JUN2009 (8)
	9. 26JUN2009 (9) - 26JUN2009 (9)
	10. 04JUL2009 (17) - --JUL2009 (.)
	11. 04JUL2009 (17) - 04JUL2009 (17)
	12. 20AUG2009 (64) - 27AUG2009 (71)
	13. 20AUG2009 (64) - 31AUG2009 (75)
	14. 22AUG2009 (66) - 23AUG2009 (67)
	15. 24AUG2009 (68) - 24AUG2009 (68)
	16. 27AUG2009 (71) - 27AUG2009 (71)
	17. 17SEP2009 (92) - 17SEP2009 (92)
	18. 01OCT2009 (106) - --OCT2009 (.)
	19. 20OCT2009 (125) - --------- (.)
	20. 20OCT2009 (125) - --------- (.)
Duration of AE	1. 7
	2. 2
	3. 1
	4. 61
	5. 1
	6. 1
	7. 2
	8. 1
	9. 1
	10. .
	11. 1
	12. 8
	13. 12
	14. 2
	15. 1
	16. 1
	17. 1
	18. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213029

Parameter	Value
	19. .
	20. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213029

Parameter	Value
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. OTHER
	13. OTHER
	14. NONE
	15. NONE
	16. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	17. NONE
	18. NONE
	19. NONE
	20. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213029

Parameter	Value
	20. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160213029[1),1)]	PREGNANCY（PT：妊娠） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、投与中の偶発症と考え、エノキサパリンとの因果関係は否定できると考える。 VOLUNTARY ABORTION（PT：人工流産） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、投与中の偶発症である妊娠の処置と考え、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213031

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160213031/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/47/N.A./FRANCE/YES
Medical history	Marfan's syndrome, Mitral valve incompetence, Tuberculosis, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLOPIDOGREL, DETENSIEL, KARDEGIC
Adverse Events (AE) Preferred term	1. Angina unstable 2. Metrorrhagia 3. Chest pain 4. Metrorrhagia 5. Anaemia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/YES/NO/YES 3. MILD/NO/YES/YES 4. MODERATE/YES/NO/YES 5. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. --SEP2009 (.) - 18DEC2009 (143) 2. 01OCT2009 (65) - --OCT2009 (.) 3. 28OCT2009 (92) - 31OCT2009 (95) 4. 01NOV2009 (96) - --NOV2009 (.) 5. 09DEC2009 (134) - 11DEC2009 (136)
Duration of AE	1. . 2. . 3. 4 4. . 5. 3
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. . 5. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. NONE 4. NONE 5. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED 4. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213031

Parameter	Value
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213035

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160213035/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/50/N.A./FRANCE/YES
Medical history	Hypersensitivity, Anxiety, Asthma, Allergic granulomatous angiitis, Chronic obstructive pulmonary disease, Depression, Gastroduodenal ulcer, Obesity, Intervertebral disc operation, Pain, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, AUGMENTIN 10, COLCHIMAX [COLCHICINE + PAPAVER SOMNIFERUM POWDER + TIEMONIUM METHYLSULPHATE], INEXIUM, KALEORID 1000, LOVENOX, OFLOCET, SYMBICORT 400
Adverse Events (AE) Preferred term	1. Heparin-induced thrombocytopenia 2. Headache 3. Hypokalaemia 4. Ischaemic stroke 5. Vomiting 6. Pyrexia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 21JAN2010 (2) - --------- (.) 2. 21JAN2010 (2) - --------- (.) 3. 21JAN2010 (2) - 22JAN2010 (3) 4. 22JAN2010 (3) - 22JAN2010 (3) 5. 22JAN2010 (3) - 22JAN2010 (3) 6. 22JAN2010 (3) - --------- (.)
Duration of AE	1. . 2. . 3. 2 4. 1 5. 1 6. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 15 mg 6. 15 mg
Dose status on AE onset	1. . 2. . 3. . 4. F 5. F 6. F

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213035

Parameter	Value
Action taken	1. OTHER
	2. REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. IMPROVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213036

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160213036/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/81/N.A./FRANCE/YES
Medical history	Pyelonephritis acute, Cholecystectomy, Depression, Diabetes mellitus, Hypertension, Hysterectomy, Colitis ischaemic, Obesity, Uterine neoplasm, Drug detoxification, Venous insufficiency, Slipping rib syndrome
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT, BRICANYL, COUMADINE, CYMBALTA, ENOXAPARIN, FORLAX, GOMÉNOL, INEXIUM, LOXEN, SERESTA, SPASFON, TRAMADOL, WARFARIN
Adverse Events (AE) Preferred term	1. Constipation 2. Presyncope 3. Bronchitis 4. Systolic hypertension 5. Insomnia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 11MAR2010 (1) - 17MAR2010 (7) 2. 11MAR2010 (1) - 11MAR2010 (1) 3. 07JUN2010 (89) - 12JUN2010 (94) 4. 17JUN2010 (99) - 18JUN2010 (100) 5. 03JUL2010 (115) - --------- (.)
Duration of AE	1. 7 2. 1 3. 6 4. 2 5. .
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY 4. NONE 5. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213036

Parameter	Value
	3. RESOLVED
	4. RESOLVED
	5. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213037

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160213037/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/67/N.A./FRANCE/YES
Medical history	Hypercholesterolaemia, Hypertension, Mastectomy, Menopause, Obesity, Thyroidectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, BEFIZAL, CACIT D3, CONTRAMAL, DESFLURANE, DOLIPRANE, ENOXAPARIN, FENOFIBRATE, FOSAMAX, FOSAVANCE, GENTAMICINE, INEXIUM, LEVOTHYROX, LOVENOX, MIDAZOLAM, NEFOPAM, PERFALGAN, PROPOFOL INDUCTION, PROTOXYDE D'AZOTE, REMIFENTANIL AIVOC, ROCEPHINE, TANAKAN, TRANSIPEG [MACROGOL 3350, KCL, NA BICARBONATE, NACL, NA SULFATE ANHYDROUS], WARFARIN
Adverse Events (AE) Preferred term	1. Weight increased 2. Constipation 3. Renal colic 4. Infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --APR2010 (.) - --------- (.) 2. 28MAR2010 (3) - 02APR2010 (8) 3. 08JAN2011 (289) - 11JAN2011 (292) 4. 08JAN2011 (289) - 10JAN2011 (291)
Duration of AE	1. . 2. 6 3. 4 4. 3
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213037

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213041

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160213041/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/62/N.A./FRANCE/YES
Medical history	Foot fracture, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, DOLIPRANE, ENOXAPARIN, INEXIUM, LOVENOX, PARACETAMOL, WARFARIN
Adverse Events (AE) Preferred term	1. Musculoskeletal pain
	2. Arthralgia
	3. Insomnia
	4. Weight decreased
	5. Headache
	6. Prostate cancer
	7. Arthralgia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/NO/YES
	4. MILD/NO/NO/YES
	5. MILD/NO/NO/YES
	6. SEVERE/NO/YES/YES
	7. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --APR2011 (.) - --------- (.)
	2. --APR2011 (.) - --------- (.)
	3. --APR2011 (.) - --------- (.)
	4. --APR2011 (.) - --------- (.)
	5. 07DEC2010 (69) - 07DEC2010 (69)
	6. 04FEB2011 (128) - --------- (.)
	7. 25APR2011 (208) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. 1
	6. .
	7. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
Dose status on AE onset	1.
	2.
	3.
	4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213041

Parameter	Value
	5.
	6.
	7.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. RESOLVED
	6. UNCHANGED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160213042

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160213042/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/90/N.A./FRANCE/YES
Medical history	Back pain, Cholecystectomy, Constipation, Hiatus hernia, Hyperkalaemia, Hypertension, Hysterectomy, Knee arthroplasty, Mean cell haemoglobin decreased, Myocardial infarction, Oesophagitis, Rash
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DEBRIDAT, ECONAZOLE, EUPANTHOL, FORLAX, GYNOPEVARYL, KAYEXALATE, LASILIX, NORMACOL, PARACETAMOL, RISORDAN, TAVANIC, UNFRACTIONATED HEPARIN
Adverse Events (AE) Preferred term	1. Vulvovaginal mycotic infection 2. Tachycardia 3. Haematemesis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 17DEC2010 (4) - 18DEC2010 (5) 2. 22DEC2010 (9) - 22DEC2010 (9) 3. 03JAN2011 (21) - 03JAN2011 (21)
Duration of AE	1. 2 2. 1 3. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160223001/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/48/N.A./FRANCE/YES
Medical history	Dyspnoea, Pneumonia, Renal colic, Dyspepsia, Chest pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLINE + CLAVULANATE POSTASSIUM, BRONCHODUAL, DIFFU K, DOLIPRANE, DUPHALAC [LACTULOSE], FLAGYL, FLUISEDAL, HÉPARINE, IMOVANE, INEXIUM, OGAST, PARACETAMOL, POTASSIUM, PREDNISOLONE, PRIMPERAN, SODIUM, SPASFON, SPIRIVA, STILNOX, SYMBICORT, TAVANIC, TOPAAL, TOPALGIC [TRAMADOL HYDROCHLORIDE], XANAX
Adverse Events (AE) Preferred term	1. Constipation 2. Pyrexia 3. Dyspnoea 4. Gastroenteritis salmonella 5. Diarrhoea haemorrhagic 6. Proctitis 7. Renal failure 8. Dehydration 9. Tachycardia 10. Abdominal pain 11. Cough 12. Tachypnoea 13. Dyspnoea 14. Dyspnoea 15. Pain in extremity 16. Bronchitis 17. Pain in extremity
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MODERATE/YES/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MILD/NO/NO/YES 15. MILD/NO/NO/YES 16. MILD/NO/NO/YES 17. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 10JUL2007 (1) - 18JUL2007 (9) 2. 10JUL2007 (1) - 11JUL2007 (2)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223001

Parameter	Value
	3. 02AUG2007 (24) - 09OCT2007 (92)
	4. 04AUG2007 (26) - 10AUG2007 (32)
	5. 05AUG2007 (27) - 09AUG2007 (31)
	6. 05AUG2007 (27) - 09AUG2007 (31)
	7. 05AUG2007 (27) - 09AUG2007 (31)
	8. 05AUG2007 (27) - 09AUG2007 (31)
	9. 05AUG2007 (27) - 13SEP2007 (66)
	10. 06AUG2007 (28) - 06AUG2007 (28)
	11. 13SEP2007 (66) - 06DEC2007 (150)
	12. 13SEP2007 (66) - --------- (.)
	13. 09OCT2007 (92) - 15OCT2007 (98)
	14. 15OCT2007 (98) - --------- (.)
	15. 15OCT2007 (98) - 06DEC2007 (150)
	16. 24DEC2007 (168) - 30DEC2007 (174)
	17. 20JAN2008 (195) - --------- (.)
Duration of AE	1. 9
	2. 2
	3. 69
	4. 7
	5. 5
	6. 5
	7. 5
	8. 5
	9. 40
	10. 1
	11. 85
	12. .
	13. 7
	14. .
	15. 53
	16. 7
	17. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223001

Parameter	Value
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. I
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. NONE
	13. NONE
	14. NONE
	15. NONE
	16. REMEDIAL DRUG THERAPY
	17. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. WORSENED
	4. RESOLVED
	5. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223001

Parameter	Value
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED
	13. IMPROVED
	14. UNCHANGED
	15. RESOLVED
	16. RESOLVED
	17. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160223006/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/23/N.A./FRANCE/YES
Medical history	Insomnia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AERIUS, DIANTALVIC, ENOXAPARIN, FORLAX, PARACETAMOL, SKENAN, TETRAZEPAM, TOPALGIC [TRAMADOL HYDROCHLORIDE], WARFARIN, XANAX
Adverse Events (AE) Preferred term	1. Rash 2. Collateral circulation 3. Constipation 4. Pyrexia 5. Cough 6. Transaminases increased 7. Gingival bleeding 8. Osteorrhagia 9. Back pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/YES/YES/YES 7. MILD/YES/NO/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --MAY2008 (.) - --------- (.) 2. --MAR2008 (.) - --------- (.) 3. 10NOV2007 (3) - 10NOV2007 (3) 4. 10NOV2007 (3) - 10NOV2007 (3) 5. 10NOV2007 (3) - 10NOV2007 (3) 6. 22NOV2007 (15) - 18DEC2007 (41) 7. 01FEB2008 (86) - --MAR2008 (.) 8. 10MAR2008 (124) - 09APR2008 (154) 9. 03APR2008 (148) - 09APR2008 (154)
Duration of AE	1. . 2. . 3. 1 4. 1 5. 1 6. 27 7. . 8. 31 9. 7
Dose on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223006

Parameter	Value
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. INSUFFICIENT FOLLOW-UP
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160223006[4)]	INCREASED TRANSAMINASES（PT：トランスアミナーゼ上昇） 治験担当医は、ワルファリンとの因果関係を否定できると判断した。弊社は、ワルファリン投与と報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160223007/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/48/N.A./FRANCE/YES
Medical history	Cough, Depression
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPRAZOLAM, CLAMOXYL [AMOXICILLIN], CORTANCYL, COUMADINE, CYCLO 3, DOLIPRANE, EFFERALGAN, HEXASPRAY, HÉLICIDINE, TOPLEXIL [OXOMEMAZINE, NA BENZOATE], VOLTARENE EMULGEL 1%
Adverse Events (AE) Preferred term	1. Asthenia 2. Sensation of heaviness 3. Tendonitis 4. Depression 5. Bone pain 6. Pain in extremity 7. Musculoskeletal chest pain 8. Hepatomegaly 9. Splenomegaly 10. Contusion 11. Pain in extremity 12. Prothrombin time shortened 13. Gene mutation 14. Laryngitis 15. Depression 16. Depression
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MODERATE/YES/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES 15. SEVERE/NO/YES/YES 16. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --JUN2008 (.) - --NOV2008 (.) 2. --JUN2008 (.) - --JUL2008 (.) 3. --JUL2008 (.) - --------- (.) 4. --OCT2008 (.) - 30OCT2008 (337) 5. --AUG2008 (.) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223007

Parameter	Value
	6. --FEB2008 (.) - --FEB2008 (.)
	7. --FEB2008 (.) - --FEB2008 (.)
	8. 03DEC2007 (5) - --------- (.)
	9. 03DEC2007 (5) - --------- (.)
	10. 01MAR2008 (94) - --APR2008 (.)
	11. 08APR2008 (132) - --APR2008 (.)
	12. 11APR2008 (135) - 30MAY2008 (184)
	13. 29SEP2008 (306) - --------- (.)
	14. 29OCT2008 (336) - 04NOV2008 (342)
	15. 31OCT2008 (338) - 06NOV2008 (344)
	16. 07NOV2008 (345) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. 50
	13. .
	14. 7
	15. 7
	16. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8. 15 mg
	9. 15 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
Dose status on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223007

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. WORSENED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223007

Parameter	Value
	14. RESOLVED
	15. IMPROVED
	16. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223018

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160223018/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/84/N.A./FRANCE/YES
Medical history	Hypertension, Enuresis, Hysterectomy, Insomnia, Multiple myeloma, Abdominal pain upper, Sciatica, Facial neuralgia, Constipation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTISKENAN, ALKERAN, CEFIXIME, COLTRAMYL, CORTANCYL, DETENSIEL, DOLIPRANE, FORLAX, HEXASPRAY, HYDROCORTANCYL, LAROXYL, LORAZEPAM, LOVENOX, METEOSPASMYL, MONOCRIXO, MONURIL, PARACETAMOL, RAMIPRIL, TRANSIPEG [MACROGOL], ZOMETA
Adverse Events (AE) Preferred term	1. Axillary pain 2. Dyspnoea 3. Haemoptysis 4. Subcutaneous haematoma 5. Subcutaneous haematoma 6. Oropharyngeal pain 7. Urinary tract infection 8. Haematoma 9. Subcutaneous haematoma 10. Epistaxis 11. Haemoptysis 12. Sciatica 13. Ecchymosis 14. Cystitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/YES/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES 10. MILD/YES/NO/YES 11. MILD/YES/NO/YES 12. MILD/NO/YES/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --NOV2010 (.) - 30NOV2010 (54) 2. --AUG2011 (.) - --AUG2011 (.) 3. 09OCT2010 (2) - 09OCT2010 (2) 4. 01NOV2010 (25) - --NOV2010 (.) 5. 01NOV2010 (25) - --------- (.) 6. 10NOV2010 (34) - 14NOV2010 (38) 7. 27NOV2010 (51) - 27NOV2010 (51)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223018

Parameter	Value
	8. 01JAN2011 (86) - --------- (.)
	9. 03JAN2011 (88) - --------- (.)
	10. 24JAN2011 (109) - 24JAN2011 (109)
	11. 25JAN2011 (110) - 25JAN2011 (110)
	12. 20APR2011 (195) - 29APR2011 (204)
	13. 22APR2011 (197) - --MAY2011 (.)
	14. 07SEP2011 (335) - 12SEP2011 (340)
Duration of AE	1. .
	2. .
	3. 1
	4. .
	5. .
	6. 5
	7. 1
	8. .
	9. .
	10. 1
	11. 1
	12. 10
	13. .
	14. 6
Dose on AE onset	1.
	2.
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223018

Parameter	Value
	10. .
	11. .
	12. .
	13. I
	14. .
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	13. NONE
	14. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160223020/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/65/N.A./FRANCE/YES
Medical history	Amyotrophy, Hypoaesthesia, Inguinal hernia repair, Insomnia, Miller Fisher syndrome, Foot deformity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	COLECALCIFEROL VIT D3, DOLIPRANE, PARACETAMOL, STILNOX, TEGELINE, UVEDOSE
Adverse Events (AE) Preferred term	1. Pain in extremity 2. Collateral circulation 3. Dyspnoea 4. Chest pain 5. Tachycardia 6. Gynaecomastia 7. Headache 8. Renal cyst 9. Headache 10. Breast pain 11. Headache 12. Calcium deficiency 13. Vitamin D deficiency 14. Lung disorder
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/YES/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/YES 14. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. --DEC2010 (.) - --DEC2010 (.) 2. --DEC2010 (.) - --------- (.) 3. --DEC2010 (.) - --JAN2011 (.) 4. --DEC2010 (.) - --JAN2011 (.) 5. --DEC2010 (.) - --JAN2011 (.) 6. --JAN2011 (.) - --OCT2011 (.) 7. 25NOV2010 (3) - 25NOV2010 (3) 8. 01DEC2010 (9) - --------- (.) 9. 16DEC2010 (24) - 16DEC2010 (24) 10. 16FEB2011 (86) - --OCT2011 (.) 11. 10MAY2011 (169) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223020

Parameter	Value
	12. 15JUN2011 (205) - --------- (.)
	13. 15JUN2011 (205) - --------- (.)
	14. 13SEP2011 (295) - 22SEP2011 (304)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. 1
	8. .
	9. 1
	10. .
	11. .
	12. .
	13. .
	14. 10
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7. 15 mg
	8. 15 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160223020

Parameter	Value
	14. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED
	10. RESOLVED
	11. UNCHANGED
	12. UNCHANGED
	13. UNCHANGED
	14. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/79/N.A./FRANCE/YES
Medical history	Bronchitis chronic, Varicella
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARIXTRA, ASPEGIC, ATROVENT, AUGMENTIN, BRICANYL, BRONCHODUAL, DIFFU K, DOLIPRANE, ENOXAPARIN, FLAGYL, HEXAQUINE, IMOVANE, INIPOMP, LOVENOX, MAGNE B6, PULMICORT, PYOSTACINE, SERETIDE, SMECTA [DIOSMECTITE], SYMBICORT, TAHOR, TAVANIC, TRANSIPEG [MACROGOL/NATRIUM CL,BICARBONATE,ANHYDRE SULPHATE,K CHLORATE,ASPARTAM], WARFARIN
Adverse Events (AE) Preferred term	1. Anaemia 2. Giardiasis 3. Carotid arteriosclerosis 4. Constipation 5. Occult blood positive 6. Pneumonia 7. Hypokalaemia 8. Somnolence 9. Diarrhoea 10. Bronchitis 11. Gingival bleeding 12. Transient ischaemic attack 13. Haematuria 14. Muscle spasms
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MODERATE/NO/YES/YES 11. MILD/YES/NO/YES 12. MODERATE/NO/YES/YES 13. MILD/YES/NO/YES 14. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --AUG2007 (.) - --AUG2007 (.) 2. --AUG2007 (.) - --AUG2007 (.) 3. --APR2008 (.) - --------- (.) 4. 07JUL2007 (3) - 30JUL2007 (26) 5. 10JUL2007 (6) - 10JUL2007 (6) 6. 28JUL2007 (24) - 10AUG2007 (37) 7. 30JUL2007 (26) - --FEB2008 (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233003

Parameter	Value
	8. 30JUL2007 (26) - 04SEP2007 (62)
	9. 30JUL2007 (26) - 04SEP2007 (62)
	10. 05FEB2008 (216) - 17FEB2008 (228)
	11. 05MAR2008 (245) - 06MAR2008 (246)
	12. 06APR2008 (277) - 06APR2008 (277)
	13. 15MAY2008 (316) - 17MAY2008 (318)
	14. 03JUN2008 (335) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. 24
	5. 1
	6. 14
	7. .
	8. 37
	9. 37
	10. 13
	11. 2
	12. 1
	13. 3
	14. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233003

Parameter	Value
	10.
	11.
	12.
	13.
	14.
Action taken	1. OTHER
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	11. DOSE OF STUDY DRUG REDUCED
	12. NONE
	13. NONE
	14. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233009/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/67/N.A./FRANCE/YES
Medical history	Bronchitis chronic, Deafness, Hypertension, Hyperuricaemia, Neoplasm prostate, Visual acuity reduced, Lung disorder, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, AMLOR, AUGMENTIN, CAPTEA, COZAAR, DIFFU K, FENOFIBRATE, GLUCOPHAGE, INSULINE, KARDEGIC, LEVEMIR, LODOZ, OXEOL, QUESTRAN, TANAKAN
Adverse Events (AE) Preferred term	1. Epistaxis 2. Dry mouth 3. Hyperglycaemia 4. Diabetes mellitus 5. Hypokalaemia 6. Pyrexia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 01JAN2008 (117) - --JAN2008 (.) 2. 17FEB2008 (164) - --APR2008 (.) 3. 01APR2008 (208) - 10APR2008 (217) 4. 01APR2008 (208) - --------- (.) 5. 02APR2008 (209) - --------- (.) 6. 09APR2008 (216) - 10APR2008 (217)
Duration of AE	1. . 2. . 3. 10 4. . 5. . 6. 2
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. .
Action taken	1. OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233009

Parameter	Value
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. IMPROVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233010/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/78/N.A./FRANCE/YES
Medical history	Anaemia, Anxiety, Arrhythmia, Cauda equina syndrome, Depression, Osteoporosis, Musculoskeletal pain, Urinary incontinence, Oedema peripheral, Parkinson's disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTONEL, ATHYMIL, CALCIUM VIT D3, CLAMOXYL, CORTANCYL, DIFFU K, DOLIPRANE, FLECAINE, INIPOMP, LASILIX, MODOPAR, MOTILIUM, NOROXINE, PROCTOLOG, TARDYFERON [FERROUS SULFATE], TEMESTA, TRANSIPEG [TRANSIPEG IS MACROGOL AND EXCIPIENTS ARE : NATRIUM CHLORATE, NATRIUM
Adverse Events (AE) Preferred term	1. Constipation 2. Haematuria 3. Urinary tract infection 4. Haematuria 5. Intestinal haemorrhage 6. Haematuria 7. Nausea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES 5. MODERATE/YES/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 22SEP2007 (2) - 16JUN2008 (270) 2. 23SEP2007 (3) - 26SEP2007 (6) 3. 08NOV2007 (49) - 12NOV2007 (53) 4. 01APR2008 (194) - --APR2008 (.) 5. 14MAY2008 (237) - 21MAY2008 (244) 6. 25JUN2008 (279) - 25JUN2008 (279) 7. 22SEP2008 (368) - --------- (.)
Duration of AE	1. 269 2. 4 3. 5 4. . 5. 8 6. 1 7. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233010

Parameter	Value
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. . 7. F
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY 4. NONE 5. STUDY DRUG DISCONTINUED AND RESTARTED 6. NONE 7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED 4. RESOLVED 5. RESOLVED 6. RESOLVED 7. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233013/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/71/N.A./FRANCE/YES
Medical history	Bronchitis chronic, Hypercholesterolaemia, Hypothyroidism, Hysterectomy, Insomnia, Pyelonephritis, Urinary tract infection, Iodine allergy, Bipolar disorder, Depression
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMIKLIN, CRESTOR, DEPAMIDE, DEROXAT, FUNGIZONE, HEPARINE, IMODIUM, INIPOMP, LEVOTHYROX, LEXOMIL, MEPRONIZINE, ORACILLINE, PENTASA, SMECTA [SMECTITE,VANILLIN,SACCHARIN SODIUM,GLUCOSE MONOHYDRATE], SPECIAFOLDINE, TAZOCILLINE, TIORFAN, VITAMIN B12
Adverse Events (AE) Preferred term	1. Diarrhoea 2. Diarrhoea 3. Vertigo 4. Infectious peritonitis 5. Diarrhoea 6. Gastroenteritis 7. Gastroenteritis 8. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --MAR2008 (.) - --MAY2008 (.) 2. 12NOV2007 (2) - 25NOV2007 (15) 3. 12NOV2007 (2) - 12NOV2007 (2) 4. 17NOV2007 (7) - 05DEC2007 (25) 5. 03DEC2007 (23) - 17DEC2007 (37) 6. 08FEB2008 (90) - 10FEB2008 (92) 7. 26MAY2008 (198) - 28MAY2008 (200) 8. 02JUN2008 (205) - --------- (.)
Duration of AE	1. . 2. 14 3. 1 4. 19 5. 15 6. 3 7. 3 8. .
Dose on AE onset	1. 2. 15 mg 3. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233013

Parameter	Value
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233017/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/44/N.A./FRANCE/YES
Medical history	Diverticulum intestinal, Inguinal hernia repair, Intestinal obstruction, Varicose vein operation, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLAMOXYL, DIANTALVIC, ENOXAPARIN, IMOVANE, INIPOMP, LOVENOX, TARDYFERON, WARFARIN
Adverse Events (AE) Preferred term	1. Tendon injury 2. Tachycardia 3. Headache 4. Insomnia 5. Chest pain 6. Medical device complication 7. Device deposit issue 8. Anaemia 9. Haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/YES/YES 8. MILD/NO/NO/YES 9. MILD/YES/NO/YES
Start/stop date of event with relative date	1. --APR2008 (.) - --APR2008 (.) 2. --JAN2008 (.) - --FEB2008 (.) 3. 13DEC2007 (1) - 13DEC2007 (1) 4. 14DEC2007 (2) - 03JAN2008 (22) 5. 14DEC2007 (2) - --------- (.) 6. 06MAR2008 (85) - 12MAR2008 (91) 7. 12MAR2008 (91) - 27MAR2008 (106) 8. 14MAR2008 (93) - 24MAR2008 (103) 9. 21MAR2008 (100) - 15APR2008 (125)
Duration of AE	1. . 2. . 3. 1 4. 21 5. . 6. 7 7. 16 8. 11 9. 26
Dose on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233017

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED AND RESTARTED
	7. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	8. NONE
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. IMPROVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160233017[1)]	HIP PROTHESIS CALCIFICATION（PT：医療機器沈着物の問題） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、人工股関節の石灰化は血腫の大きさや筋壊死の進行度によると考え、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233020/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/71/N.A./FRANCE/YES
Medical history	Osteoarthritis, Back pain, Breast neoplasm, Cerebral haemorrhage, Drug hypersensitivity, Gastrooesophageal reflux disease, Hypercholesterolaemia, Hypertension, Knee arthroplasty, Menopause, Obesity, Intervertebral disc operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	APROVEL, COAPROVEL, DETENSIEL, DIANTALVIC, DIFFU K, DUPHALAC [LACTULOSE], ENDOTELON, LIPANTHYL, LOVENOX, MOVICOL, OFLOCET
Adverse Events (AE) Preferred term	1. Hypokalaemia 2. Constipation 3. Urinary tract infection 4. Hepatomegaly 5. Type 2 diabetes mellitus 6. Dizziness 7. Breast neoplasm
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 04JAN2008 (1) - 07JAN2008 (4) 2. 06JAN2008 (3) - 12JAN2008 (9) 3. 07JAN2008 (4) - 11JAN2008 (8) 4. 11JAN2008 (8) - --------- (.) 5. 15JAN2008 (12) - --------- (.) 6. 24FEB2008 (52) - 25FEB2008 (53) 7. 03MAR2008 (60) - 13MAR2008 (70)
Duration of AE	1. 4 2. 7 3. 5 4. . 5. . 6. 2 7. 11
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 15 mg 6. 20 mg 7. 20 mg
Dose status on AE onset	1. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233020

Parameter	Value
	2. .
	3. .
	4. .
	5. .
	6. .
	7. I
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233022

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233022/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/74/N.A./FRANCE/YES
Medical history	Osteoarthritis, Cholecystectomy, Cardiovascular disorder, Dyspnoea, Gastrooesophageal reflux disease, Hypercholesterolaemia, Hypertension, Insomnia, Menopause, Osteoporosis, Urinary tract infection, Gastrointestinal disorder, Pericardial disease, Varicose vein operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, BACTRIM FORTE, BONVIVA, CALCIUM, COZAAR, DEDROGYL, DOLIPRANE, DUPHALAC [LACTULOSE ONLY], IMOVANE, INEXIUM, KETUM, MINOXIDIL, NOROXINE, OROKEN, STRUCTUM, TAHOR, TANAKAN, XYZALL
Adverse Events (AE) Preferred term	1. Alopecia 2. Arthralgia 3. Toothache 4. Gastroenteritis 5. Rash 6. Anxiety 7. Constipation 8. Epistaxis 9. Neck pain 10. Lung infection 11. Urinary tract infection 12. Epistaxis 13. Haematoma 14. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/YES/YES/YES 9. MILD/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/YES/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --APR2008 (.) - --JUL2008 (.) 2. --MAY2008 (.) - --------- (.) 3. --OCT2008 (.) - --OCT2008 (.) 4. --DEC2008 (.) - --DEC2008 (.) 5. 21JAN2008 (3) - --FEB2008 (.) 6. 21JAN2008 (3) - --------- (.) 7. 22JAN2008 (4) - 25JAN2008 (7)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233022

Parameter	Value
	8. 28JAN2008 (10) - 28JAN2008 (10)
	9. 28JAN2008 (10) - 31JAN2008 (13)
	10. 28JAN2008 (10) - 04FEB2008 (17)
	11. 07MAR2008 (49) - 14MAR2008 (56)
	12. 01APR2008 (74) - 01APR2008 (74)
	13. 01NOV2008 (288) - --NOV2008 (.)
	14. 01NOV2008 (288) - 08NOV2008 (295)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. 4
	8. 1
	9. 4
	10. 8
	11. 8
	12. 1
	13. .
	14. 8
Dose on AE onset	1.
	2.
	3.
	4.
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4.
	5. .
	6. .
	7. .
	8. .
	9. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233022

Parameter	Value
	10. .
	11. .
	12. .
	13. .
	14. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY,OTHER
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. NONE
	14. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. IMPROVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233027

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233027/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/68/N.A./FRANCE/YES
Medical history	Anxiety, Basal cell carcinoma, Arrhythmia, Cerebrovascular accident, Bronchitis chronic, Depression, Herpes zoster, Hypertension, Myocardial infarction, Obesity, Osteoporosis, Rheumatoid arthritis, Penile prosthesis insertion, Myocardial ischaemia, Dyslipidaemia, Seminal vesicle operation, Shoulder operation, Shoulder operation, Peripheral arterial occlusive disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTISKENAN, ALLOPURINOL, AMLOR, ATARAX, ATHYMIL, AUGMENTIN, BACTRIM, CACIT 1000 D3, CALCIUM, CARDENSIEL, CIFLOX, CLAFORAN, COLCHICINE, COLCHIMAX [COLCHICINE + PAPAVER SOMNIFERUM POWDER + TIEMONIUM METHYLSULPHATE], CORDI PATCH, CORTANCYL, DEDROGYL, DEROXAT, DIFFU K, DOLIPRANE, ELISOR, ENOXAPARIN, FASTURTEC, FLECAINE, FORADIL, FOSAVANCE, HYDROCORTISONE, INIPOMP, KONAKION, LASILIX, LEXOMIL, MOVICOL, NOVATREX [METHOTREXATE], OROKEN, PLAVIX, SPIRIVA, STABLON, TOPALGIC [TRAMADOL], TRIATEC, TRIFLUCAN, WARFARIN, XATRAL LP
Adverse Events (AE) Preferred term	1. Gout 2. Ventricular hypokinesia 3. Bundle branch block left 4. Oral fungal infection 5. Back pain 6. Bronchitis 7. Gingival bleeding 8. Epistaxis 9. Diarrhoea 10. Priapism 11. Penile haematoma 12. International normalised ratio increased 13. Constipation 14. Chest pain 15. Pyelonephritis acute 16. Oral fungal infection 17. Benign prostatic hyperplasia 18. Arthralgia 19. Haematoma 20. Cardiac failure acute 21. Lung infection 22. Arrhythmia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/YES/NO/YES 8. MILD/YES/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233027

Parameter	Value
	9. MILD/NO/NO/YES
	10. MODERATE/YES/YES/YES
	11. MODERATE/YES/NO/YES
	12. MODERATE/YES/YES/YES
	13. MILD/NO/NO/YES
	14. MODERATE/NO/NO/YES
	15. MODERATE/NO/YES/YES
	16. MILD/NO/NO/YES
	17. MILD/NO/NO/YES
	18. MODERATE/NO/YES/YES
	19. MILD/NO/NO/YES
	20. MILD/NO/YES/YES
	21. MODERATE/NO/YES/YES
	22. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --MAY2008 (.) - --------- (.)
	2. --JAN2009 (.) - --------- (.)
	3. --JAN2009 (.) - --------- (.)
	4. 18MAR2008 (1) - 10APR2008 (24)
	5. 19MAR2008 (2) - --MAY2008 (.)
	6. 20MAR2008 (3) - 06APR2008 (20)
	7. 25MAR2008 (8) - 25MAR2008 (8)
	8. 01MAY2008 (45) - --MAY2008 (.)
	9. 20MAY2008 (64) - 26MAY2008 (70)
	10. 25MAY2008 (69) - 27MAY2008 (71)
	11. 25MAY2008 (69) - 27MAY2008 (71)
	12. 25MAY2008 (69) - 28MAY2008 (72)
	13. 31MAY2008 (75) - --------- (.)
	14. 16JUN2008 (91) - --------- (.)
	15. 13AUG2008 (149) - 26AUG2008 (162)
	16. 13AUG2008 (149) - 04SEP2008 (171)
	17. 15AUG2008 (151) - 26AUG2008 (162)
	18. 04SEP2008 (171) - 13SEP2008 (180)
	19. 13NOV2008 (241) - --DEC2008 (.)
	20. 31DEC2008 (289) - 05JAN2009 (294)
	21. 23JAN2009 (312) - 29JAN2009 (318)
	22. 23FEB2009 (343) - 05MAR2009 (353)
Duration of AE	1. .
	2. .
	3. .
	4. 24
	5. .
	6. 18
	7. 1
	8. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233027

Parameter	Value
	9. 7
	10. 3
	11. 3
	12. 4
	13. .
	14. .
	15. 14
	16. 23
	17. 12
	18. 10
	19. .
	20. 6
	21. 7
	22. 11
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233027

Parameter	Value
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. OTHER
	8. OTHER
	9. NONE
	10. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	11. STUDY DRUG DISCONTINUED AND RESTARTED
	12. DOSE OF STUDY DRUG REDUCED
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. REMEDIAL DRUG THERAPY
	19. NONE
	20. REMEDIAL DRUG THERAPY
	21. REMEDIAL DRUG THERAPY
	22. OTHER
Outcome of event	1. IMPROVED
	2. UNCHANGED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233027

Parameter	Value
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. IMPROVED
	14. IMPROVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233028

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233028/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/65/N.A./FRANCE/YES
Medical history	Angina pectoris, Appendicectomy, Haematoma, Hypokalaemia, Hypothyroidism, Insomnia, Neoplasm prostate, Lung disorder, Dyslipidaemia, Lung infection, Diarrhoea, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARCALION, ASPEGIC, AUGMENTIN, DIFFU K, DOLIPRANE, IMOVANE, LEVOTHYROX, LOVENOX, SMECTA [SMECTITE + VANILLIN + SACCHARIN SODIUM + GLUCOSE MONOHYDRATE OR GLUCOSE, TAHOR, ULTRA LEVURE
Adverse Events (AE) Preferred term	1. Apathy 2. Epistaxis 3. Dyspnoea 4. Epistaxis 5. Atrial thrombosis 6. Ischaemic stroke 7. Angina pectoris 8. Anxiety 9. Muscle haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/NO 9. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --MAY2008 (.) - 10JUL2008 (113) 2. 14APR2008 (26) - 14APR2008 (26) 3. 15APR2008 (27) - --------- (.) 4. 06OCT2008 (201) - 08OCT2008 (203) 5. 04NOV2008 (230) - --------- (.) 6. 05NOV2008 (231) - 19NOV2008 (245) 7. 07NOV2008 (233) - 16DEC2008 (272) 8. 09NOV2008 (235) - 08JAN2009 (295) 9. 22DEC2008 (278) - 22DEC2008 (278)
Duration of AE	1. . 2. 1 3. . 4. 3 5. . 6. 15 7. 40 8. 61 9. 1

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233028

Parameter	Value
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg 8. 20 mg 9. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. . 5. I 6. . 7. F 8. F 9. F
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. STUDY DRUG DISCONTINUED AND RESTARTED 4. NONE 5. NONE 6. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 7. REMEDIAL DRUG THERAPY 8. REMEDIAL DRUG THERAPY 9. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. UNCHANGED 4. RESOLVED 5. UNCHANGED 6. RESOLVED 7. RESOLVED 8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233028

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233031

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233031/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/90/N.A./FRANCE/YES
Medical history	Appendicectomy, Bronchitis, Gastrooesophageal reflux disease, Mydriasis, Spinal laminectomy, Tonsillectomy, Osteoarthritis, Dyslipidaemia, Parkinson's disease, Muscle operation, Depression
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CHONDROSULF, FLUOXETINE, INIPOMP, LIPANTHYL, LYRICA, MODOPAR, MOVICOL, NORSET, PARACETAMOL, PERMIXON, TOPALGIC [TRAMADOL], TRANSIPEG [MACROGOL 3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORID, TRIFLUCAN
Adverse Events (AE) Preferred term	1. Prostatism 2. Constipation 3. Sciatica 4. Constipation 5. Dental caries
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/YES/YES
Start/stop date of event with relative date	1. --JUL2008 (.) - --------- (.) 2. --AUG2008 (.) - --------- (.) 3. 16APR2008 (2) - --------- (.) 4. 19APR2008 (5) - 29APR2008 (15) 5. 04JUN2008 (51) - 07JUN2008 (54)
Duration of AE	1. . 2. . 3. . 4. 11 5. 4
Dose on AE onset	1. 2. 3. 15 mg 4. 15 mg 5. 20 mg
Dose status on AE onset	1. 2. 3. . 4. . 5. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY 5. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233031

Parameter	Value
Outcome of event	1. IMPROVED
	2. IMPROVED
	3. IMPROVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233036

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233036/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/87/N.A./FRANCE/YES
Medical history	Anxiety, Osteoarthritis, Arrhythmia, Constipation, Depression, Hypercholesterolaemia, Hypertension, Hyperuricaemia, Macular degeneration
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DIFFU K, DOLIPRANE, ELISOR, ENOXAPARIN, FRAGMIN, FUNGIZONE, HEMIGOXINE, LASILIX, LOVENOX, MOVICOL, OFLOCET, STABLON, TEMESTA, TIAPRIDAL, TRIATEC, TRIFLUCAN, WARFARIN, ZYLORIC
Adverse Events (AE) Preferred term	1. Delirium 2. Urinary tract infection 3. Anxiety 4. Depression 5. Subcutaneous haematoma 6. Oral fungal infection 7. Cardiac failure chronic 8. Muscle haemorrhage 9. Haematoma 10. Hypertension 11. Subcutaneous haematoma 12. Hypertension 13. Cardiac failure
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/YES/YES/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MODERATE/NO/NO/YES 13. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 28JUN2008 (2) - 08JUL2008 (12) 2. 29JUN2008 (3) - 15JUL2008 (19) 3. 30JUN2008 (4) - 10JUL2008 (14) 4. 05JUL2008 (9) - 09JUL2008 (13) 5. 11JUL2008 (15) - 11JUL2008 (15) 6. 11JUL2008 (15) - 19JUL2008 (23) 7. 11JUL2008 (15) - 22APR2009 (300) 8. 15JUL2008 (19) - 22JUL2008 (26) 9. 20OCT2008 (116) - 21OCT2008 (117) 10. 28NOV2008 (155) - 21APR2009 (299)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233036

Parameter	Value
	11. 23DEC2008 (180) - --JAN2009 (.)
	12. 22APR2009 (300) - --------- (.)
	13. 23APR2009 (301) - --------- (.)
Duration of AE	1. 11
	2. 17
	3. 11
	4. 5
	5. 1
	6. 9
	7. 286
	8. 8
	9. 2
	10. 145
	11. .
	12. .
	13. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233036

Parameter	Value
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. STUDY DRUG DISCONTINUED AND RESTARTED
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. OTHER
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. WORSENED
	8. RESOLVED
	9. RESOLVED
	10. WORSENED
	11. RESOLVED
	12. UNCHANGED
	13. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233064

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233064/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/31/N.A./FRANCE/YES
Medical history	Depression, Paraparesis, Mental disorder, Rectal haemorrhage
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, TARDYFERON, TRANXENE, WARFARIN, ZYPREXA
Adverse Events (AE) Preferred term	1. Eschar
	2. Depression
	3. Eschar
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MODERATE/NO/YES/YES
	3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --DEC2009 (.) - --DEC2009 (.)
	2. 24MAR2010 (286) - --------- (.)
	3. 01JUN2010 (355) - 29JUN2010 (383)
Duration of AE	1. .
	2. .
	3. 29
Dose on AE onset	1.
	2.
	3.
Dose status on AE onset	1.
	2.
	3.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233070

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233070/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/57/N.A./FRANCE/YES
Medical history	Appendicitis, Cholecystitis, Depression, Obesity, Ovarian cyst, Postmenopause, Dyslipidaemia, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARIXTRA, DOGMATIL, ENOXAPARIN, FLUOXETINE, GENTAMICINE, IXPRIM, KETODERM, LYSANXIA, MOVICOL, PARACETAMOL, PROZAC, ROCEPHINE, SOLIAN, TAVANIC, TRIFLUCAN, WARFARIN, XANAX
Adverse Events (AE) Preferred term	1. Flushing 2. Vertigo 3. Vulvovaginal mycotic infection 4. Haematochezia 5. Haematoma 6. Bronchitis 7. Metrorrhagia 8. Pyelonephritis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/YES/NO/YES 8. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --MAR2010 (.) - --MAR2010 (.) 2. --JUN2010 (.) - --JUN2010 (.) 3. --JUL2010 (.) - 22JUL2010 (345) 4. 16AUG2009 (5) - 16AUG2009 (5) 5. 18AUG2009 (7) - 30AUG2009 (19) 6. 04OCT2009 (54) - 10OCT2009 (60) 7. 10NOV2009 (91) - 12NOV2009 (93) 8. 24JUN2010 (317) - 30JUN2010 (323)
Duration of AE	1. . 2. . 3. . 4. 1 5. 13 6. 7 7. 3 8. 7
Dose on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233070

Parameter	Value
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233075

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233075/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/62/N.A./FRANCE/YES
Medical history	Arterial disorder, Bronchitis chronic, Diverticulitis, Dysphagia, Dysphonia, Gastrooesophageal reflux disease, Hypercholesterolaemia, Hypertension, Hypertrophic cardiomyopathy, Overweight, Chest pain, Weight decreased, Osteoarthritis, Alcoholism, Colectomy, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTONE [SPIRONOLACTONE], ATROVENT, B1 VITAMIN, CHONDROSULF, CRESTOR, DI-ANTALVIC, DOLIPRANE, ENOXAPARIN, INEXIUM, LASILIX, MOVICOL, NICOPASS, PLAVIX, PRAXILENE, SERESTA, SPIRIVA, TRIATEC, VASTAREL, VITAMINE B1, WARFARIN
Adverse Events (AE) Preferred term	1. Constipation 2. Asthenia 3. Chest pain 4. Hypertension 5. Headache 6. Neck pain 7. Back pain 8. Asthenia 9. Amyotrophic lateral sclerosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 26OCT2009 (3) - 26OCT2009 (3) 2. 27OCT2009 (4) - 01NOV2009 (9) 3. 24NOV2009 (32) - --------- (.) 4. 08JAN2010 (77) - --------- (.) 5. 26JAN2010 (95) - --------- (.) 6. 26JAN2010 (95) - --------- (.) 7. 26JAN2010 (95) - --------- (.) 8. 26JAN2010 (95) - --------- (.) 9. 06FEB2010 (106) - 22APR2010 (181)
Duration of AE	1. 1 2. 6 3. . 4. . 5. . 6. . 7. . 8. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233075

Parameter	Value
	9. 76
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED
	7. UNCHANGED
	8. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233075

Parameter	Value
	9. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233078

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233078/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/73/N.A./FRANCE/YES
Medical history	Appendicectomy, Cardiac failure, Deafness, Empyema, Pericarditis, Parkinson's disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DIFFU K, INEXIUM, LASILIX, LYRICA, MODOPAR, MOVICOL, MUTESA, OLMIFON, REQUIP, SINEMET, VASTAREL
Adverse Events (AE) Preferred term	1. Intervertebral disc degeneration 2. Asthenia 3. Constipation 4. Haematoma 5. Right ventricular failure
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --APR2010 (.) - --------- (.) 2. --MAY2010 (.) - --------- (.) 3. 20NOV2009 (2) - 23NOV2009 (5) 4. 01DEC2009 (13) - --DEC2009 (.) 5. 03JUN2010 (197) - 18JUN2010 (212)
Duration of AE	1. . 2. . 3. 4 4. . 5. 16
Dose on AE onset	1. 2. 3. 15 mg 4. 15 mg 5. 20 mg
Dose status on AE onset	1. 2. 3. . 4. . 5. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY 4. NONE 5. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. UNCHANGED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233078

Parameter	Value
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233079

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233079/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/63/N.A./FRANCE/YES
Medical history	Appendicectomy, Osteoarthritis, Haemorrhoids, Gastrooesophageal reflux disease, Hiatus hernia, Benign prostatic hyperplasia, Limb operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CHONDROSULF, DOLIPRANE, ENOXAPARIN, OMEPRAZOLE, OMEXEL, PERMIXON, WARFARIN, XYZAAL
Adverse Events (AE) Preferred term	1. Lung infection 2. Acne 3. Oedema 4. Benign prostatic hyperplasia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 24NOV2009 (1) - 02DEC2009 (9) 2. 29NOV2009 (6) - 02DEC2009 (9) 3. 21JUL2010 (240) - 18AUG2010 (268) 4. 01DEC2010 (373) - 06DEC2010 (378)
Duration of AE	1. 9 2. 4 3. 29 4. 6
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. OTHER 4. OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233079

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233083

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233083/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/53/N.A./FRANCE/YES
Medical history	Sciatica, Knee operation, Venous insufficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DOLIPRANE, ENOXAPARIN, PREVISCAN, WARFARIN
Adverse Events (AE) Preferred term	1. Hepatic enzyme increased 2. Dysaesthesia 3. Haematoma 4. Sinusitis 5. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/NO 4. MODERATE/NO/NO/NO 5. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 12JAN2010 (6) - 08FEB2010 (33) 2. 12JAN2010 (6) - 12JAN2010 (6) 3. 01FEB2010 (26) - --FEB2010 (.) 4. 27FEB2010 (52) - --MAR2010 (.) 5. 07JUL2010 (182) - 14JUL2010 (189)
Duration of AE	1. 28 2. 1 3. . 4. . 5. 8
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,STUDY DRUG DISCONTINUED PERMANENTLY 2. NONE 3. NONE 4. REMEDIAL DRUG THERAPY 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233083

Parameter	Value
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233085

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233085/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/85/N.A./FRANCE/YES
Medical history	Anxiety, Arterial disorder, Osteoarthritis, Asthenia, Renal failure chronic, Constipation, Depression, Hypertension, Infectious peritonitis, Urinary tract infection, Hip arthroplasty, Hip arthroplasty, Postmenopause, Varicose vein operation, Bladder polypectomy, Cataract operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, BORAX, CELLUVISC, CHIBROCADRON, COALGAN, ENOXAPARIN, FLUOXETINE, INDO COLLYRE, LEXOMIL, LOVENOX, MOVICOL, OLICLINOMEL, PARACETAMOL, PERFALGAN, PROZAC, TENORMINE, TOPALGIC [TRAMADOL HYDROCHLORIDE.], WARFARIN
Adverse Events (AE) Preferred term	1. Arthralgia 2. Epistaxis 3. Diarrhoea 4. Anxiety 5. Rectal haemorrhage 6. Large intestine perforation
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --AUG2010 (.) - --------- (.) 2. 07FEB2010 (5) - 09FEB2010 (7) 3. 15FEB2010 (13) - --------- (.) 4. 19FEB2010 (17) - 19FEB2010 (17) 5. 01JUN2010 (119) - --JUL2010 (.) 6. 10SEP2010 (220) - 27SEP2010 (237)
Duration of AE	1. . 2. 3 3. . 4. 1 5. . 6. 18
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233085

Parameter	Value
	6.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. NONE
	6. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233086

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233086/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/60/N.A./FRANCE/YES
Medical history	Hyperglycaemia, Hypertension, Pertussis, Prostatic adenoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, AUGMENTIN, BACTRIM FORT, CLAMOXYL, DEBRIDAT, DIAMICRON, INEXIUM, LANSOYL, LOGIFLOX, LOXEN, MOTILIUM, MOVICOL, NORMACOL, OXYCONTIN, OXYNORM, PARACETAMOL, PERMIXON, TAREG, TOPALGIC [TRAMADOL]
Adverse Events (AE) Preferred term	1. Asthenia 2. Insomnia 3. Constipation 4. Lung infection 5. Nausea 6. Anxiety 7. Gastrointestinal disorder 8. Rectal haemorrhage 9. Diverticulum intestinal 10. Gastroduodenitis 11. Vertigo 12. Bronchitis 13. Pyrexia 14. Operative haemorrhage 15. Haematospermia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/YES/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES 15. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --MAR2010 (.) - --MAR2010 (.) 2. --MAR2010 (.) - --MAR2010 (.) 3. 10FEB2010 (2) - 16FEB2010 (8) 4. 10FEB2010 (2) - 17FEB2010 (9) 5. 12FEB2010 (4) - 12FEB2010 (4) 6. 12FEB2010 (4) - 12FEB2010 (4) 7. 16MAR2010 (36) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233086

Parameter	Value
	8. 03MAY2010 (84) - 05AUG2010 (178)
	9. 07MAY2010 (88) - --------- (.)
	10. 07MAY2010 (88) - --------- (.)
	11. 05JUL2010 (147) - 06JUL2010 (148)
	12. 04OCT2010 (238) - 14OCT2010 (248)
	13. 22OCT2010 (256) - 21NOV2010 (286)
	14. 26JAN2011 (352) - 26JAN2011 (352)
	15. 01FEB2011 (358) - --------- (.)
Duration of AE	1. .
	2. .
	3. 7
	4. 8
	5. 1
	6. 1
	7. .
	8. 95
	9. .
	10. .
	11. 2
	12. 11
	13. 31
	14. 1
	15. .
Dose on AE onset	1.
	2.
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233086

Parameter	Value
	7. .
	8. .
	9. I
	10. I
	11. .
	12. .
	13. .
	14. F
	15. F
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	8. STUDY DRUG DISCONTINUED AND RESTARTED
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. OTHER
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED
	9. UNCHANGED
	10. UNCHANGED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233086

Parameter	Value
	15. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233089

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233089/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/83/N.A./FRANCE/YES
Medical history	Osteoarthritis, Cholecystectomy, Hiatus hernia, Hypertension, Incisional hernia, Abdominal pain upper, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, CAVE FILTER, CHONDROSULF, DOLIPRANE, ENOXAPARIN, HYPERIUM, INIPOMP, KASKADIL, LANSOYL, LOVENOX, MOTILIUM, OXYNORM, PERFALGAN, PRIMPERAN, ROCEPHINE, SPECIAFOLDINE, TAVANIC, TOPALGIC [TRAMADOL HYDROCHLORIDE], TRANSIPEG [MACROGOL], TRIFLUCAN, VITAMIN B12, VITAMIN K, VOLTARENE, WARFARIN, XANAX, XATRAL, XPREP, XYZALL
Adverse Events (AE) Preferred term	1. Pollakiuria 2. Fall 3. Orthostatic hypotension 4. Muscle haemorrhage 5. Nausea 6. Anaemia 7. Biliary dilatation 8. Ovarian cyst 9. Constipation 10. Neck pain 11. Headache 12. Abdominal infection 13. Anxiety 14. Liver disorder 15. Rash erythematous 16. Urinary retention 17. Eye haemorrhage 18. Glaucoma 19. Osteoarthritis 20. Asthenia 21. Subcutaneous haematoma 22. Conjunctival haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/YES/YES/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MODERATE/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233089

Parameter	Value
	13. MODERATE/NO/NO/YES
	14. MILD/NO/NO/YES
	15. MODERATE/NO/NO/YES
	16. MILD/NO/NO/YES
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MILD/NO/NO/YES
	20. MILD/NO/NO/YES
	21. MILD/NO/NO/YES
	22. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 18APR2010 (7) - --APR2010 (.)
	2. 20APR2010 (9) - 20APR2010 (9)
	3. 22APR2010 (11) - 28MAY2010 (47)
	4. 23APR2010 (12) - 29MAY2010 (48)
	5. 23APR2010 (12) - 29APR2010 (18)
	6. 23APR2010 (12) - 29MAY2010 (48)
	7. 23APR2010 (12) - --------- (.)
	8. 23APR2010 (12) - --------- (.)
	9. 25APR2010 (14) - --------- (.)
	10. 25APR2010 (14) - 10MAY2010 (29)
	11. 26APR2010 (15) - 27APR2010 (16)
	12. 27APR2010 (16) - 07MAY2010 (26)
	13. 27APR2010 (16) - 27APR2010 (16)
	14. 27APR2010 (16) - 27MAY2010 (46)
	15. 30APR2010 (19) - 05MAY2010 (24)
	16. 01MAY2010 (20) - 04MAY2010 (23)
	17. 29SEP2010 (171) - 29SEP2010 (171)
	18. 12NOV2010 (215) - --------- (.)
	19. 09MAR2011 (332) - --------- (.)
	20. 09MAR2011 (332) - --------- (.)
	21. 22MAR2011 (345) - --APR2011 (.)
	22. 27APR2011 (381) - --------- (.)
Duration of AE	1. .
	2. 1
	3. 37
	4. 37
	5. 7
	6. 37
	7. .
	8. .
	9. .
	10. 16
	11. 2
	12. 11

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233089

Parameter	Value
	13. 1
	14. 31
	15. 6
	16. 4
	17. 1
	18. .
	19. .
	20. .
	21. .
	22. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233089

Parameter	Value
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. NONE
	18. NONE
	19. REMEDIAL DRUG THERAPY
	20. NONE
	21. NONE
	22. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. UNCHANGED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233089

Parameter	Value
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. UNCHANGED
	19. UNCHANGED
	20. UNCHANGED
	21. RESOLVED
	22. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233093

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233093/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/25/N.A./FRANCE/YES
Medical history	Headache, Infectious peritonitis, Pneumonia, Genital infection, Colour blindness, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDARA, AUGMENTIN, DOLIPRANE, TAVANIC, TOPALGIC [TRAMADOL CHLORHYDRATE], VITAMIN B6
Adverse Events (AE) Preferred term	1. Hepatic enzyme increased 2. Epistaxis 3. Alopecia 4. Pelvic pain 5. Anosmia 6. Memory impairment 7. Tremor
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 20MAY2010 (4) - 26MAY2010 (10) 2. 25JUN2010 (40) - 25JUN2010 (40) 3. 01AUG2010 (77) - --------- (.) 4. 15AUG2010 (91) - 15AUG2010 (91) 5. 15SEP2010 (122) - --------- (.) 6. 15SEP2010 (122) - --------- (.) 7. 15SEP2010 (122) - --------- (.)
Duration of AE	1. 7 2. 1 3. . 4. 1 5. . 6. . 7. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 15 mg 6. 15 mg 7. 15 mg
Dose status on AE onset	1. . 2. . 3. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233093

Parameter	Value
	4. .
	5. .
	6. .
	7. .
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. UNCHANGED
	6. UNCHANGED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233099

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233099/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/77/N.A./FRANCE/YES
Medical history	Anaemia, Erysipelas, Hiatus hernia, Hypercholesterolaemia, Insomnia, Osteitis deformans, Phlebitis, Pleural effusion, Prostatic adenoma, Lung neoplasm, Bronchitis, Renal mass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CERULYSE, DOLIPRANE, ENOXAPARIN, IMOVANE, INEXIUM, MONURIL, SIMVASTATINE, TARDYFERON
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Haematuria 3. Epistaxis 4. Deafness 5. Anaemia 6. Prostatic adenoma 7. Haematuria
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JAN2011 (.) - 15FEB2011 (189) 2. 13AUG2010 (3) - 18AUG2010 (8) 3. 13AUG2010 (3) - 13AUG2010 (3) 4. 17AUG2010 (7) - 18AUG2010 (8) 5. 19AUG2010 (9) - --------- (.) 6. 08DEC2010 (120) - 12DEC2010 (124) 7. 09DEC2010 (121) - 14DEC2010 (126)
Duration of AE	1. . 2. 6 3. 1 4. 2 5. . 6. 5 7. 6
Dose on AE onset	1. 2. 15 mg 3. 15 mg 4. 15 mg 5. 15 mg 6. 20 mg 7. 20 mg
Dose status on AE onset	1. 2. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233099

Parameter	Value
	3. .
	4. .
	5. .
	6. .
	7. I
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	7. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233104

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233104/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/83/N.A./FRANCE/YES
Medical history	Osteoarthritis, Depression, Diabetes mellitus, Hypertension, Hypothyroidism, Obesity, Renal failure chronic, Sciatica, Postmenopause, Hepatitis A immunisation, Cataract operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLODONT, BETAHISTIDINE, BIRODOGYL, COALGAN, COVERSYL, DAFALGAN, DIAMICRON, EDUCTYL, EFFEXOR, FORLAX, HYPERIUM, LEVOTHYROX, LOVENOX, LOXEN, MOTILIUM, MOXONIDINE, NORMACOL, NOROXINE, NOVORAPID, OGAST, PROPOFAN [PARACETAMOL, CAFFEINE, DEXTROPROPOXYPHENE], ZOPICLONE
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Epistaxis 3. Dyspnoea exertional 4. Erythema 5. Asthenia 6. Constipation 7. Hypothyroidism 8. Diverticulum intestinal 9. Hypertension 10. Cytolytic hepatitis 11. Anaemia 12. Rectal haemorrhage 13. Haematuria 14. Haemorrhoids 15. Toothache 16. Dyspnoea 17. Epistaxis 18. Insomnia 19. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MODERATE/YES/YES/YES 11. MILD/NO/NO/YES 12. MILD/YES/NO/YES 13. MILD/YES/NO/YES 14. MILD/NO/NO/YES 15. MILD/NO/NO/YES 16. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233104

Parameter	Value
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 22DEC2010 (1) - 02JAN2011 (12)
	2. 23DEC2010 (2) - 02JAN2011 (12)
	3. 23DEC2010 (2) - 29DEC2010 (8)
	4. 24DEC2010 (3) - 24DEC2010 (3)
	5. 27DEC2010 (6) - 27DEC2010 (6)
	6. 27DEC2010 (6) - 28DEC2010 (7)
	7. 28DEC2010 (7) - --------- (.)
	8. 29DEC2010 (8) - --------- (.)
	9. 29DEC2010 (8) - --------- (.)
	10. 30DEC2010 (9) - 07JAN2011 (17)
	11. 30DEC2010 (9) - --------- (.)
	12. 31DEC2010 (10) - 02JAN2011 (12)
	13. 01JAN2011 (11) - 03JAN2011 (13)
	14. 16FEB2011 (57) - 17FEB2011 (58)
	15. 02MAR2011 (71) - 08APR2011 (108)
	16. 25MAR2011 (94) - --------- (.)
	17. 27APR2011 (127) - 25MAY2011 (155)
	18. 25MAY2011 (155) - --------- (.)
	19. 28MAY2011 (158) - 30MAY2011 (160)
Duration of AE	1. 12
	2. 11
	3. 7
	4. 1
	5. 1
	6. 2
	7. .
	8. .
	9. .
	10. 9
	11. .
	12. 3
	13. 3
	14. 2
	15. 38
	16. .
	17. 29
	18. .
	19. 3
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233104

Parameter	Value
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 15 mg
	12. 15 mg
	13. 15 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. I
	13. I
	14. .
	15. .
	16. .
	17. .
	18. .
	19. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. OTHER
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233104

Parameter	Value
	10. STUDY DRUG DISCONTINUED AND RESTARTED
	11. NONE
	12. NONE
	13. NONE
	14. NONE
	15. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	16. NONE
	17. REMEDIAL DRUG THERAPY,OTHER
	18. REMEDIAL DRUG THERAPY
	19. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. UNCHANGED
	9. UNCHANGED
	10. RESOLVED
	11. UNCHANGED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. UNCHANGED
	17. RESOLVED
	18. UNCHANGED
	19. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160233104[2)]	DRUG RELATED ASYMPTOMATIC HEPATIC CYTOLYSIS（PT：肝細胞損傷） 治験担当医はリバーロキサバンと報告事象との関連性があると判断した。弊社は、合併症（A 型肝炎）及び併用薬（アセトアミノフェン)による影響が考えられ、また罹患率の高い高齢女性患者であることから、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233107

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160233107/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/55/N.A./FRANCE/YES
Medical history	Alcoholism, Depression, Diabetes mellitus, Insomnia, Musculoskeletal pain, Overweight, Lung neoplasm, Dyslipidaemia, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATHYMIL, AUGMENTIN, DOLIPRANE, ENOXAPARIN, INIPOMP, LIPANTHYL, MOTILIUM, NICOPATCH, NICOTINEL, NOCTRAN, SERESTA, VIT B1 B6, WARFARIN
Adverse Events (AE) Preferred term	1. Lung infection 2. Abdominal pain upper 3. Lung neoplasm 4. Nausea 5. Alveolitis allergic 6. Dyslipidaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 04FEB2011 (1) - 19FEB2011 (16) 2. 17FEB2011 (14) - --------- (.) 3. 04APR2011 (60) - 06APR2011 (62) 4. 04APR2011 (60) - 06APR2011 (62) 5. 05APR2011 (61) - --------- (.) 6. 02AUG2011 (180) - --------- (.)
Duration of AE	1. 16 2. . 3. 3 4. 3 5. . 6. .
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160233107

Parameter	Value
	2. REMEDIAL DRUG THERAPY
	3. OTHER
	4. REMEDIAL DRUG THERAPY
	5. OTHER
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160243009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160243009/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/35/N.A./FRANCE/YES
Medical history	Depression, Bipolar I disorder, Bipolar disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ABILIFY, EFFEXOR, TERALITHE, TERCIAN
Adverse Events (AE) Preferred term	1. Hypertension 2. Mania
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --JUN2008 (.) - --JUN2008 (.) 2. 27AUG2008 (64) - 05SEP2008 (73)
Duration of AE	1. . 2. 10
Dose on AE onset	1. 2. 20 mg
Dose status on AE onset	1. 2. .
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160243015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160243015/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/82/N.A./FRANCE/YES
Medical history	Hypertension, Hysterectomy, Insomnia, Iodine allergy, Thyroidectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, AUGMENTIN, CALCIDOSE D3, ENALAPRIL, ENOXAPARIN, LEVOTHYROX, LEXOMIL, LUCENTIS, OXYGEN, SOLUPRED, SOTALOL, WARFARIN
Adverse Events (AE) Preferred term	1. Eye haemorrhage 2. Age-related macular degeneration 3. Retinal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/YES/YES 3. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 27DEC2008 (38) - --------- (.) 2. 27DEC2008 (38) - --------- (.) 3. 22APR2009 (154) - 27APR2009 (159)
Duration of AE	1. . 2. . 3. 6
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. UNCHANGED 2. UNCHANGED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160243015[4)]	INTRAOCULAR BLEEDING（PT：網膜出血） 治験担当医は、因果関係は否定できると判断した。弊社は、ワルファリン投与と報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160243026

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160243026/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/61/N.A./FRANCE/YES
Medical history	Anxiety, Asthma, Breast cancer, Erythema nodosum, Gastrooesophageal reflux disease, Inguinal hernia, Thrombophlebitis, Intestinal polyp, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, ATARAX, CARBOSYLANE(SIMETHICONE AND ACTIVATED COAL), DEBRIDAT, EDUCTYL(POTASSIUM TARTRATE-SODIUM BICARBONATE), ENOXAPARIN, GAVISCON, INEXIUM, PARACETAMOL, SERETIDE DISKUS, SPASFON, TRIMEBUTINE, VENTOLINE, WARFARIN
Adverse Events (AE) Preferred term	1. Periarthritis 2. Anxiety 3. Epistaxis 4. Lung neoplasm malignant 5. Neck pain 6. Pyelonephritis
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --AUG2009 (.) - --------- (.) 2. 28MAY2009 (3) - 29MAY2009 (4) 3. 03OCT2009 (131) - 03OCT2009 (131) 4. 07OCT2009 (135) - --------- (.) 5. 09OCT2009 (137) - --------- (.) 6. 14OCT2009 (142) - 22OCT2009 (150)
Duration of AE	1. . 2. 2 3. 1 4. . 5. . 6. 9
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160243026

Parameter	Value
	6.
Action taken	1. NONE
	2. OTHER
	3. NONE
	4. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. IMPROVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160243028

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160243028/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/87/N.A./FRANCE/YES
Medical history	Femoral neck fracture, Hypertension, Insomnia, Osteoarthritis, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	INEXIUM, LOXEN, PARACETAMOL, RIVOTRIL, STILNOX, TARDYFERON(IRON/FOLIC ACID), TRAMADOL CHLORHYDRATE
Adverse Events (AE) Preferred term	1. Haemoglobin decreased 2. Death
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 03JUL2009 (1) - --------- (.) 2. 15NOV2009 (136) - 15NOV2009 (136)
Duration of AE	1. . 2. 1
Dose on AE onset	1. 15 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. NONE 2. NONE
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160243028[2)]	DEATH (UNKNOWN CAUSE) (PT：死亡) 治験担当医はリバーロキサバンと報告事象との関連性はあると判断した。弊社は、死亡状況の詳細が不明で剖検も施行されていないものの、患者の原疾患（肺塞栓症）や状態（高齢患者での大腿骨頚部骨折による運動減少）との関連性が高いと考え、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1) 治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2) 治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3) 治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4) 治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5) 治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6) 治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

被験者番号：11702-160243028

死亡に至るまでの経過

被験者は87歳、女性。2009年7月1日に肺塞栓症と診断され、2009年7月3日にリバーロキサバン（30mg）の投与を開始した。

2009年11月15日、被験者は死亡した〔死亡（原因不明の死亡）〕。本事象は死亡に至ったため重篤な有害事象とされた。治験責任（分担）医師は、本事象の重症度は高度で、治験薬との因果関係は「あり」と判断した。被験者は、動脈性高血圧症、膝関節症、大腿骨頸部骨折の病歴を有していた。2009年11月15日、被験者は就寝中に死亡した。臨床検査評価及びその他関連検査は実施されず、本事象に対して治療は行われなかった。剖検は実施されなかった。

CIACは、死亡原因は不明であり肺塞栓症である可能性は否定できないとした。

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
Hemoglobin	Local: 12.0-16.0 g/dL	03 Jul 2009	**9.0 g/dL (L)**	07 Jul 2009	**9.6 g/dL (L)**		
Platelets	Local: 150-400 giga/L	03 Jul 2009	**532 giga/L (H)**	07 Jul 2009	**505 giga/L (H)**		
Alkaline Phosphatase	Central: 36-118 U/L	03 Jul 2009	94 U/L	29 Jul 2009	97 U/L	07 Oct 2009	86 U/L
		17 Jul 2009	98 U/L	26 Aug 2009	97 U/L	04 Nov 2009	71 U/L
Amylase	Central: 28-100 U/L	03 Jul 2009	**177 U/L (H)**				
Bilirubin, Direct	Central: 0.10-0.32 mg/dL	17 Jul 2009	0.20 mg/dL	26 Aug 2009	0.13 mg/dL	04 Nov 2009	0.15 mg/dL
		29 Jul 2009	**<0.10 mg/dL (L)**	07 Oct 2009	0.11 mg/dL		
Bilirubin, Total	Central: 0.22-1.28 mg/dL	03 Jul 2009	0.30 mg/dL	29 Jul 2009	0.34 mg/dL	07 Oct 2009	0.38 mg/dL
		17 Jul 2009	0.57 mg/dL	26 Aug 2009	0.42 mg/dL	04 Nov 2009	0.44 mg/dL
SGOT/AST	Central: 11-37 U/L	03 Jul 2009	16 U/L	29 Jul 2009	14 U/L	07 Oct 2009	17 U/L
		17 Jul 2009	16 U/L	26 Aug 2009	18 U/L	04 Nov 2009	15 U/L
SGPT/ALT	Central: 8-43 U/L [a] Local: 0-50 U/L	03 Jul 2009	12 U/L [a]	29 Jul 2009	**6 U/L (L)**	04 Nov 2009	10 U/L
		03 Jul 2009	13 U/L	26 Aug 2009	12 U/L		
		17 Jul 2009	12 U/L	07 Oct 2009	**7 U/L (L)**		
PICT Seconds	Central: 24.80-36.40 S	03 Jul 2009	**38.90 S (H)**	17 Jul 2009	**39.00 S (H)**	07 Oct 2009	<33.20 S
		17 Jul 2009	<33.20 S	26 Aug 2009	<33.20 S		

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
Prothrombin Time (PT)	Central: 11.80-15.50 S	03 Jul 2009	12.60 S	17 Jul 2009	**29.00 S (H)**	07 Oct 2009	**32.30 S (H)**
		17 Jul 2009	**16.10 S (H)**	26 Aug 2009	**25.00 S (H)**		
PT Ratio	Central: 0.70-1.20 %	03 Jul 2009	1.00 %	17 Jul 2009	**0.27 % (L)**	07 Oct 2009	**0.23 % (L)**
		17 Jul 2009	**0.65 % (L)**	26 Aug 2009	**0.33 % (L)**		
PT, INR	Central: 0.9-1.2	03 Jul 2009	1.0	17 Jul 2009	**2.9 (H)**	07 Oct 2009	**3.4 (H)**
		17 Jul 2009	**1.3 (H)**	26 Aug 2009	**2.4 (H)**		

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160243029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160243029/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/84/N.A./FRANCE/YES
Medical history	Dementia Alzheimer's type, Cerebrovascular disorder, Gastrooesophageal reflux disease, Hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	EBIXA, ENOXAPARIN, HYZAAR(LLOSARTAN/HYDROCHLOROTHIAZIDE), LEXOMIL, PARIET, WARFARIN
Adverse Events (AE) Preferred term	1. Dementia Alzheimer's type 2. Confusional state 3. Pneumothorax 4. Rib fracture 5. Fall 6. Fall 7. Fall 8. Hypertension 9. Haemorrhage intracranial
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 23JAN2010 (142) - --------- (.) 2. 27JAN2010 (146) - 27JAN2010 (146) 3. 29JAN2010 (148) - 30JAN2010 (149) 4. 29JAN2010 (148) - --------- (.) 5. 29JAN2010 (148) - 29JAN2010 (148) 6. 06FEB2010 (156) - 06FEB2010 (156) 7. 07FEB2010 (157) - 07FEB2010 (157) 8. 08FEB2010 (158) - 09FEB2010 (159) 9. 16FEB2010 (166) - 19FEB2010 (169)
Duration of AE	1. . 2. 1 3. 2 4. . 5. 1 6. 1 7. 1 8. 2 9. 4
Dose on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160243029

Parameter	Value
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. OTHER
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号：11702-160243029

死亡に至るまでの経過

被験者は 84 歳、男性。2009 年 9 月 4 日に肺塞栓症と診断され、同日エノキサパリン（16,000IU）／用量調節ワルファリンの投与を開始した。

2010 年 1 月 23 日、被験者はアルツハイマー型認知症（アルツハイマー病の悪化）を発現した。本事象により被験者は入院に至ったため、本事象は重篤とされた。治験責任（分担）医師は、本事象の重症度は高度で、治験薬との因果関係は「なし」と判断した。被験者はアルツハイマー病の病歴を有していた。被験者は高度の錯乱状態を発現し（非重篤な有害事象として報告）、精査、加療目的により入院した。2010 年 1 月 26 日、全身の CT スキャンを実施したが、虚血性脳卒中は確認されなかった。本事象により治験薬は変更されなかった。本事象に対し、bromazepam が投与された。本事象の最終転帰は継続中及び不変と報告された。

2010 年 1 月 29 日、被験者は気胸（気胸）を発現した。本事象により入院期間が延長したため、重篤とされた。治験責任（分担）医師は、本事象の重症度は中等度で、治験薬との因果関係は「なし」と判断した。2010 年 1 月 29 日、被験者は転倒（転倒）及び肋骨骨折（肋骨骨折 3 本）を発現し、いずれも非重篤な有害事象として報告された。被験者は呼吸困難及び胸痛の症状を呈した。血液検査の結果、PT-INR は 3.18。2010 年 1 月 30 日、胸部 CT スキャンにより気胸が、頭部 CT スキャンにより頭蓋内出血が確認された。本事象により治験薬は変更されなかった。2010 年 1 月 30 日、本事象は無処置にて消失した。

2010 年 2 月 16 日、被験者は頭蓋内出血（頭蓋内出血）を発現した。本事象により死亡に至ったため重篤とされた。本事象により被験者の治験は中止された。治験責任（分担）医師は、本事象の重症度は高度で、治験薬との因果関係は「あり」と判断した。2010 年 2 月 15 日、PT-INR は 3.61 であった。事象発現前の 2010 年 2 月 6 日及び 2 月 7 日に転倒（転倒）を発現し、2010 年 2 月 8 日に高血圧（高血圧）を発現した（いずれも非重篤な有害事象として報告）。被験者は昏睡状態に陥った。2010 年 2 月 14 日、治験薬の投与は中止された。本事象に対する治療は行われなかった。2010 年 2 月 19 日、本事象により被験者は死亡に至った。剖検は実施されなかった。

CIAC は、頭蓋内出血（頭蓋内出血）を「重大な出血事象」とみなし、死亡原因を出血と判定した。

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
Hemoglobin	Local: 13.0-18.0 g/dL	04 Sep 2009	14.2 g/dL				
Platelets	Local: 150-400 giga/L	04 Sep 2009	195 giga/L				
Alkaline Phosphatase	Central: 35-123 U/L	04 Sep 2009	55 U/L	26 Oct 2009	53 U/L	29 Jan 2010	49 U/L
		21 Sep 2009	54 U/L	08 Dec 2009	56 U/L		
		28 Sep 2009	51 U/L	04 Jan 2010	49 U/L		
Amylase	Central: 28-100 U/L	04 Sep 2009	48 U/L				

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
Bilirubin, Direct	Central: 0.10-0.32 mg/dL	21 Sep 2009	0.10 mg/dL	26 Oct 2009	0.14 mg/dL	04 Jan 2010	0.11 mg/dL
		28 Sep 2009	**<0.10 mg/dL (L)**	08 Dec 2009	0.17 mg/dL		
Bilirubin, Total	Central: 0.22-1.28 mg/dL	04 Sep 2009	0.93 mg/dL	26 Oct 2009	0.64 mg/dL	29 Jan 2010	0.54 mg/dL
		21 Sep 2009	0.27 mg/dL	08 Dec 2009	0.78 mg/dL		
		28 Sep 2009	0.42 mg/dL	04 Jan 2010	0.45 mg/dL		
SGOT/AST	Central: 11-39 U/L	04 Sep 2009	16 U/L	26 Oct 2009	21 U/L	29 Jan 2010	28 U/L
		21 Sep 2009	19 U/L	08 Dec 2009	17 U/L		
		28 Sep 2009	18 U/L	04 Jan 2010	33 U/L		
SGPT/ALT	Central: 8-45 U/L [a] Local: 0-50 U/L	04 Sep 2009	10 U/L [a]	28 Sep 2009	16 U/L	04 Jan 2010	30 U/L
		04 Sep 2009	11 U/L	26 Oct 2009	13 U/L	29 Jan 2010	18 U/L
		21 Sep 2009	31 U/L	08 Dec 2009	10 U/L		
PICT Seconds	Central: 24.80-36.40 S	04 Sep 2009	**63.40 S (H)**				

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160243030

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160243030/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/54/N.A./FRANCE/YES
Medical history	Aortic aneurysm, Cardiac failure chronic, Femur fracture, Myocardial infarction, Intervertebral disc operation, Alcoholism, Coronary arterial stent insertion, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLCYSTEIN, AMOXICILLINE-CLAVULANIC ACID, ASPEGIC, DETENSIEL, IKOREL, INEXIUM, KARDEGIC, LASILIX, PERINDOPRIL, PLAVIX, SPIRONOLACTONE, STILNOX, TAHOR
Adverse Events (AE) Preferred term	1. Cardiac failure acute 2. Dyspnoea 3. Chest pain 4. Cough 5. Chills 6. Oedema peripheral 7. Abdominal pain 8. Pleural effusion 9. Cardiac failure
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 26JAN2010 (53) - 10APR2010 (127) 2. 08FEB2010 (66) - 09APR2010 (126) 3. 12FEB2010 (70) - 09MAR2010 (95) 4. 12FEB2010 (70) - 09APR2010 (126) 5. 12FEB2010 (70) - 09APR2010 (126) 6. 12FEB2010 (70) - 09APR2010 (126) 7. 16FEB2010 (74) - 09MAR2010 (95) 8. 17FEB2010 (75) - 19FEB2010 (77) 9. 10APR2010 (127) - 10APR2010 (127)
Duration of AE	1. 75 2. 61 3. 26 4. 57 5. 57 6. 57 7. 22 8. 3 9. 1
Dose on AE onset	1. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160243030

Parameter	Value
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. NONE
Outcome of event	1. DEATH
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160263007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160263007/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/39/N.A./FRANCE/YES
Medical history	Osteoarthritis, Metastases to liver, Metastases to lymph nodes, Metastases to lung, Malignant melanoma, Skin graft
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTISKÉNAN, CIFLOX, DETICENE, DOLIPRANE, DUROGESIC, FORLAX, INEXIUM, LYRICA, NEORECORMON, OMEPRAZOLE, PRIMPERAN, SOLUPRED, STILNOX, TRAMADOL HYDROCHLORIDE, UNFRACTIONATED HEPARIN, VOLTARENE, XANAX, ZOMETA
Adverse Events (AE) Preferred term	1. Constipation 2. Urinary tract infection 3. Anaemia 4. Insomnia 5. Melaena 6. Anxiety 7. Skin haemorrhage 8. Acute respiratory distress syndrome
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. MODERATE/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. -----2008 (.) - --------- (.) 2. 06AUG2008 (27) - 08AUG2008 (29) 3. 11AUG2008 (32) - 14AUG2008 (35) 4. 12AUG2008 (33) - --------- (.) 5. 13AUG2008 (34) - --------- (.) 6. 13AUG2008 (34) - --------- (.) 7. 17AUG2008 (38) - 17AUG2008 (38) 8. 19AUG2008 (40) - 19AUG2008 (40)
Duration of AE	1. . 2. 3 3. 4 4. . 5. . 6. . 7. 1 8. 1
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160263007

Parameter	Value
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED
	7. RESOLVED
	8. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160263012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160263012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/85/N.A./FRANCE/YES
Medical history	Anxiety, Bladder catheterisation, Constipation, Paraplegia, Peptic ulcer, Eschar, Haematuria, Diarrhoea
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BIAFINE, CIPROFLOXACINE, DOLIPRANE, ENOXAPARIN, ENOXEPARINE, FORLAX, GABAPENTINE, INIPOMP, KARDEGIC, LAROXYL, LASILIX, MOPRAL, PHLOROGLUCINOL, WARFARIN
Adverse Events (AE) Preferred term	1. Urinary bladder polyp 2. Adrenal mass 3. Urinary tract infection 4. Pancreatitis acute 5. Left ventricular failure 6. Carotid artery stenosis 7. Carotid artery stenosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/YES/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 30OCT2008 (1) - --------- (.) 2. 30OCT2008 (1) - --------- (.) 3. 01NOV2008 (3) - 26NOV2008 (28) 4. 24NOV2008 (26) - 16DEC2008 (48) 5. 24NOV2008 (26) - 24NOV2008 (26) 6. 09DEC2008 (41) - 08JAN2009 (71) 7. 09JAN2009 (72) - --------- (.)
Duration of AE	1. . 2. . 3. 26 4. 23 5. 1 6. 31 7. .
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160263012

Parameter	Value
	3.
	4.
	5.
	6.
	7.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160263018

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160263018/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/68/N.A./FRANCE/YES
Medical history	Hip arthroplasty, Hypercholesterolaemia, Hypertension, Obesity, Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, ATARAX, BRICANYL, CIFLOX, DROLEPTAN, ENOXAPARIN, IMOVANE, KETAMINE, LODALES, MORPHINE, OMEPRAZOLE, PERFALGAN, PULMICORT, RESTORVOL, SALBUTAMOL, SODIUM CHLORURE, TOPALGIC [TRAMADOL HYDROCHLORIDE], UNFRACTIONATED HEPARIN, UNFRACTIONNED HEPARIN, VENOFER, WARFARIN, XANAX
Adverse Events (AE) Preferred term	1. Insomnia 2. Subcutaneous haematoma 3. Muscle haemorrhage 4. Renal failure 5. Anxiety 6. Respiratory distress 7. Haemothorax 8. Haematuria 9. Urinary tract infection 10. Asthenia 11. Muscle haemorrhage 12. Insomnia 13. Constipation
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. SEVERE/YES/YES/YES 4. SEVERE/YES/NO/YES 5. MILD/NO/NO/YES 6. SEVERE/YES/NO/YES 7. SEVERE/YES/YES/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. SEVERE/YES/YES/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 22MAR2010 (1) - 28MAR2010 (7) 2. 23MAR2010 (2) - --MAR2010 (.) 3. 25MAR2010 (4) - --------- (.) 4. 25MAR2010 (4) - 30MAR2010 (9) 5. 25MAR2010 (4) - 29MAR2010 (8) 6. 28MAR2010 (7) - 22APR2010 (32) 7. 29MAR2010 (8) - 01APR2010 (11) 8. 02APR2010 (12) - --------- (.) 9. 08APR2010 (18) - 18APR2010 (28) 10. 14APR2010 (24) - -----2010 (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160263018

Parameter	Value
	11. 29JUN2010 (100) - --------- (.)
	12. 30JUN2010 (101) - 02JUL2010 (103)
	13. 04JUL2010 (105) - 04JUL2010 (105)
Duration of AE	1. 7
	2. .
	3. .
	4. 6
	5. 5
	6. 26
	7. 4
	8. .
	9. 11
	10. .
	11. .
	12. 3
	13. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160263018

Parameter	Value
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY,OTHER
	7. OTHER
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED
	10. RESOLVED
	11. IMPROVED
	12. RESOLVED
	13. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160273006/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/69/N.A./FRANCE/YES
Medical history	Rhinitis allergic, Anxiety, Appendicectomy, Osteoarthritis, Bone graft, Cholecystectomy, Constipation, Bunion operation, Osteoporosis, Sciatica, Sleep apnoea syndrome, Postmenopause, Parkinson's disease, Dental implantation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CALCIUM, CORTANCYL, DOLIPRANE, FOSAMAX, INEXIUM, LAROXYL, LEXOMIL, MODOPAR, MOTILIUM, PARIET, SIFROL, STALEVO
Adverse Events (AE) Preferred term	1. Osteoarthritis 2. Sciatica 3. Urinary tract infection 4. Haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES
Start/stop date of event with relative date	1. --NOV2008 (.) - --------- (.) 2. 09AUG2008 (100) - 19AUG2008 (110) 3. 12AUG2008 (103) - 18AUG2008 (109) 4. 20OCT2008 (172) - --NOV2008 (.)
Duration of AE	1. . 2. 11 3. 7 4. .
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. NONE
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273006

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160273009/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/77/N.A./FRANCE/YES
Medical history	Dementia Alzheimer's type, Appendicectomy, Constipation, Depression, Nephrolithiasis, Postmenopause, Colorectal cancer, Colorectal cancer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DEROXAT, DIANTALVIC, ENOXAPARIN, FORLAX, OXYGEN, PARACETAMOL, REMINYL, WARFARIN
Adverse Events (AE) Preferred term	1. Rhinitis 2. Wound 3. Osteoarthritis 4. Pain in extremity 5. Dyspnoea 6. Sleep apnoea syndrome 7. Pulmonary arterial hypertension
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES 6. SEVERE/NO/NO/YES 7. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. -----2008 (.) - --NOV2008 (.) 2. -----2009 (.) - -----2009 (.) 3. 06SEP2008 (5) - --------- (.) 4. 14NOV2008 (74) - --NOV2008 (.) 5. 16APR2009 (227) - 22APR2009 (233) 6. 20APR2009 (231) - --------- (.) 7. 25AUG2009 (358) - --------- (.)
Duration of AE	1. . 2. . 3. . 4. . 5. 7 6. . 7. .
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273009

Parameter	Value
	3.
	4.
	5.
	6.
	7.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. OTHER
	5. OTHER
	6. OTHER
	7. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273024

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160273024/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/72/N.A./FRANCE/YES
Medical history	Acoustic neuroma removal, Anxiety, Appendicectomy, Aortic arteriosclerosis, Patellofemoral pain syndrome, Diverticulum intestinal, Depression, Drug hypersensitivity, Hypercholesterolaemia, Hysterectomy, Mitral valve incompetence, Urinary tract infection, Chest pain, Neurectomy, Lung infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOR, DEROXAT, ENOXAPARIN, FURADANTINE, HEXABRIX 320, KARDEGIC, MONICOR LP, NATISPRAY, PERFALGAN, PLAVIX, WARFARIN
Adverse Events (AE) Preferred term	1. Nausea 2. Vertigo 3. Dizziness 4. Chest pain 5. Anxiety 6. Headache 7. Epistaxis 8. Gastroenteritis 9. Nausea 10. Hyperhidrosis 11. Asthenia 12. Chest pain 13. Dizziness 14. Hiatus hernia 15. Pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/YES/NO/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MODERATE/NO/YES/YES 13. MODERATE/NO/YES/NO 14. MODERATE/NO/NO/NO 15. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --JUN2010 (.) - 05JUL2010 (181) 2. --JUN2010 (.) - 05JUL2010 (181) 3. --DEC2010 (.) - --------- (.) 4. --OCT2010 (.) - --------- (.) 5. --SEP2010 (.) - --NOV2010 (.) 6. 08JAN2010 (3) - 09JAN2010 (4)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273024

Parameter	Value
	7. 09JAN2010 (4) - 09JAN2010 (4)
	8. 16MAR2010 (70) - 30MAR2010 (84)
	9. 23NOV2010 (322) - 13JAN2011 (373)
	10. 23NOV2010 (322) - 25NOV2010 (324)
	11. 29NOV2010 (328) - 31DEC2010 (360)
	12. 06DEC2010 (335) - 07DEC2010 (336)
	13. 28DEC2010 (357) - 31DEC2010 (360)
	14. 29DEC2010 (358) - --------- (.)
	15. 29DEC2010 (358) - 31DEC2010 (360)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. 2
	7. 1
	8. 15
	9. 52
	10. 3
	11. 33
	12. 2
	13. 4
	14. .
	15. 3
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273024

Parameter	Value
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. OTHER
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273024

Parameter	Value
	15. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273026

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160273026/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/77/N.A./FRANCE/YES
Medical history	Osteoarthritis, Constipation, Diabetes mellitus, Abdominal pain upper, Gout, Hypercholesterolaemia, Hypertension, Mitral valve incompetence, Tinnitus, Urinary tract infection, Urinary retention, Varicose vein, Cataract operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMIODARONE, ATROPINE 1%, AUGMENTIN, COLCHIMAX [COLCHICINE + PAPAVER SOMNIFERUM POWDER + TIEMONIUM METHYLSULPHATE], COUMADINE, CRESTOR, DOLIPRANE, ENOXAPARIN, FRAKIDEX, PERFALGAN, PRETERAX, WARFARIN, ZYLORIC
Adverse Events (AE) Preferred term	1. Hyperthyroidism 2. Epistaxis 3. Nausea 4. Gout 5. Atrial fibrillation 6. Dyspnoea 7. Epistaxis 8. Conjunctivitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/YES/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. -----2010 (.) - 13SEP2010 (205) 2. 21FEB2010 (1) - 27FEB2010 (7) 3. 22FEB2010 (2) - 22FEB2010 (2) 4. 25FEB2010 (5) - 28FEB2010 (8) 5. 18APR2010 (57) - 20APR2010 (59) 6. 18APR2010 (57) - 20APR2010 (59) 7. 20APR2010 (59) - 21APR2010 (60) 8. 08JUN2010 (108) - 22JUN2010 (122)
Duration of AE	1. . 2. 7 3. 1 4. 4 5. 3 6. 3 7. 2 8. 15
Dose on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273026

Parameter	Value
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. OTHER
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. OTHER
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273027

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160273027/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/40/N.A./FRANCE/YES
Medical history	Anxiety, Appendicectomy, Cholecystectomy, Diabetes mellitus, Head injury, Back pain, Melanocytic naevus, Pleural effusion, Liver disorder, Diarrhoea
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, AUGMENTIN, CEFTRIAXONE, CONTRAMAL, CONTRAMAL LP, CORTANCYL, IMODIUM, METFORMINE, PERFALGAN, TRANXENE, UMULINE, VOLTARENE
Adverse Events (AE) Preferred term	1. Nausea 2. Haemoptysis 3. Nausea 4. Phlebitis 5. Alanine aminotransferase increased 6. Alanine aminotransferase increased 7. Diabetes mellitus
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/YES/YES
Start/stop date of event with relative date	1. --JUN2010 (.) - 30AUG2010 (180) 2. 07MAR2010 (4) - 07MAR2010 (4) 3. 08MAR2010 (5) - 09MAR2010 (6) 4. 08MAR2010 (5) - 09MAR2010 (6) 5. 03JUN2010 (92) - 14JUN2010 (103) 6. 30JUN2010 (119) - --JUL2010 (.) 7. 30JUL2010 (149) - 02AUG2010 (152)
Duration of AE	1. . 2. 1 3. 2 4. 2 5. 12 6. . 7. 4
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273027

Parameter	Value
	3.
	4.
	5.
	6.
	7.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273041

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160273041/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/70/N.A./FRANCE/YES
Medical history	Appendicectomy, Osteoarthritis, Back pain, Bone neoplasm malignant, Carpal tunnel decompression, Constipation, Diplopia, Epistaxis, Hip arthroplasty, Insomnia, Nasal sinus cancer, Osteotomy, Prostatism, Rhinoscopy, Thyroidectomy, Headache
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, AVODART, CHONDROSULF, CONTALAX, CORTANCYL, CYMBALTA, DOTAREM, ENOXAPARIN, FORLAX, GAVISCON, METHYLPREDNISOLONE, MORPHIN SULFATE, OXYCODONE, PARACETAMOL, PARACETAMOL CODEINE, PIASCLEDINE, STILNOX, WARFARIN, XANAX
Adverse Events (AE) Preferred term	1. Depression 2. Anxiety 3. Skin disorder 4. Abdominal pain upper 5. Spinal cord compression 6. Metastatic neoplasm 7. Infection 8. Pyrexia 9. Nausea 10. Diarrhoea 11. Infection 12. Oral fungal infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. SEVERE/NO/YES/YES 6. SEVERE/NO/YES/YES 7. MILD/NO/NO/NO 8. MILD/NO/NO/NO 9. MODERATE/NO/NO/NO 10. MILD/NO/NO/NO 11. MILD/NO/NO/NO 12. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --MAR2011 (.) - --------- (.) 2. --MAR2011 (.) - --------- (.) 3. --MAY2011 (.) - --------- (.) 4. 10FEB2011 (2) - --------- (.) 5. 31MAR2011 (51) - --------- (.) 6. 31MAR2011 (51) - 21MAY2011 (102) 7. 06APR2011 (57) - 13APR2011 (64) 8. 03MAY2011 (84) - 15MAY2011 (96) 9. 04MAY2011 (85) - --------- (.) 10. 07MAY2011 (88) - 11MAY2011 (92)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273041

Parameter	Value
	11. 10MAY2011 (91) - 14MAY2011 (95)
	12. 19MAY2011 (100) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. 52
	7. 8
	8. 13
	9. .
	10. 5
	11. 5
	12. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160273041

Parameter	Value
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. DEATH
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160283004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160283004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/34/N.A./FRANCE/YES
Medical history	Pulmonary embolism, Pulmonary embolism
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	PARACETAMOL, TRIAMCINOLONE, WARFARINE
Adverse Events (AE) Preferred term	1. Rhinitis allergic 2. Tachycardia 3. Tachypnoea 4. Abdominal pain upper 5. Nasopharyngitis 6. Tachycardia 7. Pain in extremity 8. Seasonal allergy 9. Chest pain 10. Extrasystoles
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/NO 10. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --SEP2010 (.) - --SEP2010 (.) 2. 17SEP2010 (23) - 18SEP2010 (24) 3. 17SEP2010 (23) - 17SEP2010 (23) 4. 27OCT2010 (63) - --DEC2010 (.) 5. 18JAN2011 (146) - 18MAR2011 (205) 6. 13MAR2011 (200) - 18MAR2011 (205) 7. 13MAR2011 (200) - 18MAR2011 (205) 8. 06MAY2011 (254) - --------- (.) 9. 19AUG2011 (359) - 20AUG2011 (360) 10. 16SEP2011 (387) - --------- (.)
Duration of AE	1. . 2. 2 3. 1 4. . 5. 60 6. 6 7. 6 8. . 9. 2

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160283004

Parameter	Value
	10. .
Dose on AE onset	1.
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. F
	10. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. OTHER
	3. OTHER
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160283004

Parameter	Value
	10. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160283008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160283008/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/36/N.A./FRANCE/YES
Medical history	
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DESOGESTREL, ENOXAPARIN, FUMAFER, NEFOPAM, PARACETAMOL, PREGABALDINE, TRAMADOL, TRIPTORELINE, WARFARIN
Adverse Events (AE) Preferred term	1. Nocturnal dyspnoea 2. Dyspnoea 3. Insomnia 4. Metrorrhagia 5. Anxiety 6. Rectal haemorrhage 7. Back pain 8. Menorrhagia 9. Pain in extremity 10. Oedema peripheral 11. Asthenia 12. Rectal haemorrhage 13. Oedema peripheral
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/YES/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/YES/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/YES/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/YES/NO/YES 13. MILD/NO/YES/YES
Start/stop date of event with relative date	1. --JAN2011 (.) - 20JUL2011 (209) 2. --MAY2011 (.) - 22MAY2011 (150) 3. --JUN2011 (.) - 20JUL2011 (209) 4. 27DEC2010 (4) - 29DEC2010 (6) 5. 30DEC2010 (7) - 20JUL2011 (209) 6. 04JAN2011 (12) - 04JAN2011 (12) 7. 10JAN2011 (18) - 20JUL2011 (209) 8. 10JAN2011 (18) - 15JAN2011 (23) 9. 16JAN2011 (24) - --MAR2011 (.) 10. 16JAN2011 (24) - 20JUL2011 (209) 11. 08MAY2011 (136) - 20JUL2011 (209) 12. 16MAY2011 (144) - 22MAY2011 (150)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160283008

Parameter	Value
	13. 17MAY2011 (145) - 23MAY2011 (151)
Duration of AE	1. .
	2. .
	3. .
	4. 3
	5. 203
	6. 1
	7. 192
	8. 6
	9. .
	10. 186
	11. 74
	12. 7
	13. 7
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160283008

Parameter	Value
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. NONE
	13. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/81/N.A./FRANCE/YES
Medical history	Anxiety, Atrial fibrillation, Cardiac failure chronic, Depression, Hiatus hernia, Hypertension, Insomnia, Laparotomy, Myocardial infarction, Benign prostatic hyperplasia, Ischaemic stroke, Ischaemic stroke
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMIODARON, ATACAND [ATACAND=CANDESERTAN ALONE], ATARAX, AVODART, BISOPROLOL, CARDENSIEL, COVERSYL, INEXIUM, KARDEGIC, PLAVIX, STILNOX, UNFRACTIONATED HEPARIN, VASTEN
Adverse Events (AE) Preferred term	1. Ventricular tachycardia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 11APR2008 (136) - 21APR2008 (146)
Duration of AE	1. 11
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293022

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293022/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/69/N.A./FRANCE/YES
Medical history	Arrhythmia, Colon cancer, Depression, Diabetes mellitus, Hiatus hernia, Hypertension, Proctocolectomy, Postmenopause, Abdominal abscess
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, CLAMOXYL, CORDARONE, DIAMICRON, DIFFU-K, FLAGYL, INEXIUM, KENZEN, LANZOR, MOPRAL, PROZAC, UNFRACTIONAT HEPARINE, UNFRACTIONATE HEPARINE, XANAX
Adverse Events (AE) Preferred term	1. Intra-abdominal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 16JUN2008 (3) - 27JUN2008 (14)
Duration of AE	1. 12
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293025

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293025/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/63/N.A./FRANCE/YES
Medical history	Hypertension, Menopause, Obesity, Phlebitis superficial, Urinary tract infection, Retroperitoneal fibrosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	COKENZEN, CORTANCYL, OROKEN, PREVISCAN, SELOKEN
Adverse Events (AE) Preferred term	1. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 09JAN2009 (190) - 17JAN2009 (198)
Duration of AE	1. 9
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. F
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293030

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293030/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/63/N.A./FRANCE/YES
Medical history	Colon cancer, Breast cancer, Hypertension, Mastectomy, Menopause, Musculoskeletal pain, Periarthritis, Splenectomy, Colon operation, Oophorectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	EFFERALGAN, INEXIUM, KYTRIL, SECTRAL, VITAMINE B1 B6
Adverse Events (AE) Preferred term	1. Hemiparesis 2. Visual acuity reduced 3. Arterial stenosis 4. Ischaemic stroke 5. Epistaxis 6. Haematoma 7. Vaginal haemorrhage 8. Headache 9. Nausea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/NO 5. MILD/NO/NO/NO 6. MILD/NO/NO/NO 7. MILD/NO/NO/NO 8. MILD/NO/NO/NO 9. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --MAY2009 (.) - --------- (.) 2. --MAY2009 (.) - --------- (.) 3. --MAY2009 (.) - 04JUN2009 (212) 4. 10MAY2009 (187) - 10JUN2009 (218) 5. 14MAY2009 (191) - 14MAY2009 (191) 6. 25MAY2009 (202) - --------- (.) 7. 25MAY2009 (202) - 25MAY2009 (202) 8. 25MAY2009 (202) - --------- (.) 9. 04JUN2009 (212) - 04JUN2009 (212)
Duration of AE	1. . 2. . 3. . 4. 32 5. 1 6. . 7. 1 8. . 9. 1
Dose on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293030

Parameter	Value
	3.
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4. F
	5. F
	6. F
	7. F
	8. F
	9. F
Action taken	1. NONE
	2. NONE
	3. OTHER
	4. REMEDIAL DRUG THERAPY,OTHER
	5. OTHER
	6. OTHER
	7. OTHER
	8. REMEDIAL DRUG THERAPY,OTHER
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. IMPROVED
	7. RESOLVED
	8. IMPROVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293044

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293044/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/57/N.A./FRANCE/YES
Medical history	Cholecystectomy, Diabetes mellitus, Hypertension, Menopause, Obesity, Ovarian cystectomy, Uterine leiomyoma, Sigmoiditis, Uterine dilation and curettage
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, ENANTONE, ENOXAPARINE, FORTZAR, HYZAAR, LERCAN, LEXOMIL, LUTERAN, PERFALGAN, PHYSIOTENS, PREVISCAN, SECTRAL, VENOFER
Adverse Events (AE) Preferred term	1. Asthenia 2. Anxiety 3. Metrorrhagia 4. Anxiety 5. Alanine aminotransferase increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/YES/YES/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --MAY2009 (.) - --------- (.) 2. 22APR2009 (6) - 02MAY2009 (16) 3. 23APR2009 (7) - 30JUN2009 (75) 4. 03MAY2009 (17) - --------- (.) 5. 06MAY2009 (20) - --JUN2009 (.)
Duration of AE	1. . 2. 11 3. 69 4. . 5. .
Dose on AE onset	1. 2. 15 mg 3. 15 mg 4. 15 mg 5. 15 mg
Dose status on AE onset	1. 2. . 3. . 4. I 5. I
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 4. REMEDIAL DRUG THERAPY 5. NONE
Outcome of event	1. IMPROVED 2. WORSENED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293044

Parameter	Value
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293045

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293045/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/71/N.A./FRANCE/YES
Medical history	Anaemia, Cholecystectomy, Chronic respiratory failure, Cystocele, Tooth abscess, Depression, Pulmonary fibrosis, Hiatus hernia, Hyperlipidaemia, Hypertension, Interstitial lung disease, Menopause, Osteoporosis, Drug hypersensitivity, Pyelonephritis, Rheumatoid arthritis, Uterine prolapse, Varicose vein operation, Lumbar vertebral fracture, Myocardial ischaemia, Eventration procedure, Prolapse repair, Vertebral wedging
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACEBUTOLOL, ALDACTAZINE, ARAVA, ATARAX, BRICANYL, CONTRAMAL, CORTANCYL, DEDROGYL, DIFFU-K, ENOXAPARIN, FENOFIBRATE, FORSTEO, INEXIUM, LOVENOX, MONOALGIC, MOPRAL, NOVATREX [METHOTREXATE], PANENZA, PYOSTACINE, SOLUPRED, SOPROL, SPIRONOLACTONE, STILNOX, TARDYFERON, TAVANIC, TOPALGIC [TRAMADOL CHLORHYDRATE], WARFARIN, ZANIDIP, ZIPREXA
Adverse Events (AE) Preferred term	1. Colonoscopy 2. Osteoarthritis 3. Musculoskeletal chest pain 4. Lung infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 17JUN2009 (41) - 17JUN2009 (41) 2. 20OCT2009 (166) - 23OCT2009 (169) 3. 23NOV2009 (200) - 27NOV2009 (204) 4. 08FEB2010 (277) - 26FEB2010 (295)
Duration of AE	1. 1 2. 4 3. 5 4. 19
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED 2. REMEDIAL DRUG THERAPY 3. NONE 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293045

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293054

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293054/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/58/N.A./FRANCE/YES
Medical history	Appendicectomy, Chronic obstructive pulmonary disease, Abdominal pain upper, Gastritis, Metal poisoning, Nephrolithiasis, Obesity, Syncope
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	INEXIUM, ULCAR
Adverse Events (AE) Preferred term	1. Gait disturbance 2. Balance disorder
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 12NOV2009 (16) - 16NOV2009 (20) 2. 12NOV2009 (16) - 16NOV2009 (20)
Duration of AE	1. 5 2. 5
Dose on AE onset	1. 15 mg 2. 15 mg
Dose status on AE onset	1. . 2. .
Action taken	1. NONE 2. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293055

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293055/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/59/N.A./FRANCE/YES
Medical history	Depression, Insomnia, Hepatic cirrhosis, Obesity, Phlebitis, Phlebitis superficial, Phlebitis superficial, Portal hypertension, Splenectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DOLIPRANE, ENOXAPARIN, EQUANIL, INEXIUM, KASKADIL, KETUM GEL, NOCTRAN, SANDOSTATINE, SEROPLEX, VALIUM, VIT B1, VIT B6, WARFARIN, ZOLOFT
Adverse Events (AE) Preferred term	1. Gastric haemorrhage 2. Haematuria 3. Gastritis 4. Epistaxis 5. Diarrhoea 6. Sensation of heaviness 7. Arthritis 8. Ecchymosis 9. Epistaxis 10. Gastrointestinal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. SEVERE/YES/YES/YES 3. MODERATE/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/YES/NO/YES 9. MILD/YES/NO/YES 10. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 20NOV2009 (21) - 25NOV2009 (26) 2. 20NOV2009 (21) - 25NOV2009 (26) 3. 20NOV2009 (21) - 25NOV2009 (26) 4. 23DEC2009 (54) - 03FEB2010 (96) 5. 13JAN2010 (75) - --------- (.) 6. 03MAR2010 (124) - --------- (.) 7. 28MAY2010 (210) - 30JUN2010 (243) 8. 07JUN2010 (220) - 19JUN2010 (232) 9. 10OCT2010 (345) - --------- (.) 10. 25OCT2010 (360) - 05NOV2010 (371)
Duration of AE	1. 6 2. 6 3. 6 4. 43 5. . 6. . 7. 34

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293055

Parameter	Value
	8. 13
	9. .
	10. 12
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. NONE
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293055

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160293055[4)]	GASTROINTESTINAL BLEEDING（PT：胃腸出血） 治験担当医は、因果関係を否定できると判断した。弊社は、ワルファリン投与と報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293056

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293056/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/84/N.A./FRANCE/YES
Medical history	Acute pulmonary oedema, Acute pulmonary oedema, Anxiety, Cardiac failure chronic, Diabetes mellitus, Goitre, Hypercholesterolaemia, Hypertension, Menopause, Skin ulcer, Uterine prolapse, Tachyarrhythmia, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, ATARAX, CARDENTIEL, CORDARONE, COVERSYL, IMMODIUM, INEXIUM, KENZEN, LASILIX, LOVENOX, METFORMINE, PROTELOS, SMECTA [SMECTITE + VANILLIN + SACCHARIN SODIUM + GLUCOSE MONOHYDRATE]
Adverse Events (AE) Preferred term	1. Femoral neck fracture
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 05SEP2010 (304) - --------- (.)
Duration of AE	1. .
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160293056[1)]	ACCIDENTLY FALLING DOWN（PT：事故） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併用薬（ベンゾジアゼピン系薬）による鎮静作用、合併症（糖尿病及び心不全）、高齢であることによるものであり、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293058

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293058/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/85/N.A./FRANCE/YES
Medical history	Appendicectomy, Blindness unilateral, Breast neoplasm, Bronchitis, Cerebrovascular accident, Cerebrovascular accident, Deafness, Depression, Diverticulum intestinal, Endarterectomy, Endarterectomy, Haemorrhoids, Hypercholesterolaemia, Hypertension, Menopause, Obesity, Parkinson's disease, Oedema
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATHYMIL, COVERSYL, CRESTOR, ENOXAPARIN, KARDEGIC, LOVENOX, MODOPAR, MOPRAL, WARFARIN
Adverse Events (AE) Preferred term	1. Rectal haemorrhage 2. Rectal haemorrhage 3. Haemorrhoidal haemorrhage 4. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 11NOV2009 (5) - 11NOV2009 (5) 2. 01DEC2009 (25) - 16DEC2009 (40) 3. 15DEC2009 (39) - 16DEC2009 (40) 4. 05JAN2010 (60) - 05JAN2010 (60)
Duration of AE	1. 1 2. 16 3. 2 4. 1
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED 3. OTHER 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293058

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293064

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293064/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/87/N.A./FRANCE/YES
Medical history	Blood alkaline phosphatase increased, Angioplasty, Carotid endarterectomy, Cholecystectomy, Cardiac failure chronic, Dementia Alzheimer's type, Hip arthroplasty, Hypercholesterolaemia, Hypertension, Hypothyroidism, Knee arthroplasty, Myocardial infarction, Overweight, Phlebitis, Renal failure, Urinary incontinence, Upper limb fracture, Bronchopneumopathy, Myocardial ischaemia, Haemoglobin decreased
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATENOLOL, INEXIUM, LEVOTHYROX, SIMVASTATINE, SPECIAFOLDINE, TANAKAN
Adverse Events (AE) Preferred term	1. Joint abscess 2. Blood bilirubin increased
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 09DEC2009 (3) - 19DEC2009 (13) 2. 19DEC2009 (13) - 06JAN2010 (31)
Duration of AE	1. 11 2. 19
Dose on AE onset	1. 15 mg 2.
Dose status on AE onset	1. I 2.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293076

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293076/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/73/N.A./FRANCE/YES
Medical history	Anaemia, Atrial fibrillation, Cardiac failure chronic, Dementia, Diarrhoea, Erysipelas, Abscess limb, Haematoma, Haemorrhoids, Hip arthroplasty, Hypercholesterolaemia, Hypertension, Knee arthroplasty, Knee arthroplasty, Periarthritis, Phlebitis, Acute coronary syndrome, Acute coronary syndrome, Eschar, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, BISOPROLOL, CARDENSIEL, CORDARONE, COUMADINE, COVERSYL, DAFALGAN, DIGOXINE, DOBUTAMINE, INEXIUM, INOHEP, INSPRA, KARDEGIC, LASILIX, LEVOTHYROX, POTASSIUM CHLORIDE, SERESTA, TAHOR, TRIATEC
Adverse Events (AE) Preferred term	1. Oedema peripheral 2. Ascites 3. Cardiac failure chronic 4. Haematuria 5. Cardiac failure 6. Epistaxis 7. Hypothyroidism 8. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/YES/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/YES/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --APR2010 (.) - --------- (.) 2. --APR2010 (.) - 22APR2010 (78) 3. 05FEB2010 (2) - 08FEB2010 (5) 4. 11FEB2010 (8) - 13FEB2010 (10) 5. 16APR2010 (72) - 26APR2010 (82) 6. 16APR2010 (72) - 22APR2010 (78) 7. 23APR2010 (79) - --------- (.) 8. 22NOV2010 (292) - 30NOV2010 (300)
Duration of AE	1. . 2. . 3. 4 4. 3 5. 11 6. 7 7. . 8. 9
Dose on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293076

Parameter	Value
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
Action taken	1. NONE
	2. NONE
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293078

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293078/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/87/N.A./FRANCE/YES
Medical history	Appendicectomy, Cardiac pacemaker insertion, Cholecystectomy, Hypertension, Insomnia, Knee arthroplasty, Knee arthroplasty, Parkinsonism, Pneumoconiosis, Vertigo
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AERIUS, ENOXAPARIN, IMOVANE, KARDEGIC, LERCAN, LOCOÏD, MODOPAR, MODOPAR LP, MOPRAL, VASTAREL, WARFARIN, ZANIDIP
Adverse Events (AE) Preferred term	1. Cerebral haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 14JUL2010 (135) - 14JUL2010 (135)
Duration of AE	1. 1
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号：11702-160293078

死亡に至るまでの経過

被験者は 87 歳、男性。2010 年 3 月 1 日に肺塞栓症と診断され、翌日エノキサパリン（160mg）／用量調節ワルファリンの投与を開始した。

2010 年 7 月 14 日、被験者は脳出血（出血：脳出血）を発現した。本事象により被験者は死亡に至ったため、重篤とされた。本事象により被験者の治験は中止された。治験責任（分担）医師は、本事象の重症度は高度で、治験薬との因果関係は「あり」と判断した。被験者は、回転性めまい及びパーキンソン病の病歴を有していた。被験者は階段から落ちて脳出血を発現し、心肺停止に陥った。脳スキャンが実施された。ビタミン K が静脈内投与されたが、2010 年 7 月 14 日に本事象により死亡に至った。剖検は実施されなかった。

CIAC は、脳出血（出血：脳出血）を「重大な出血事象」と考え、死亡原因を出血と判定した。

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
Hemoglobin	Local: 13.0-18.0 g/dL	01 Mar 2010	**11.5 g/dL (L)**				
Platelets	Local: 150-400 giga/L	01 Mar 2010	226 giga/L				
Alkaline Phosphatase	Central: 35-123 U/L	02 Mar 2010	121 U/L	07 Apr 2010	123 U/L	02 Jun 2010	**131 U/L (H)**
		17 Mar 2010	**153 U/L (H)**	05 May 2010	**127 U/L (H)**	29 Jun 2010	119 U/L
Amylase	Central: 28-100 U/L	02 Mar 2010	56 U/L				
Bilirubin, Direct	Central: 0.10-0.32 mg/dL	02 Mar 2010	0.14 mg/dL	07 Apr 2010	0.19 mg/dL	02 Jun 2010	0.18 mg/dL
		17 Mar 2010	0.18 mg/dL	05 May 2010	**<0.10 mg/dL (L)**	29 Jun 2010	0.16 mg/dL
Bilirubin, Total	Central: 0.22-1.28 mg/dL	02 Mar 2010	0.28 mg/dL	07 Apr 2010	0.53 mg/dL	02 Jun 2010	0.54 mg/dL
		17 Mar 2010	0.61 mg/dL	05 May 2010	**0.19 mg/dL (L)**	29 Jun 2010	0.43 mg/dL
Creatinine	Local: 0.90-1.50 mg/dL	01 Mar 2010	**0.80 mg/dL (L)**				
SGOT/AST	Central: 11-39 U/L	02 Mar 2010	33 U/L	07 Apr 2010	30 U/L	02 Jun 2010	34 U/L
		17 Mar 2010	**40 U/L (H)**	05 May 2010	39 U/L	29 Jun 2010	24 U/L

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
SGPT/ALT	Central: 8-45 U/L [a] Local: 0-38 U/L	01 Mar 2010	37 U/L [a]	07 Apr 2010	32 U/L	29 Jun 2010	24 U/L
		02 Mar 2010	**49 U/L (H)**	05 May 2010	**55 U/L (H)**		
		17 Mar 2010	35 U/L	02 Jun 2010	43 U/L		
PICT Seconds	Central: 24.80-36.40 S	02 Mar 2010	**84.10 S (H)**				

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293080

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293080/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/51/N.A./FRANCE/YES
Medical history	Bronchitis, Inflammation, Menopause, Intervertebral disc protrusion, Lung disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARIXTRA, AUGMENTIN, CARDENSIEL, DAFALGAN, INEXIUM, LEXOMIL, LOVENOX, MOTILIUM, PARACETAMOL, TAVANIC, VITAMINE B1 B6
Adverse Events (AE) Preferred term	1. Vomiting 2. Ischaemic stroke 3. Endocarditis 4. Respiratory failure 5. Tachycardia 6. Sepsis 7. Platelet count decreased 8. Lung disorder 9. Pleural effusion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. SEVERE/NO/YES/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/NO 9. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 10MAR2010 (1) - 11MAR2010 (2) 2. 16MAR2010 (7) - --------- (.) 3. 16MAR2010 (7) - 26MAR2010 (17) 4. 16MAR2010 (7) - --------- (.) 5. 16MAR2010 (7) - --------- (.) 6. 16MAR2010 (7) - 26MAR2010 (17) 7. 20MAR2010 (11) - --------- (.) 8. 23MAR2010 (14) - --------- (.) 9. 23MAR2010 (14) - --------- (.)
Duration of AE	1. 2 2. . 3. 11 4. . 5. . 6. 11 7. . 8. . 9. .
Dose on AE onset	1. 15 mg 2. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293080

Parameter	Value
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. F
	8. F
	9. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. DEATH
	4. UNCHANGED
	5. UNCHANGED
	6. DEATH
	7. UNCHANGED
	8. UNCHANGED
	9. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293083

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293083/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/46/N.A./FRANCE/YES
Medical history	Neck pain, Cyst, Cyst, Back pain, Iron deficiency anaemia, Obesity, Musculoskeletal pain, Chest pain, Dyspnoea exertional, Gastric banding, Gastric banding reversal
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, AMIKLIN, AUGMENTIN, BRICANYL, CERAZETTE, CONTRAMAL, FLAGYL, FUNGIZONE, INEXIUM, KLIPAL CODEINE, LOVENOX, MORPHINE, OMEPRAZOLE, PERFALGAN, PRIMPERAN, PROFENID, ROCEPHINE, TAVANIC, TAZOCILLINE, TRANXENE, TRIFLUCAN, VOLUVEN
Adverse Events (AE) Preferred term	1. Asthenia 2. Infectious peritonitis 3. Dyspnoea 4. Respiratory failure 5. Confusional state 6. Lung disorder 7. Oral fungal infection 8. Candidiasis 9. Large intestine perforation
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/YES/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/YES/YES
Start/stop date of event with relative date	1. --JUL2010 (.) - --------- (.) 2. 30JUN2010 (45) - 14JUL2010 (59) 3. 04JUL2010 (49) - 07JUL2010 (52) 4. 05JUL2010 (50) - 14JUL2010 (59) 5. 06JUL2010 (51) - --JUL2010 (.) 6. 07JUL2010 (52) - 14JUL2010 (59) 7. 11JUL2010 (56) - 17JUL2010 (62) 8. 26JUL2010 (71) - --AUG2010 (.) 9. 28SEP2010 (135) - 05OCT2010 (142)
Duration of AE	1. . 2. 15 3. 4 4. 10 5. . 6. 8 7. 7 8. . 9. 8

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293083

Parameter	Value
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg 8. 20 mg 9. 20 mg
Dose status on AE onset	1. 2. I 3. I 4. I 5. I 6. I 7. I 8. . 9. .
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. STUDY DRUG DISCONTINUED AND RESTARTED 5. NONE 6. REMEDIAL DRUG THERAPY 7. REMEDIAL DRUG THERAPY 8. REMEDIAL DRUG THERAPY 9. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. UNCHANGED 2. RESOLVED 3. RESOLVED 4. RESOLVED 5. RESOLVED 6. RESOLVED 7. RESOLVED 8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293083

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293084

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293084/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/84/N.A./FRANCE/YES
Medical history	Appendicectomy, Osteoarthritis, Bone cyst, Breast cancer, Breast cancer, Breast cancer, Cholecystectomy, Clavicle fracture, Cognitive disorder, Cyst, Depression, Hiatus hernia, Lymphoedema, Malaise, Rib fracture, Urinary incontinence, Renal failure chronic, Arthralgia, Arthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPRAZOLAM, AROMASINE, DAFALGAN, EFFEXOR, GAVISCON, LANZOR, MOTILIUM, OXYBUTINE, PIASCLEDINE, ROCEPHINE, TAMOXIFENE, TEMESTA
Adverse Events (AE) Preferred term	1. Asthenia 2. Urinary tract infection 3. Constipation 4. Anaemia 5. Haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/NO 4. MODERATE/YES/NO/NO 5. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 15JUN2010 (7) - --------- (.) 2. 21OCT2010 (135) - 27OCT2010 (141) 3. 08JUN2011 (365) - 12JUN2011 (369) 4. 11JUN2011 (368) - 21JUN---- (.) 5. 11JUN2011 (368) - 21JUN2011 (378)
Duration of AE	1. . 2. 7 3. 5 4. . 5. 11
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. F 4. F 5. F
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. NONE 4. NONE 5. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293084

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293099

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293099/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/85/N.A./FRANCE/YES
Medical history	Anxiety, Hypertension, Hiatus hernia, Hypercholesterolaemia, Renal colic, Renal failure, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOR, ATACAND [CANDESARTAN CILEXETIL], CARDENSIEL, COUMADINE, INNOHEP, KARDEGIC, MOPRAL, PRAVASTATINE, PRESTOL, SERESTA, TAHOR
Adverse Events (AE) Preferred term	1. Haematuria 2. Prostatic adenoma 3. Haematuria
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/YES/NO/YES
Start/stop date of event with relative date	1. 15DEC2010 (28) - --JAN2011 (.) 2. 03FEB2011 (78) - 11FEB2011 (86) 3. 04FEB2011 (79) - 21FEB2011 (96)
Duration of AE	1. . 2. 9 3. 18
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. I
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED 2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 3. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293102

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293102/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/74/N.A./FRANCE/YES
Medical history	Aortic aneurysm, Cataract, Ex-tobacco user, Cyanosis, Hyperlipidaemia, Hypertension, Malaise, Deep vein thrombosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, ENOXAPARIN, HEPARINE, INEXIUM, LASILX, LOVENOX, NORMACOL, OFLOCET, TAHOR, TEMERIT, VITAMINE B1 B6, WARFARIN
Adverse Events (AE) Preferred term	1. Prostate cancer 2. Anal haemorrhage 3. Aortic aneurysm rupture 4. Anaemia 5. Retroperitoneal haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/NO 4. MODERATE/NO/NO/NO 5. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 30NOV2010 (8) - --------- (.) 2. 30NOV2010 (8) - 30DEC2010 (38) 3. 22DEC2010 (30) - 04JAN2011 (43) 4. 22DEC2010 (30) - 24DEC2010 (32) 5. 22DEC2010 (30) - 22DEC2010 (30)
Duration of AE	1. . 2. 31 3. 14 4. 3 5. 1
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY 2. NONE 3. REMEDIAL DRUG THERAPY 4. OTHER 5. NONE
Outcome of event	1. UNCHANGED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293102

Parameter	Value
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293103

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293103/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/80/N.A./FRANCE/YES
Medical history	Dyspnoea, Glaucoma, Herpes zoster, Hiatus hernia, Hypertension, Hypothyroidism, Lung disorder, Nausea, Osteoporosis, Cardiac murmur, Hysterectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMIKLIN, DAFALGAN, FLUINDIONE, FRAGMINE, INEXIUM, INSULINE, LASILIX, LEVOTHYROX, OROKEN, PARIET, SMECTA [SMECTITE + VANILLIN + SACCHARIN SODIUM + GLUCOSE MONOHYDRATE], SOLMUCOL, TAZOCILLINE, XALATAN, XANAX
Adverse Events (AE) Preferred term	1. Lung infection 2. Haematemesis 3. Acute myocardial infarction 4. Hyperglycaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --------- (.) - --------- (.) 2. 01DEC2010 (6) - --------- (.) 3. 12DEC2010 (17) - 17DEC2010 (22) 4. 12DEC2010 (17) - --------- (.)
Duration of AE	1. . 2. . 3. 6 4. .
Dose on AE onset	1. 2. 15 mg 3. 15 mg 4. 15 mg
Dose status on AE onset	1. 2. . 3. . 4. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. INSUFFICIENT FOLLOW-UP 3. DEATH

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293103

Parameter	Value
	4. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293107

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293107/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/79/N.A./FRANCE/YES
Medical history	Diabetes mellitus, Hypertension, Renal failure chronic, Upper limb fracture, Hip arthroplasty, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CALCIPARINE, CARDENSIEL, COUMADINE, CRESTOR, DAFALGAN, ENOXAPARIN, GLUCOPHAGE, INNOHEP, LERCAPRESS [ENALAPRIL MALEATE,LERCANIDIPINE CHLORHYDRATE], LOVENOX, PRIMPERAN, TOPALGIC [TRAMADOL HYDROCHLORIDE], WARFARIN
Adverse Events (AE) Preferred term	1. Abdominal pain upper 2. Nausea 3. Rib fracture 4. Cerebral haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. --FEB2011 (.) - --------- (.) 2. --FEB2011 (.) - --FEB2011 (.) 3. --FEB2011 (.) - --------- (.) 4. 08FEB2011 (27) - 25FEB2011 (44)
Duration of AE	1. . 2. . 3. . 4. 18
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. NONE 3. NONE 4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. IMPROVED 2. RESOLVED 3. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293107

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293110

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293110/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/67/N.A./FRANCE/YES
Medical history	Rhinitis allergic, Cholecystectomy, Bronchitis chronic, Chronic obstructive pulmonary disease, Hypercholesterolaemia, Hypertension, Inguinal hernia, Knee arthroplasty, Menopause, Drug hypersensitivity, Scoliosis, Hip arthroplasty, Vaginal prolapse, Phlebectomy, Bronchitis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, ESBERIVEN, MIZOLLEN, PRAVASTATINE, TAVANIC
Adverse Events (AE) Preferred term	1. Pneumonia 2. Weight decreased
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 22FEB2011 (19) - --------- (.) 2. 05MAR2011 (30) - --------- (.)
Duration of AE	1. . 2. .
Dose on AE onset	1. 15 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY 2. OTHER
Outcome of event	1. IMPROVED 2. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293113

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160293113/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/81/N.A./FRANCE/YES
Medical history	Aortic stenosis, Asthenia, Atrial fibrillation, Oedema, Hypercholesterolaemia, Hypertension, Obesity, Tachyarrhythmia, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTONE [SPIRONOLACTONE], ATENOLOL, COVERSYL, CRESTOR, DIFFU K, DIGOXINE, IKOREL, KARDEGIC, MOPRAL, TEMERIT
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Epistaxis 3. Cardiac failure acute 4. Atrial fibrillation
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/NO 4. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 15JUN2011 (120) - --------- (.) 2. 04JUL2011 (139) - 04JUL2011 (139) 3. 09SEP2011 (206) - --------- (.) 4. 09SEP2011 (206) - --------- (.)
Duration of AE	1. . 2. 1 3. . 4. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. F 4. F
Action taken	1. NONE 2. NONE 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED 2. RESOLVED 3. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160293113

Parameter	Value
	4. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303003/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/57/N.A./FRANCE/YES
Medical history	Anaemia, Hypertension, Joint dislocation, Myocardial infarction, Nervous system disorder, Radius fracture, Renal artery stenosis, Ulna fracture, Cerebral haemorrhage traumatic, Aortic bypass, Dyslipidaemia, Peripheral arterial occlusive disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOR, ARTANE, CARDENSIEL, COVERSYL, DAFALGAN CODEINE, DETENSIEL, DOLIPRANE, FUMAFER, INEXIUM, INIPOMP, KARDEGIC, LESCOL, NOZINAN, PIPORTIL, TARDYFERON, UNFRACTIONATED HEPARIN, ZOCOR
Adverse Events (AE) Preferred term	1. General physical health deterioration 2. General physical health deterioration
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 01MAR2008 (40) - 02APR2008 (72) 2. 02APR2008 (72) - 05APR2008 (75)
Duration of AE	1. 33 2. 4
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE
Outcome of event	1. WORSENED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303009/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/46/N.A./FRANCE/YES
Medical history	Liver function test abnormal, Cholestasis, Depression, Hepatitis viral
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DOLIPRANE, ENOXAPARIN, LEXOMIL, LOVENOX, NOROXINE, RISPERDAL, TRANXENE, WARFARIN
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Liver function test abnormal 3. International normalised ratio decreased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/YES/YES 3. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 23SEP2008 (1) - 04OCT2008 (12) 2. 27SEP2008 (5) - 17NOV2008 (56) 3. 19JAN2009 (119) - 24JAN2009 (124)
Duration of AE	1. 12 2. 52 3. 6
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303010/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/53/N.A./FRANCE/YES
Medical history	Appendicectomy, Hypertension, Cholecystectomy, Constipation, Depression, Blood cholesterol increased, Osteoarthritis, Thyroiditis, Uterine leiomyoma, Postmenopause, Adenomyosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ABUFENE, ACUPAN, ALDACTAZINE, ATACAND [CANDESRTAN CILEXETIL ALONE], ATARAX, AVLOCARDYL, CARBOCISTEINE, CONTRAMAL, DOLIPRANE, ESIDREX, HYTACAND, LEVOTHYROX, LEXOMIL, LIPANTHYL, LOVENOX, PECTOSAN [CARBOCISTEINE], PERFALGAN, PIASCLEDINE, PROFENID, PROZAC, SPIRONOLACTONE, TAHOR, TRANSIPEG [MACROGEL+KCL+NAHCO3+NACL+SODIUMSULFATE ANHYDROUS]
Adverse Events (AE) Preferred term	1. Cough 2. Nasopharyngitis 3. Uterine leiomyoma 4. Angina unstable 5. Subcutaneous haematoma 6. Tracheitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 22OCT2008 (9) - 03NOV2008 (21) 2. 09MAR2009 (147) - 14MAR2009 (152) 3. 09APR2009 (178) - 14APR2009 (183) 4. 31MAY2009 (230) - 01JUN2009 (231) 5. 08SEP2009 (330) - 13SEP2009 (335) 6. 01NOV2009 (384) - --------- (.)
Duration of AE	1. 13 2. 6 3. 6 4. 2 5. 6 6. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. I 4. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303010

Parameter	Value
	5. .
	6. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303011/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/36/N.A./FRANCE/YES
Medical history	Anxiety, Appendicectomy, Caesarean section, Chest pain, Gastroenteritis, Wisdom teeth removal, Renal colic, Sciatica, Tonsillectomy, Paraesthesia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTISKENAN, ACUPAN, ARIXTRA, ATARAX, AUGMENTIN, BIPROFENID, CIFLOX, CONTRAMAL, COUMADINE, DAFALGAN, DAFALGAN CODEINE, DUROGESIC, HEPARIN, HYDROCORTISONE, INEXIUM, INIPOMP, KARDEGIC, KETAMINE, LASILIX, LEXOMIL, MOTILIUM, NEURONTIN, PARACETAMOL, PERFALGAN, RIVOTRIL, SMECTA [DIOSMECTITE,GLYCEROL,SACCHARINE SODIUM,SILICIUM DIOXI,VANILLA,MALTODEXTR, SPASFON, SPECIAFOLDINE, TARDYFERON, UNFRACTIONATED HEPARIN, VENOFER
Adverse Events (AE) Preferred term	1. Myalgia 2. Fatigue 3. Paradoxical embolism 4. Anaemia 5. Paradoxical embolism 6. Gastroenteritis 7. Epistaxis 8. Paraesthesia 9. Pain in extremity 10. Pain in extremity
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. SEVERE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/YES/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JUN2009 (.) - --------- (.) 2. --JUN2009 (.) - --------- (.) 3. 23OCT2008 (3) - 07NOV2008 (18) 4. 26OCT2008 (6) - 06FEB2009 (109) 5. 07NOV2008 (18) - --------- (.) 6. 04MAR2009 (135) - 05MAR2009 (136) 7. 04MAR2009 (135) - 04MAR2009 (135) 8. 13MAY2009 (205) - 13MAY2009 (205) 9. 13MAY2009 (205) - 14MAY2009 (206) 10. 14OCT2009 (359) - --------- (.)
Duration of AE	1. . 2. . 3. 16

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303011

Parameter	Value
	4. 104
	5. .
	6. 2
	7. 1
	8. 1
	9. 2
	10. .
Dose on AE onset	1.
	2.
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. I
	5. .
	6. .
	7. .
	8. .
	9. .
	10. F
Action taken	1. NONE
	2. NONE
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. NONE
	10. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. IMPROVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303011

Parameter	Value
	8. RESOLVED
	9. RESOLVED
	10. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/76/N.A./FRANCE/YES
Medical history	Anxiety, Appendicectomy, Osteoarthritis, Hypertension, Drug hypersensitivity, Drug hypersensitivity, Gastric ulcer, Hepatic cyst, Ovarian cyst, Renal cyst, Iodine allergy, Cartilage operation, Headache, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOR, ATARAX, DAFALGAN CODEINE, DETENSIEL, ENOXAPARIN, INIPOMP, LEXOMIL, LODOZ, MORPHINE, PERFALGAN, PIASCLEDINE, PREDNISOLONE, SOLUMEDROL, TEMESTA, UNFRACTIONATED HEPARIN, VASTAREL, WARFARIN
Adverse Events (AE) Preferred term	1. Haematuria 2. International normalised ratio increased 3. Ovarian cyst 4. Gingival bleeding
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 04NOV2008 (1) - 12FEB2009 (101) 2. 08NOV2008 (5) - 11NOV2008 (8) 3. 01DEC2008 (28) - 16FEB2009 (105) 4. 01DEC2008 (28) - 10FEB2009 (99)
Duration of AE	1. 101 2. 4 3. 78 4. 72
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303012

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303014/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/81/N.A./FRANCE/YES
Medical history	Appendicectomy, Chronic obstructive pulmonary disease, Hypertension, Insomnia, Tonsillectomy, Pneumonia viral, Myocardial ischaemia, Meniscus removal, Dyslipidaemia, Cardiac valve disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT, AUGMENTIN, BRICANYL, COVERSYL, DOLIPRANE, INEXIUM, INIPOMP, LASILIX, LEXOMIL, NOCTAMIDE, OXYGEN, PHENAZONE, PROFENID, PYOSTACINE, SERETIDE, SIMVASTATINE, SPIRIVA, TIMOFEROL
Adverse Events (AE) Preferred term	1. Asthenia 2. Electrophoresis protein abnormal 3. Asthenia 4. Epistaxis 5. Ecchymosis 6. Bronchial disorder 7. Iron deficiency 8. Epistaxis 9. Anaemia 10. Anaemia 11. Chest pain 12. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/YES/NO/YES 8. MILD/YES/NO/YES 9. SEVERE/YES/YES/YES 10. MILD/YES/NO/NO 11. MILD/NO/NO/NO 12. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --MAR2009 (.) - 14MAY2009 (179) 2. --JUL2009 (.) - --------- (.) 3. --OCT2009 (.) - --------- (.) 4. 20NOV2008 (4) - 20NOV2008 (4) 5. 20NOV2008 (4) - 08JAN2009 (53) 6. 03MAR2009 (107) - 29APR2009 (164) 7. 28APR2009 (163) - 11JUL2009 (237) 8. 30APR2009 (165) - 30APR2009 (165) 9. 25JUN2009 (221) - 11JUL2009 (237) 10. 12JUL2009 (238) - --------- (.) 11. 08OCT2009 (326) - 08OCT2009 (326) 12. 09NOV2009 (358) - 09NOV2009 (358)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303014

Parameter	Value
Duration of AE	1. . 2. . 3. . 4. 1 5. 50 6. 58 7. 75 8. 1 9. 17 10. . 11. 1 12. 1
Dose on AE onset	1. 2. 3. 4. 15 mg 5. 15 mg 6. 20 mg 7. 20 mg 8. 20 mg 9. 20 mg 10. 20 mg 11. 20 mg 12. 20 mg
Dose status on AE onset	1. 2. 3. 4. . 5. . 6. . 7. . 8. . 9. . 10. F 11. F 12. F
Action taken	1. NONE 2. OTHER 3. NONE 4. NONE 5. NONE 6. REMEDIAL DRUG THERAPY 7. REMEDIAL DRUG THERAPY 8. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303014

Parameter	Value
	9. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	10. REMEDIAL DRUG THERAPY
	11. OTHER
	12. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. UNCHANGED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303016

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303016/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/61/N.A./FRANCE/YES
Medical history	Aortic aneurysm, Atrial fibrillation, Hypertension, Goitre, Prostatism, Renal cyst, Calculus urinary, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADRENALINE, ATARAX, CALCIPARINE, CONTRAMAL, COZAAR, CRESTOR, DAFALGAN, DIPRIVAN, EFFERALGAN EFFERVESCENT, ENOXAPARIN, FUROSEMIDE, HEPARINE CALCIQUE, HYZAAR, INEXIUM, INIPOMP, KARDEGIC, LASILIX, LEUKOCYTE-DEPLETED PLATELET CONCENTRATES, LEXOMIL, LYSANXIA, MONOTILDIEM, MOPRAL, PARACETAMOL, PERFALGAN, PLASMA SECURE, UNFRACTIONATED HEPARIN, WARFARIN, XATRAL
Adverse Events (AE) Preferred term	1. Back pain 2. Nasopharyngitis 3. Anxiety 4. Periorbital haematoma 5. Aortic aneurysm 6. Cough 7. Anxiety 8. Constipation 9. Abdominal pain upper 10. Pericardial effusion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. SEVERE/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/NO 8. MILD/NO/NO/NO 9. SEVERE/NO/YES/NO 10. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --DEC2009 (.) - 28JAN2010 (384) 2. --DEC2009 (.) - 07DEC2009 (332) 3. 19MAY2009 (130) - 28MAY2009 (139) 4. 04JUN2009 (146) - 08JUN2009 (150) 5. 13DEC2009 (338) - 24DEC2009 (349) 6. 15DEC2009 (340) - 05JAN2010 (361) 7. 25DEC2009 (350) - 07JAN2010 (363) 8. 01JAN2010 (357) - 07JAN2010 (363) 9. 05JAN2010 (361) - 28JAN2010 (384) 10. 06JAN2010 (362) - --------- (.)
Duration of AE	1. . 2. . 3. 10 4. 5

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303016

Parameter	Value
	5. 12
	6. 22
	7. 14
	8. 7
	9. 24
	10. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303016

Parameter	Value
	9. RESOLVED
	10. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303021/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/72/N.A./FRANCE/YES
Medical history	Hypertension, Arrhythmia, Carpal tunnel syndrome, Obesity, Urinary tract infection, Colon operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, COUMADINE, COVERSYL, DERINOX [PREDNISOLONE+NAPHAZOLINE. INDIC: COLD], DOLIPRANE, FURANDANTINE, HEXOMEDINE [HEXAMIDINE (DCI) DIIS?TIONATE], LASILIX, LOCOID, SOTALEX, SOTALOL, STRESAM
Adverse Events (AE) Preferred term	1. Musculoskeletal pain 2. Tachycardia 3. Pain in extremity 4. Labile hypertension 5. Cystitis 6. Arthropod bite 7. Nasopharyngitis 8. Dental caries 9. Pulmonary hypertension
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/YES/NO
Start/stop date of event with relative date	1. --JAN2010 (.) - --JAN2010 (.) 2. --FEB2009 (.) - --------- (.) 3. 04FEB2009 (8) - 16FEB2009 (20) 4. 05FEB2009 (9) - --------- (.) 5. 19FEB2009 (23) - 25FEB2009 (29) 6. 02SEP2009 (218) - 11SEP2009 (227) 7. 08NOV2009 (285) - 11NOV2009 (288) 8. 25NOV2009 (302) - 25NOV2009 (302) 9. 08FEB2010 (377) - --------- (.)
Duration of AE	1. . 2. . 3. 13 4. . 5. 7 6. 10 7. 4 8. 1 9. .
Dose on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303021

Parameter	Value
	2.
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. I
	9. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	9. OTHER
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303024

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303024/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/48/N.A./FRANCE/YES
Medical history	Umbilical hernia repair, Lung disorder, Spinal column injury
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, DOLIPRANE, ENOXAPARIN, INEXIUM, INNOHEP, LOVENOX, STRESSAN, WARFARIN
Adverse Events (AE) Preferred term	1. Renal cyst 2. Anxiety 3. Dysphagia 4. Gingival bleeding 5. Renal cyst 6. Dyspepsia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. SEVERE/NO/YES/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 23MAR2009 (22) - 16SEP2009 (199) 2. 20APR2009 (50) - 14MAY2009 (74) 3. 23APR2009 (53) - --------- (.) 4. 28AUG2009 (180) - 28AUG2009 (180) 5. 16SEP2009 (199) - 23SEP2009 (206) 6. 07OCT2009 (220) - 30OCT2009 (243)
Duration of AE	1. 178 2. 25 3. . 4. 1 5. 8 6. 24
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303024

Parameter	Value
	3. NONE
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. IMPROVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303025

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303025/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/46/N.A./FRANCE/YES
Medical history	Seasonal allergy, Skin ulcer, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, AERIUS, AUGMENTIN, CHAMPIX, DOLIPRANE, HUMEX [BENZALKONIUM CHLORIDE], PERFALGAN
Adverse Events (AE) Preferred term	1. Nervousness 2. Chest pain 3. Chest pain 4. Pain in extremity 5. Vein pain 6. Oedema
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/NO 5. MILD/NO/NO/NO 6. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --SEP2009 (.) - --OCT2009 (.) 2. 25MAR2009 (16) - 27MAR2009 (18) 3. 27MAR2009 (18) - 28MAR2009 (19) 4. 22MAR2010 (378) - 25MAR2010 (381) 5. 22MAR2010 (378) - 25MAR2010 (381) 6. 22MAR2010 (378) - 25MAR2010 (381)
Duration of AE	1. . 2. 3 3. 2 4. 4 5. 4 6. 4
Dose on AE onset	1. 2. 15 mg 3. 15 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. F 5. F 6. F
Action taken	1. OTHER 2. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303025

Parameter	Value
	3. REMEDIAL DRUG THERAPY
	4. OTHER
	5. OTHER
	6. OTHER
Outcome of event	1. RESOLVED
	2. WORSENED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303027

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303027/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/59/N.A./FRANCE/YES
Medical history	Alcoholism, Atrial fibrillation, Hypertension, Chronic obstructive pulmonary disease, Diabetes mellitus, Diarrhoea, Pulmonary infarction, Bronchitis, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, ACUPAN, AMLOR, ATROVENT, AUGMENTIN, BRICANYL, COVERSYL, DOLIPRANE, ECONAZOLE, FLECAINE, FORADIL, FORTUM, HEMIGOXINE, IPRATROPIUM, IZILOX, LACTEOL, LANTUS, LASILIX, NICO PATCH, SMECTA [DIOSMECTITE ONLY], SOLUMEDROL, SOLUPRED, SPIRIVA, TOPLEXIL [OXOMEMAZINE ONLY]
Adverse Events (AE) Preferred term	1. Tinea pedis 2. Bronchopulmonary aspergillosis 3. Bronchitis 4. Pulmonary haemorrhage 5. Diabetes mellitus
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 06APR2009 (20) - 08APR2009 (22) 2. 30APR2009 (44) - 23JUN2009 (98) 3. 30APR2009 (44) - --------- (.) 4. 01JUN2009 (76) - 23JUN2009 (98) 5. 15JUN2009 (90) - --------- (.)
Duration of AE	1. 3 2. 55 3. . 4. 23 5. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. F
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. OTHER 5. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303027

Parameter	Value
Outcome of event	1. RESOLVED 2. DEATH 3. UNCHANGED 4. DEATH 5. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160303027[1)]	LUNG ABSCESS（PT：肺膿瘍） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症（肺感染）による合併症と考え、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303031

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303031/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/49/N.A./FRANCE/YES
Medical history	Anxiety, Venous insufficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CARBOLEVURE, CERAZETTE, CONTRAMAL, DOLIPRANE, ENOXAPARIN, INEXIUM, LOVENOX, PERFALGAN, SOLUPRED, WARFARIN
Adverse Events (AE) Preferred term	1. Gastritis 2. Abdominal pain upper 3. Paraesthesia 4. Uterine leiomyoma 5. Ovarian enlargement 6. Polycystic ovaries 7. Intestinal polyp 8. Neck pain 9. Alopecia 10. International normalised ratio decreased 11. Splenic haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/YES/NO/YES 10. MILD/YES/NO/YES 11. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. --MAY2009 (.) - --------- (.) 2. 20APR2009 (7) - 21APR2009 (8) 3. 20APR2009 (7) - 21APR2009 (8) 4. 07MAY2009 (24) - --------- (.) 5. 07MAY2009 (24) - --------- (.) 6. 07MAY2009 (24) - --------- (.) 7. 28MAY2009 (45) - 28MAY2009 (45) 8. 28MAY2009 (45) - --------- (.) 9. 25JUN2009 (73) - --------- (.) 10. 09JUL2009 (87) - --------- (.) 11. 27JUL2009 (105) - --------- (.)
Duration of AE	1. . 2. 2 3. 2 4. . 5. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303031

Parameter	Value
	6. .
	7. 1
	8. .
	9. .
	10. .
	11. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. OTHER
	5. NONE
	6. NONE
	7. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303031

Parameter	Value
	6. UNCHANGED
	7. RESOLVED
	8. UNCHANGED
	9. UNCHANGED
	10. UNCHANGED
	11. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160303031[2)]	SPLEEN HEMATOMA（PT：脾血腫） 治験担当医はエノキサパリンと報告事象との関連性があると判断した。弊社は、エノキサパリン投与終了 12 週間後の発現であり、時間的関連性がないことから、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303036

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303036/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/35/N.A./FRANCE/YES
Medical history	Pertussis, Pilonidal cyst
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, BIPROFENID, CLARITHROMYCINE, DOLIPRANE, EFFERALGAN CODEINE, ENOXAPARIN, EUPHON, GYNÉPÉVARYL, INEXIUM, LEXOMIL, NASONEX, NAXY, PERFALGAN, PRIMPERAN, SMECTA [DIOSMECTITE], SOLUPRED, SPASFON, TIORFAN, WARFARIN
Adverse Events (AE) Preferred term	1. Nausea 2. Anxiety 3. International normalised ratio increased 4. Gastroenteritis 5. Bronchitis 6. Sciatica 7. Rectal haemorrhage 8. Haemoptysis 9. Candidiasis 10. Colon cancer
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/YES/NO/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/YES/NO
Start/stop date of event with relative date	1. 19OCT2009 (5) - 19OCT2009 (5) 2. 20OCT2009 (6) - 21OCT2009 (7) 3. 21OCT2009 (7) - 22OCT2009 (8) 4. 03FEB2010 (112) - 07FEB2010 (116) 5. 03MAR2010 (140) - 10MAR2010 (147) 6. 10MAR2010 (147) - --------- (.) 7. 02AUG2010 (292) - 02AUG2010 (292) 8. 04AUG2010 (294) - 04AUG2010 (294) 9. 09SEP2010 (330) - 12SEP2010 (333) 10. 01NOV2010 (383) - 02NOV2010 (384)
Duration of AE	1. 1 2. 2 3. 2 4. 5 5. 8 6. . 7. 1

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303036

Parameter	Value
	8. 1
	9. 4
	10. 2
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. OTHER
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303036

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303041

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303041/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/64/N.A./FRANCE/YES
Medical history	Menopause, Nephrotic syndrome, Pneumonia, Prolactinoma, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPINE, BACTRIM FORT, COAPROVEL, COVERSYL, DOLIPRANE, LASILIX, LEXOMIL, OFLOCET, PERINDOPRIL, RITUXIMAB, ROCEPHINE, TAVANIC, UNFRACTIONATED HEPARIN, ZOCOR
Adverse Events (AE) Preferred term	1. Anxiety 2. Glomerulonephritis membranous 3. Glomerulonephritis membranous 4. Glomerulonephritis membranous 5. Glomerulonephritis membranous
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 10JAN2010 (6) - 14JAN2010 (10) 2. 01FEB2010 (28) - 02FEB2010 (29) 3. 02FEB2010 (29) - 18FEB2010 (45) 4. 18FEB2010 (45) - 19FEB2010 (46) 5. 19FEB2010 (46) - --------- (.)
Duration of AE	1. 5 2. 2 3. 17 4. 2 5. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. I 3. . 4. . 5. .
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303041

Parameter	Value
	3. IMPROVED
	4. IMPROVED
	5. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303044

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303044/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/75/N.A./FRANCE/YES
Medical history	Prostate cancer, Aortic valve incompetence, Cough, Arrhythmia, Hyperthyroidism, Sleep apnoea syndrome, Shoulder arthroplasty, Hyperhomocysteinaemia, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, ATENOLOL, CORDARONE, FOSFOMYCINE, KARDEGIC, LIPANTHYL, PULMICORT, RULID, SPECIAFOLDINE
Adverse Events (AE) Preferred term	1. Left ventricular failure 2. Anxiety 3. Chest discomfort 4. Arteriosclerosis 5. Lung neoplasm 6. Pancreatic cyst 7. Adrenal mass 8. Bronchitis 9. Urinary tract infection 10. Atrial flutter 11. Ischaemic stroke
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MODERATE/NO/YES/YES 11. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. -----2010 (.) - --------- (.) 2. --FEB2010 (.) - --FEB2010 (.) 3. --FEB2010 (.) - --FEB2010 (.) 4. --OCT2010 (.) - --------- (.) 5. 23FEB2010 (36) - --------- (.) 6. 23FEB2010 (36) - --------- (.) 7. 23FEB2010 (36) - --------- (.) 8. 02MAR2010 (43) - 12MAR2010 (53) 9. 23JUL2010 (186) - 13AUG2010 (207) 10. 02AUG2010 (196) - 05AUG2010 (199) 11. 06OCT2010 (261) - 14OCT2010 (269)
Duration of AE	1. . 2. . 3. . 4. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303044

Parameter	Value
	5. .
	6. .
	7. .
	8. 11
	9. 22
	10. 4
	11. 9
Dose on AE onset	1.
	2.
	3.
	4.
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4.
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
Action taken	1. OTHER
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. OTHER
	6. OTHER
	7. OTHER
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY,OTHER
	11. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303044

Parameter	Value
	5. UNCHANGED
	6. UNCHANGED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303047

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303047/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/35/N.A./FRANCE/YES
Medical history	Appendicectomy, Caesarean section, Caesarean section, Pulmonary hypertension, Renal atrophy, Venous insufficiency, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AERIUS, BI PROFENID, DALACINE T TOPIC, ENOXOR, GINKOR FORT, INEXIUM, INIPOMP, LEXOMIL, PARACETAMOL, TAHOR, UNFRACTIONATED HEPARIN
Adverse Events (AE) Preferred term	1. Folliculitis 2. Pruritus 3. Gingival bleeding 4. Anxiety 5. Chest pain 6. Dyspnoea 7. Atrial septal defect 8. Atrial septal defect 9. Atrial septal defect 10. Cardiac septal defect 11. Anomalous pulmonary venous connection 12. Urinary tract infection 13. Pericarditis 14. Furuncle
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/YES/YES 8. MILD/NO/YES/YES 9. MILD/NO/YES/YES 10. MODERATE/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MILD/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JUN2010 (.) - 28JUL2010 (127) 2. 03APR2010 (11) - 07APR2010 (15) 3. 01MAY2010 (39) - --MAY2010 (.) 4. 23JUN2010 (92) - --------- (.) 5. 16SEP2010 (177) - 17SEP2010 (178) 6. 16SEP2010 (177) - --------- (.) 7. 19OCT2010 (210) - 23OCT2010 (214) 8. 09NOV2010 (231) - 10NOV2010 (232) 9. 25NOV2010 (247) - 27NOV2010 (249)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303047

Parameter	Value
	10. 26NOV2010 (248) - --------- (.)
	11. 26NOV2010 (248) - --------- (.)
	12. 03JAN2011 (286) - 07JAN2011 (290)
	13. 04JAN2011 (287) - 20JAN2011 (303)
	14. 07JAN2011 (290) - 11JAN2011 (294)
Duration of AE	1. .
	2. 5
	3. .
	4. .
	5. 2
	6. .
	7. 5
	8. 2
	9. 3
	10. .
	11. .
	12. 5
	13. 17
	14. 5
Dose on AE onset	1.
	2. 15 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303047

Parameter	Value
	12. .
	13. .
	14. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. UNCHANGED
	11. UNCHANGED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303048

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303048/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/55/N.A./FRANCE/YES
Medical history	Drug hypersensitivity, Rhinitis allergic, Anal fissure excision, Chest pain, Depression, Drug hypersensitivity, Haemorrhoids, Pneumonitis, Renal aplasia, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CITALOPRAM, DEPAKOTE, FRAXIPARINE, IXEL, LEXOMIL, LYSANXIA, MEPRONIZINE, SOLIAN, STABLON, TAHOR, TERCIAN, UNFRACTIONATED HEPARIN, VIRLIX
Adverse Events (AE) Preferred term	1. Gastrooesophageal reflux disease 2. Depression 3. Urinary tract infection 4. Prostatism 5. Tremor 6. Depression
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/NO 4. MILD/NO/NO/NO 5. MILD/NO/NO/NO 6. MILD/NO/YES/NO
Start/stop date of event with relative date	1. --JAN2011 (.) - --------- (.) 2. 09SEP2010 (112) - 23OCT2010 (156) 3. 20DEC2010 (214) - 27DEC2010 (221) 4. 20DEC2010 (214) - --------- (.) 5. 02FEB2011 (258) - --------- (.) 6. 01APR2011 (316) - 15APR2011 (330)
Duration of AE	1. . 2. 45 3. 8 4. . 5. . 6. 15
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. 2. . 3. F 4. F 5. F 6. F
Action taken	1. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303048

Parameter	Value
	2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. OTHER
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. IMPROVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303051

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160303051/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/20/N.A./FRANCE/YES
Medical history	Abortion, Lung disorder, Hepatitis, Gastric ulcer, Haemoptysis, Abortion spontaneous, Pharyngitis, Tobacco user, Bronchitis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, ADVIL, BI PROFENID, BIPERIDYS, BIPROFENID, CERAZETTE, CONTRAMAL, DOLIPRANE, ENOXAPARIN, INIPOMP, NICOPATCH, PARACETAMOL, PERFALGAN, SMECTA [DIOSMECTITE], TOPALGIC [TRAMADOL (DCI) CHLORHYDRATE], VOGALENE, WARFARIN
Adverse Events (AE) Preferred term	1. Lung disorder 2. Chest pain 3. Anxiety 4. Tachycardia 5. International normalised ratio abnormal 6. Head injury 7. Epistaxis 8. Ligament sprain 9. Epistaxis 10. Ecchymosis 11. International normalised ratio increased 12. Subcutaneous haematoma 13. Haematuria 14. Gastroenteritis 15. Acute tonsillitis 16. Thoracic vertebral fracture 17. Nasopharyngitis 18. Thoracic vertebral fracture
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/YES/NO/YES 11. MILD/YES/NO/YES 12. MILD/YES/NO/YES 13. MILD/YES/NO/YES 14. MILD/NO/NO/YES 15. MILD/NO/NO/YES 16. MODERATE/NO/YES/YES 17. MILD/NO/NO/NO 18. MILD/NO/NO/NO

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303051

Parameter	Value
Start/stop date of event with relative date	1. 30SEP2010 (9) - 02OCT2010 (11) 2. 20OCT2010 (29) - 22OCT2010 (31) 3. 20OCT2010 (29) - 22OCT2010 (31) 4. 20OCT2010 (29) - 20OCT2010 (29) 5. 10NOV2010 (50) - 19NOV2010 (59) 6. 17DEC2010 (87) - 10JAN2011 (111) 7. 01FEB2011 (133) - 01FEB2011 (133) 8. 29APR2011 (220) - 10MAY2011 (231) 9. 05MAY2011 (226) - 05MAY2011 (226) 10. 07JUN2011 (259) - 20JUN2011 (272) 11. 08JUN2011 (260) - 14JUN2011 (266) 12. 12JUN2011 (264) - 01JUL2011 (283) 13. 28JUN2011 (280) - 28JUN2011 (280) 14. 07JUL2011 (289) - 11JUL2011 (293) 15. 08JUL2011 (290) - 11JUL2011 (293) 16. 11AUG2011 (324) - 06OCT2011 (380) 17. 26SEP2011 (370) - 30SEP2011 (374) 18. 06OCT2011 (380) - --------- (.)
Duration of AE	1. 3 2. 3 3. 3 4. 1 5. 10 6. 25 7. 1 8. 12 9. 1 10. 14 11. 7 12. 20 13. 1 14. 5 15. 4 16. 57 17. 5 18. .
Dose on AE onset	1. 2. 3. 4. 5. 6. 7. 8.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303051

Parameter	Value
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. NONE
	6. OTHER
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. STUDY DRUG DISCONTINUED AND RESTARTED
	12. NONE
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
	16. OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160303051

Parameter	Value
	17. REMEDIAL DRUG THERAPY
	18. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. IMPROVED
	17. RESOLVED
	18. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160303051[1)]	EQUILIBRATION OF INR（PT：国際標準比異常） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併用被疑薬（ワルファリン）によるものであり、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160323002/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/87/N.A./FRANCE/YES
Medical history	Anaemia, Breast cancer, Syncope, Hiatus hernia, Hypertension, Postmenopause, Coronary artery disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, CORVASAL, KARDEGIC, KAYEXALATE, LANSOPRAZOL, LASILIX, LOVENOX, NACL INFUSION, PERFALGAN, PRAVASTATINE, RINGER INFUSION, TAGAMET, TARDYFERON, TRIATEC
Adverse Events (AE) Preferred term	1. Syncope 2. Hyperkalaemia 3. Anaemia 4. Syncope 5. Vertigo 6. Cardiac failure
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. SEVERE/YES/YES/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 21AUG2008 (4) - 25AUG2008 (8) 2. 23AUG2008 (6) - 12SEP2008 (26) 3. 08SEP2008 (22) - 11SEP2008 (25) 4. 08SEP2008 (22) - 17SEP2008 (31) 5. 19NOV2008 (94) - 19NOV2008 (94) 6. 13MAR2009 (208) - --------- (.)
Duration of AE	1. 5 2. 21 3. 4 4. 10 5. 1 6. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. F
Action taken	1. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323002

Parameter	Value
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY,OTHER
	4. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160323002[4)]	ANEMIA（PT：貧血） 治験担当医は、因果関係は否定できると判断した。弊社は、リバーロキサバンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160323014/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/27/N.A./FRANCE/YES
Medical history	Asthma, Cholecystectomy, Lymphadenopathy mediastinal, Obesity, Habitual abortion, Salpingitis, Latex allergy, Gastric banding, Sex chromosome abnormality
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, ATARAX, IMOVANE, LEXOMIL, PERFALGAN, PYOSTACINE, SEROPLEX, SINGULAIR, SYMBICORT, TOPALGIC [TRAMADOL CHLORYDRATE], TRINORDIOL, UNFRACTIONATED HEPARIN, VENTOLINE, XANAX, ZOPHREN
Adverse Events (AE) Preferred term	1. Alcohol use 2. Paronychia 3. Koilonychia 4. Chest pain 5. Weight decreased 6. Change of bowel habit 7. Syncope 8. Sarcoidosis 9. Postoperative wound infection 10. Affective disorder 11. Anxiety 12. Suicide attempt 13. Chest discomfort 14. Dysuria 15. Sarcoidosis 16. Hyperthyroidism
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. SEVERE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MODERATE/NO/YES/YES 13. MODERATE/NO/NO/YES 14. MODERATE/NO/NO/YES 15. MODERATE/NO/YES/YES 16. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --JUL2009 (.) - --AUG2009 (.) 2. --DEC2009 (.) - --DEC2009 (.) 3. --DEC2009 (.) - --------- (.) 4. 16JUN2009 (12) - 16JUN2009 (12)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323014

Parameter	Value
	5. 17JUN2009 (13) - --------- (.)
	6. 20JUN2009 (16) - 20JUN2009 (16)
	7. 20JUN2009 (16) - 20JUN2009 (16)
	8. 23JUN2009 (19) - --------- (.)
	9. 15JUL2009 (41) - --SEP2009 (.)
	10. 15JUL2009 (41) - --------- (.)
	11. 15JUL2009 (41) - --------- (.)
	12. 27JUL2009 (53) - 31JUL2009 (57)
	13. 30JUL2009 (56) - 30JUL2009 (56)
	14. 31JUL2009 (57) - 06AUG2009 (63)
	15. 27OCT2009 (145) - 29OCT2009 (147)
	16. 30NOV2009 (179) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. 1
	5. .
	6. 1
	7. 1
	8. .
	9. .
	10. .
	11. .
	12. 5
	13. 1
	14. 7
	15. 3
	16. .
Dose on AE onset	1.
	2.
	3.
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323014

Parameter	Value
Dose status on AE onset	1.
	2.
	3.
	4. I
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. NONE
	14. OTHER
	15. NONE
	16. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. IMPROVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED
	10. IMPROVED
	11. IMPROVED
	12. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323014

Parameter	Value
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160323020/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/78/N.A./FRANCE/YES
Medical history	Cholecystectomy, Gastrooesophageal reflux disease, Hypertension, Nocturia, Prostatic adenoma, Renal failure chronic, Hydrocele operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMILORIDE, CIFLOX, DEBRIDAT, DUPHALAC [LACTULOSE ALONE], ENOXAPARIN, GAVISCON, LOVENOX, OGASTORO, OMIX, TANAKAN, UNFRACTIONATED HEPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Constipation 2. Urinary tract infection 3. Haematuria 4. Renal cancer 5. Weight decreased 6. Asthenia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/YES/YES/YES 4. SEVERE/NO/YES/NO 5. MODERATE/NO/NO/NO 6. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 04OCT2009 (4) - 14OCT2009 (14) 2. 06OCT2009 (6) - 23OCT2009 (23) 3. 18OCT2009 (18) - 27OCT2009 (27) 4. 11NOV2009 (42) - 17NOV2009 (48) 5. 30NOV2009 (61) - --------- (.) 6. 30NOV2009 (61) - --------- (.)
Duration of AE	1. 11 2. 18 3. 10 4. 7 5. . 6. .
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323020

Parameter	Value
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED PERMANENTLY
	4. OTHER
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160323023/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/37/N.A./FRANCE/YES
Medical history	Appendicectomy, Osteoarthritis, Crohn's disease, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, AUGMENTIN, CIFLOX, CLAMOXYL, DAFLON [DIOSMINE ALONE], DIFFU K, DOLIPRANE, ENOXAPARIN, FLAGYL, FORLAX, LACTEOL, LEXOMIL, MEDROL, OGASTORO, ROWASA, SPASFON, STILNOX, TOPALGIC [TRAMADOL CHLORYDRATE], UFH, ULTRA LEVURE, UNFRACTIONATED HEPARIN, UNFRACTIONNED HEPARIN
Adverse Events (AE) Preferred term	1. Aphthous stomatitis 2. Anxiety 3. Aphthous stomatitis 4. Pyrexia 5. Constipation 6. Pulmonary infarction 7. Pleural effusion 8. Depression 9. Colitis 10. Genital ulceration 11. Colitis 12. Insomnia 13. Arthralgia 14. Colitis 15. Hypokalaemia 16. Muscle spasms 17. Tremor 18. Rash vesicular 19. Weight increased
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. SEVERE/NO/YES/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/NO/YES 11. SEVERE/NO/YES/YES 12. MODERATE/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MILD/NO/NO/YES 15. MODERATE/NO/NO/YES 16. MODERATE/NO/NO/YES 17. MODERATE/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323023

Parameter	Value
	18. MODERATE/NO/NO/YES
	19. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --AUG2010 (.) - 27SEP2010 (227)
	2. 14FEB2010 (2) - --JUN2010 (.)
	3. 15FEB2010 (3) - 07JUN2010 (115)
	4. 15FEB2010 (3) - 22FEB2010 (10)
	5. 17FEB2010 (5) - 19FEB2010 (7)
	6. 22FEB2010 (10) - 03MAR2010 (19)
	7. 22FEB2010 (10) - 02MAR2010 (18)
	8. 14APR2010 (61) - --JUN2010 (.)
	9. 12MAY2010 (89) - 27MAY2010 (104)
	10. 12MAY2010 (89) - 12JUL2010 (150)
	11. 27MAY2010 (104) - 03JUN2010 (111)
	12. 30MAY2010 (107) - --------- (.)
	13. 02JUN2010 (110) - 12JUL2010 (150)
	14. 03JUN2010 (111) - 07JUN2010 (115)
	15. 03JUN2010 (111) - --------- (.)
	16. 12JUL2010 (150) - 27SEP2010 (227)
	17. 12JUL2010 (150) - --------- (.)
	18. 12JUL2010 (150) - --------- (.)
	19. 27SEP2010 (227) - --------- (.)
Duration of AE	1. .
	2. .
	3. 113
	4. 8
	5. 3
	6. 10
	7. 9
	8. .
	9. 16
	10. 62
	11. 8
	12. .
	13. 41
	14. 5
	15. .
	16. 78
	17. .
	18. .
	19. .
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323023

Parameter	Value
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
	18. .
	19. F
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	7. STUDY DRUG DISCONTINUED AND RESTARTED
	8. NONE
	9. STUDY DRUG DISCONTINUED AND RESTARTED
	10. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323023

Parameter	Value
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
	16. NONE
	17. NONE
	18. NONE
	19. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. WORSENED
	10. RESOLVED
	11. IMPROVED
	12. UNCHANGED
	13. RESOLVED
	14. RESOLVED
	15. IMPROVED
	16. RESOLVED
	17. UNCHANGED
	18. IMPROVED
	19. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323026

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160323026/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/43/N.A./FRANCE/YES
Medical history	Appendicectomy, Obesity, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT, AUGMENTIN, BRICANYL, CÉRAZETTE, DAFALGAN, DOLIPRANE, ENOXAPARIN, GAVISCON, INEXIUM, WARFARIN
Adverse Events (AE) Preferred term	1. Gastrooesophageal reflux disease 2. Chest pain 3. Dyspnoea 4. Alanine aminotransferase increased 5. Lung infection 6. Lung infection 7. Oedema peripheral
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --SEP2010 (.) - --------- (.) 2. --SEP2010 (.) - 15SEP2010 (146) 3. --SEP2010 (.) - 15SEP2010 (146) 4. 06MAY2010 (14) - 25MAY2010 (33) 5. 08MAY2010 (16) - 11MAY2010 (19) 6. 11MAY2010 (19) - 12MAY2010 (20) 7. 15SEP2010 (146) - 16SEP2010 (147)
Duration of AE	1. . 2. . 3. . 4. 20 5. 4 6. 2 7. 2
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323026

Parameter	Value
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. WORSENED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323035

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160323035/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/36/N.A./FRANCE/YES
Medical history	Asthma, Insomnia, Muscle contractions involuntary, Obesity, Intervertebral disc protrusion, Meniscus removal, House dust allergy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADEPAL, BECOTIDE, STILNOX, TETRAZEPAM, UNFRACTIONATED HEPARIN, VENTOLOINE
Adverse Events (AE) Preferred term	1. Asthma
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 31DEC2010 (183) - 03JAN2011 (186)
Duration of AE	1. 4
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. F
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323036

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160323036/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/80/N.A./FRANCE/YES
Medical history	Pancreatitis acute, Rheumatoid arthritis, Breast cancer, Cystitis noninfective, Dry eye, Folate deficiency, Hypertension, Irritable bowel syndrome, Obesity, Pulmonary hypertension, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTONEL, AMLOR, ATARAX, CELLUVISC, DAFALGAN, DETENSIEL, DI-ANTALVIC, ESIDREX, LOVENOX, METHOTREXATE, MODURETIC, PIPRAM, PREDNISONE, SPASFON, SPECIALFOLDINE, UFH, UNFRACTIONATED HEPARIN
Adverse Events (AE) Preferred term	1. Benign hepatic neoplasm 2. Benign ovarian tumour 3. Metrorrhagia 4. Metrorrhagia 5. Hyperthermia 6. Pneumonia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/YES/YES/YES 5. MODERATE/NO/NO/NO 6. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 06OCT2010 (28) - --------- (.) 2. 23DEC2010 (106) - --------- (.) 3. 23DEC2010 (106) - 04JAN2011 (118) 4. 05JAN2011 (119) - 10JAN2011 (124) 5. 30MAR2011 (203) - 03APR2011 (207) 6. 01APR2011 (205) - 05APR2011 (209)
Duration of AE	1. . 2. . 3. 13 4. 6 5. 5 6. 5
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. F 6. F

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160323036

Parameter	Value
Action taken	1. NONE
	2. NONE
	3. NONE
	4. STUDY DRUG DISCONTINUED AND RESTARTED
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. WORSENED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160333001/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/83/N.A./FRANCE/YES
Medical history	Depression, Cataract, Varicose vein, Osteoarthritis, Phlebectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARIXTRA, DAFALGAN, DERINOX [NAPHAZOLINE AND PREDNISOLONE], SEROPLEX, ZINNAT, ZOPICLONE
Adverse Events (AE) Preferred term	1. Syncope 2. Syncope 3. Haematoma 4. Haematoma 5. Bronchitis 6. Blister
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MILD/YES/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 26MAY2008 (19) - 28MAY2008 (21) 2. 29MAY2008 (22) - 02JUN2008 (26) 3. 29MAY2008 (22) - 02JUN2008 (26) 4. 29MAY2008 (22) - 06AUG2008 (91) 5. 01JUL2008 (55) - 17JUL2008 (71) 6. 06AUG2008 (91) - 10SEP2008 (126)
Duration of AE	1. 3 2. 5 3. 5 4. 70 5. 17 6. 36
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. .
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333001

Parameter	Value
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160333004/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/85/N.A./FRANCE/YES
Medical history	Deafness, Depression, Dysphagia, Herpes zoster, Hypertension, Hysterectomy, Insomnia, Leukopenia, Meningitis, Migraine, Motor neurone disease, Constipation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTAZINE, ATARAX, CETORNAN, CYMBALTA, INEXIUM, KARDEGIC, LACTULOSE, LAROXYL, LAXILIX, MODOPAR, PERFALGAN, PRIMPERAN, SANMIGRAN, VASTAREL, ZOPICLONE
Adverse Events (AE) Preferred term	1. Dysphagia 2. Nausea 3. Hyponatraemia 4. Small intestinal haemorrhage 5. Vomiting 6. Acute respiratory distress syndrome 7. Pneumonia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/NO 5. MODERATE/NO/NO/NO 6. SEVERE/NO/YES/NO 7. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 13JUN2008 (2) - --------- (.) 2. 19JUN2008 (8) - 06JUL2008 (25) 3. 22JUN2008 (11) - 06JUL2008 (25) 4. 27JUN2008 (16) - 30JUN2008 (19) 5. 05JUL2008 (24) - 06JUL2008 (25) 6. 06JUL2008 (25) - 06JUL2008 (25) 7. 06JUL2008 (25) - 06JUL2008 (25)
Duration of AE	1. . 2. 18 3. 15 4. 4 5. 2 6. 1 7. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 15 mg 6. 15 mg 7. 15 mg
Dose status on AE onset	1. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333004

Parameter	Value
	2. .
	3. .
	4. F
	5. F
	6. F
	7. F
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	3. NONE
	4. OTHER
	5. NONE
	6. OTHER
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. WORSENED
	3. WORSENED
	4. RESOLVED
	5. WORSENED
	6. DEATH
	7. WORSENED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160333009/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/74/N.A./FRANCE/YES
Medical history	Anaemia, Anxiety, Colitis, Diabetes mellitus, Gastritis, Temporal arteritis, Renal cancer metastatic, Metastases to nasal sinuses
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DOMPERIDONE, ENOXAPARIN, HYPNOVEL, LANSOPRAZOLE, LORAZEPAM, MINIDIAB, PREDNISONE, SCOPOLAMINE, WARFARIN
Adverse Events (AE) Preferred term	1. Epistaxis 2. Epistaxis 3. Haemoptysis 4. Pleurisy
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. SEVERE/YES/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 17SEP2008 (14) - 17SEP2008 (14) 2. 22SEP2008 (19) - 22SEP2008 (19) 3. 10OCT2008 (37) - 10OCT2008 (37) 4. 16DEC2008 (104) - 24DEC2008 (112)
Duration of AE	1. 1 2. 1 3. 1 4. 9
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. OTHER 2. STUDY DRUG DISCONTINUED AND RESTARTED 3. NONE 4. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333009

Parameter	Value
	4. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160333012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/83/N.A./FRANCE/YES
Medical history	Haemoptysis, Hypertension, Bronchopulmonary aspergillosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARIXTRA, CHRONADALATE, ENOXAPARIN, FONDAPARINUX, WARFARIN
Adverse Events (AE) Preferred term	1. Haemoptysis
	2. Atrial fibrillation
	3. Haemoptysis
	4. Stenotrophomonas infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES
	2. MILD/NO/NO/YES
	3. MODERATE/YES/YES/YES
	4. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 20OCT2008 (6) - 27OCT2008 (13)
	2. 05NOV2008 (22) - 24NOV2008 (41)
	3. 05NOV2008 (22) - 27NOV2008 (44)
	4. 08NOV2008 (25) - 23NOV2008 (40)
Duration of AE	1. 8
	2. 20
	3. 23
	4. 16
Dose on AE onset	1.
	2.
	3.
	4.
Dose status on AE onset	1.
	2.
	3.
	4.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333012

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160333012[3),1),1)]	HEMOPTYSIS（PT：喀血）2 事象有 1）治験担当医はエノキサパリン及びワルファリンと報告事象との因果関係評価を行っていない。弊社は、エノキサパリン投与と報告事象発現との時間的関連性から、因果関係は否定できないと考える。また、ワルファリンについては、ワルファリン投与開始前の発現であることから、因果関係は否定できると考える。 2）治験担当医は報告事象との因果関係評価を行っていない。弊社は、ワルファリン投与中止 10 日後の発現であり、時間的関連性がないことから、因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160333014/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/57/N.A./FRANCE/YES
Medical history	Asthma, Sleep apnoea syndrome, Iodine allergy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT, NASONEX, SERETIDE, VENTOLINE
Adverse Events (AE) Preferred term	1. Rectal haemorrhage
	2. Rectal haemorrhage
	3. Colon cancer
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES
	2. MODERATE/YES/YES/YES
	3. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 10MAR2009 (138) - 12MAR2009 (140)
	2. 12MAR2009 (140) - 17MAR2009 (145)
	3. 18MAR2009 (146) - 08APR2009 (167)
Duration of AE	1. 3
	2. 6
	3. 22
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
Dose status on AE onset	1. .
	2. F
	3. F
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
	2. OTHER
	3. OTHER
Outcome of event	1. WORSENED
	2. RESOLVED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160333023/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/28/N.A./FRANCE/YES
Medical history	
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CHLORHYDRATE MORPHINE, CLOXACILLINE, DI ANTALVIC, DOMPERIDONE, ENOXAPARIN, ORBENINE, PARACETAMOL, SMECTA [DIOSMECTITE = SILICATES], TRIMEBUTINE, WARFARIN
Adverse Events (AE) Preferred term	1. Constipation 2. Sepsis 3. Alopecia areata 4. Asthenia 5. Hepatitis A
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 14JAN2009 (2) - 18JAN2009 (6) 2. 15JAN2009 (3) - 29JAN2009 (17) 3. 06FEB2009 (25) - --------- (.) 4. 13MAY2009 (121) - 03AUG2009 (203) 5. 25JUN2009 (164) - 07SEP2009 (238)
Duration of AE	1. 5 2. 15 3. . 4. 83 5. 75
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. NONE 4. NONE 5. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. RESOLVED 2. RESOLVED 3. INSUFFICIENT FOLLOW-UP

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333023

Parameter	Value
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333035

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160333035/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/65/N.A./FRANCE/YES
Medical history	Nervousness, Small cell lung cancer stage unspecified, Malignant mediastinal neoplasm, Chronic obstructive pulmonary disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AZANTAC, DEROXAT, EMEND, ENOXAPARIN, GRANOCYTE, GRANOCYTES, HYCAMTIN, IMMODIUM, NEORICORMON, PRIMPERAN, PROFENID, PULMICORT, PYOSTACINE, SERETIDE, SMECTA [DIOSMECTITE], SOLUMEDROL, SOLUPRED, SPIRIVA, STILNOX, TOPALGIC [TRAMADOL], VENTOLINE, WARFARIN, XANAX, ZOPHREN
Adverse Events (AE) Preferred term	1. Asthenia 2. Nausea 3. Diarrhoea 4. Mental disorder 5. Dehydration 6. Mental disorder 7. Asthenia 8. Bronchitis 9. Back pain 10. Acute respiratory failure
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. SEVERE/NO/YES/YES 10. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 05JUL2009 (10) - 21JUL2009 (26) 2. 05JUL2009 (10) - 21JUL2009 (26) 3. 05JUL2009 (10) - 21JUL2009 (26) 4. 06AUG2009 (42) - 10AUG2009 (46) 5. 06AUG2009 (42) - 10AUG2009 (46) 6. 11AUG2009 (47) - --------- (.) 7. 07SEP2009 (74) - 28SEP2009 (95) 8. 26OCT2009 (123) - --NOV2009 (.) 9. 23NOV2009 (151) - --------- (.) 10. 27NOV2009 (155) - 27NOV2009 (155)
Duration of AE	1. 17 2. 17 3. 17 4. 5 5. 5

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333035

Parameter	Value
	6. .
	7. 22
	8. .
	9. .
	10. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	10. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. IMPROVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333035

Parameter	Value
	10. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333039

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160333039/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/65/N.A./FRANCE/YES
Medical history	Hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CORENITEC, ENOXAPARIN, FONDAPARINUX, INNOHEP, LERCAN, WARFARIN, ZOVIRAX
Adverse Events (AE) Preferred term	1. Herpes zoster
	2. Coronary artery disease
	3. Coronary artery disease
	4. Coronary artery disease
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/YES/YES
	4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 08DEC2009 (112) - 30DEC2009 (134)
	2. 12JAN2010 (147) - 25JAN2010 (160)
	3. 25JAN2010 (160) - 27JAN2010 (162)
	4. 27JAN2010 (162) - --------- (.)
Duration of AE	1. 23
	2. 14
	3. 3
	4. .
Dose on AE onset	1.
	2.
	3.
	4.
Dose status on AE onset	1.
	2.
	3.
	4.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
Outcome of event	1. RESOLVED
	2. WORSENED
	3. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333039

Parameter	Value
	4. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333049

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160333049/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/N.A./FRANCE/YES
Medical history	Asthma, Gout, Hypercholesterolaemia, Hyperuricaemia, Renal failure
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BEFIZAL, CONTRAMAL, COUMADINE, ENOXAPARIN, INIPOMP, RHINOFLUIMICIDE, WARFARIN
Adverse Events (AE) Preferred term	1. Muscle haemorrhage 2. Arthralgia 3. Asthenia 4. Melaena 5. Melaena 6. Rhinitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/YES/NO/YES 5. SEVERE/YES/YES/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 10JAN2010 (12) - 25FEB2010 (58) 2. 10JAN2010 (12) - 10JAN2010 (12) 3. 30JAN2010 (32) - 30JAN2010 (32) 4. 30JAN2010 (32) - 01FEB2010 (34) 5. 01FEB2010 (34) - 06FEB2010 (39) 6. 02SEP2010 (247) - 24SEP2010 (269)
Duration of AE	1. 47 2. 1 3. 1 4. 3 5. 6 6. 23
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. DOSE OF STUDY DRUG REDUCED 2. REMEDIAL DRUG THERAPY 3. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333049

Parameter	Value
	4. REMEDIAL DRUG THERAPY
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. WORSENED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333058

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160333058/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/85/N.A./FRANCE/YES
Medical history	Appendicectomy, Endarterectomy, Hypercholesterolaemia, Hypertension, Pleural effusion, Pleural effusion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARIXTRA, BICARBONATE SODIUM COOPER, FORTZAAR, ISOPTINE, LIPANTHYL, PLAVIX, PULMICORT, TAVANIC, UNFRACTIONATED HEPARIN, UNFRACTIONED HEPARIN
Adverse Events (AE) Preferred term	1. Bronchitis 2. Haematuria 3. Urinary bladder polyp
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 29MAR2010 (32) - 12APR2010 (46) 2. 14JUN2010 (109) - 18JUL2010 (143) 3. 18JUL2010 (143) - 24JUL2010 (149)
Duration of AE	1. 15 2. 35 3. 7
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. I
Action taken	1. REMEDIAL DRUG THERAPY 2. OTHER 3. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160333068

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160333068/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/77/N.A./FRANCE/YES
Medical history	Hypertension, Obesity, Sleep apnoea syndrome, Colectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Pain in extremity
	2. Multiple injuries
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 13JUL2010 (15) - 13JUL2010 (15)
	2. 17JUL2010 (19) - 17JUL2010 (19)
Duration of AE	1. 1
	2. 1
Dose on AE onset	1.
	2.
Dose status on AE onset	1.
	2.
Action taken	1. NONE
	2. NONE
Outcome of event	1. RESOLVED
	2. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160333068[3)]	INTERNAL HEMORRHAGE AFTER CAR CRASH（PT：外傷性出血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、ワルファリンの抗凝固作用により出血リスクが高まったと考えられることから、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160343004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160343004/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/61/N.A./FRANCE/YES
Medical history	Lower limb fracture, Pain in extremity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, BRISTOPEN, CONTRAMAL, DOLIPRAN, ENOXAPARIN, INIPOMP, LOVENOX, OFLOXACINE, PERFALGAN, RIFADINE, VANCOMYCINE, WARFARIN
Adverse Events (AE) Preferred term	1. Osteomyelitis 2. Osteomyelitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 24JAN2010 (117) - 02FEB2010 (126) 2. 03FEB2010 (127) - 08APR2010 (191)
Duration of AE	1. 10 2. 65
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160343007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160343007/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/58/N.A./FRANCE/YES
Medical history	Abdominal distension, Anxiety, Appendicectomy, Arthritis, Asthma, Faeces discoloured, Bronchitis, Bronchospasm, Carpal tunnel decompression, Carpal tunnel syndrome, Chronic obstructive pulmonary disease, Constipation, Diarrhoea, Dysuria, Emphysema, Foot fracture, Gastrointestinal disorder, Haematuria, Herpes zoster, Insomnia, Atelectasis, Atelectasis, Neuropathy peripheral, Neuropathy peripheral, Phlebitis, Pulmonary infarction, Tachycardia, Tendonitis, Lung disorder, Meniscus removal, Paraesthesia, Osteochondrosis, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, ATROVENT, BRICANYL, EFFARLGAN, EFFERALGAN, FORADIL 12 MICOGRAMME, INIPOMP, INNOHEP, LYRICA 200, MONOALGIC LP 300, PARACETAMOL, PNEUMO 23, SERMION 5, TAKADOL 100 MG, THÉOSTAT LP 300
Adverse Events (AE) Preferred term	1. Dyspepsia 2. Musculoskeletal chest pain 3. Influenza
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 14SEP2010 (201) - 16SEP2010 (203) 2. 19SEP2010 (206) - 28SEP2010 (215) 3. 24DEC2010 (302) - 26DEC2010 (304)
Duration of AE	1. 3 2. 10 3. 3
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. I 2. . 3. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160343007

Parameter	Value
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160363004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160363004/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/77/N.A./FRANCE/YES
Medical history	Hypertension, Diverticulum intestinal, Diabetes mellitus, Hypercholesterolaemia, Sigmoiditis, Colectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMAREL, AVANDIA, CETIRIZINE, COZAR, ENOXAPARIN, HYDROCHLOROTHIAZIDE, METFORMINE, TAHOR, WARFARIN, XYZALL
Adverse Events (AE) Preferred term	1. Wound 2. Intestinal obstruction 3. Intestinal obstruction
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 04JAN2010 (13) - 14JAN2010 (23) 2. 21JAN2010 (30) - 23JAN2010 (32) 3. 24JAN2010 (33) - --------- (.)
Duration of AE	1. 11 2. 3 3. .
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. OTHER 3. OTHER
Outcome of event	1. RESOLVED 2. IMPROVED 3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160363005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160363005/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/68/N.A./FRANCE/YES
Medical history	Hypertension, Endarterectomy, Hypothyroidism, Insomnia, Menopause, Neurilemmoma, Neurilemmoma, Osteoporosis, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AVLOCARDYL, CACIT D3, CRESTOR, FLUDEX, LEVOTHYROX, PROTELOS, RIVOTRIL, STILNOX, STRUCTUM
Adverse Events (AE) Preferred term	1. Anxiety
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 22AUG2010 (243) - 25AUG2010 (246)
Duration of AE	1. 4
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. NONE
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160363006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160363006/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/85/N.A./FRANCE/YES
Medical history	Hypertension, Diarrhoea, Hyperuricaemia, Hypokalaemia, Insomnia, Prostatic adenoma, Prostatic adenoma, Peripheral arterial occlusive disease, Chronic obstructive pulmonary disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, CIFLOX, COVERSYL, DIFFUK, DIOSMECTITE, ENOXAPARIN, FLUDEX LP, INEXIUM, KARDEGIC, LEXOMYL, LOVENOX, WARFARIN
Adverse Events (AE) Preferred term	1. Prostatic adenoma 2. Prostatic adenoma
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 10SEP2010 (258) - 13SEP2010 (261) 2. 15SEP2010 (263) - 17SEP2010 (265)
Duration of AE	1. 4 2. 3
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160373001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/84/N.A./FRANCE/YES
Medical history	Anaemia, Constipation, Depression, Gastrooesophageal reflux disease, Hypercholesterolaemia, Hypertension, Pain in extremity, Aortic valve incompetence, Venous insufficiency, Drug hypersensitivity, Malaria
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTAZINE, CALCIPARIN, CLAMOXYL, COUMADIN, COUMADINE, DIANTALVIC, EFFEXOR, ENOXAPARIN, EZETROL, INIPOMP, ODDIBIL, PARACETAMOL, PERFALGAN, POLARAMINE, PRESTOLE, PROCORALAN, SPECIAFOLDINE, TRANSIPEG [MACROGOL 3350], UNFRACTIONED HEPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Collateral circulation 2. Dermatitis allergic 3. Fatigue 4. Haematuria 5. Renal colic 6. Haematuria 7. Renal colic 8. Calculus ureteric 9. Haematuria 10. Urinary tract infection 11. Malaise 12. Rhinolaryngitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/YES/YES/YES 7. MODERATE/NO/YES/YES 8. MODERATE/YES/NO/YES 9. MILD/YES/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --NOV2009 (.) - --------- (.) 2. 20JUN2009 (4) - 27JUN2009 (11) 3. 23JUN2009 (7) - --------- (.) 4. 14SEP2009 (90) - 19SEP2009 (95) 5. 18SEP2009 (94) - 19SEP2009 (95) 6. 19SEP2009 (95) - 25SEP2009 (101) 7. 19SEP2009 (95) - 25SEP2009 (101) 8. 19SEP2009 (95) - 25SEP2009 (101) 9. 25SEP2009 (101) - 04OCT2009 (110) 10. 07OCT2009 (113) - 12OCT2009 (118) 11. 12DEC2009 (179) - 12DEC2009 (179)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373001

Parameter	Value
	12. 23DEC2009 (190) - 30DEC2009 (197)
Duration of AE	1. .
	2. 8
	3. .
	4. 6
	5. 2
	6. 7
	7. 7
	8. 7
	9. 10
	10. 6
	11. 1
	12. 8
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. NONE
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373001

Parameter	Value
	8. STUDY DRUG DISCONTINUED AND RESTARTED
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. REMEDIAL DRUG THERAPY
Outcome of event	1. INSUFFICIENT FOLLOW-UP
	2. RESOLVED
	3. UNCHANGED
	4. WORSENED
	5. WORSENED
	6. IMPROVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160373003/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/87/N.A./FRANCE/YES
Medical history	Appendicectomy, Asthma, Cataract, Cholecystectomy, Essential tremor, Insomnia, Spinal osteoarthritis, Renal colic, Prostatectomy, Haemorrhoids
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, AVLOCARDYL, CIFLOX, CONTRAMAL, EUPANTOL, GAVISCON, LASILIX, PARACETAMOL, SERESTA, SLUMEDROL, SMECTA [SMECTITE,VANILLIN,SACCHARIN SODIUM,GLUCOSE MONOHYDRATE]
Adverse Events (AE) Preferred term	1. Myalgia 2. Oedema 3. Rectal haemorrhage 4. Pain in extremity 5. Lung infection 6. Cardiac failure 7. Abdominal pain upper 8. Pyrexia 9. Diarrhoea 10. Urinary tract infection 11. Colonic polyp
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 27JUL2009 (1) - 06OCT2009 (72) 2. 10AUG2009 (15) - 25AUG2009 (30) 3. 15AUG2009 (20) - --------- (.) 4. 30SEP2009 (66) - --NOV2009 (.) 5. 06OCT2009 (72) - 20OCT2009 (86) 6. 06OCT2009 (72) - 02NOV2009 (99) 7. 06OCT2009 (72) - 02NOV2009 (99) 8. 06OCT2009 (72) - 16OCT2009 (82) 9. 10OCT2009 (76) - 15OCT2009 (81) 10. 03NOV2009 (100) - 24NOV2009 (121) 11. 26JAN2010 (184) - --------- (.)
Duration of AE	1. 72 2. 16 3. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373003

Parameter	Value
	4. .
	5. 15
	6. 28
	7. 28
	8. 11
	9. 6
	10. 22
	11. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. OTHER
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373003

Parameter	Value
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160373005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/76/N.A./FRANCE/YES
Medical history	Appendicectomy, Blood pressure increased, Osteoarthritis, Cataract, Cholecystectomy, Headache, Hiatus hernia, Hernia hiatus repair, Hypercholesterolaemia, Hyperuricaemia, Hysterectomy, Insomnia, Knee arthroplasty, Rectal polypectomy, Rectal polypectomy, Knee arthroplasty, Umbilical hernia, Ingrowing nail, Intestinal polyp, Iodine allergy, Drug detoxification, Latex allergy, Venous insufficiency, Depression
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	4-FACTOR CONCENTRATE, ALLOPURINOL, BIPRETERAX, CALCIPARIN, COTRAMAL, DAFALGAN, DEROXAT, DIANTALVIC, ENOXAPARIN, EUPANTOL, FLUDEX, GLUCOSE 5 %, ISOPTINE, KARDEGIC, LASILIX, LIPANTHYL, LOXEN, NORMACOL, NOROXIN, OLICLINOMEL, PHYSIOLOGICAL SERUM, PLYIONIQUE 5 % TO 6.5 %, PRIMPERAN, SERESTA, STILNOX, TERBULATIN, UNFRACTION HEPARIN, UNFRACTIONATED HEPARIN, VITAMIN K1, WARFARIN
Adverse Events (AE) Preferred term	1. Abdominal wall haematoma 2. Nausea 3. Renal failure 4. Renal failure acute 5. Constipation 6. Hypertension 7. Headache 8. Diarrhoea 9. Hypertension 10. Chest pain 11. Dyspnoea 12. Melaena 13. Headache 14. Back pain 15. Cough 16. Back pain 17. Nausea 18. Abdominal pain 19. Arthralgia 20. Arthralgia 21. Pain
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MODERATE/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373005

Parameter	Value
	12. MODERATE/YES/NO/YES
	13. MILD/NO/NO/YES
	14. MILD/NO/NO/YES
	15. MILD/NO/NO/NO
	16. MILD/NO/NO/NO
	17. MILD/NO/NO/NO
	18. MILD/NO/NO/NO
	19. MILD/NO/NO/NO
	20. MILD/NO/NO/NO
	21. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 16SEP2009 (9) - 30SEP2009 (23)
	2. 16SEP2009 (9) - 28SEP2009 (21)
	3. 17SEP2009 (10) - 18SEP2009 (11)
	4. 18SEP2009 (11) - 21SEP2009 (14)
	5. 18SEP2009 (11) - 19SEP2009 (12)
	6. 18SEP2009 (11) - 18SEP2009 (11)
	7. 21SEP2009 (14) - 21SEP2009 (14)
	8. 21SEP2009 (14) - 28SEP2009 (21)
	9. 21SEP2009 (14) - 21SEP2009 (14)
	10. 23SEP2009 (16) - 25SEP2009 (18)
	11. 23SEP2009 (16) - --------- (.)
	12. 29SEP2009 (22) - 30SEP2009 (23)
	13. 30SEP2009 (23) - 30SEP2009 (23)
	14. 01OCT2009 (24) - 01OCT2009 (24)
	15. 05OCT2009 (28) - 06OCT2009 (29)
	16. 05OCT2009 (28) - 12OCT2009 (35)
	17. 05OCT2009 (28) - 07OCT2009 (30)
	18. 12OCT2009 (35) - 18OCT2009 (41)
	19. 14OCT2009 (37) - --------- (.)
	20. 19OCT2009 (42) - --------- (.)
	21. 25OCT2009 (48) - --------- (.)
Duration of AE	1. 15
	2. 13
	3. 2
	4. 4
	5. 2
	6. 1
	7. 1
	8. 8
	9. 1
	10. 3
	11. .
	12. 2
	13. 1

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373005

Parameter	Value
	14. 1
	15. 2
	16. 8
	17. 3
	18. 7
	19. .
	20. .
	21. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373005

Parameter	Value
	16.
	17.
	18.
	19.
	20.
	21.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. OTHER
	4. REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY,INFUSION RATE OF STUDY DRUG REDUCED
	15. NONE
	16. REMEDIAL DRUG THERAPY
	17. NONE
	18. REMEDIAL DRUG THERAPY
	19. REMEDIAL DRUG THERAPY
	20. REMEDIAL DRUG THERAPY
	21. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. WORSENED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. UNCHANGED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373005

Parameter	Value
	18. RESOLVED
	19. UNCHANGED
	20. UNCHANGED
	21. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160373005[4),3)]	ACUTE KIDNEY FAILURE（PT：急性腎不全） 治験担当医は、併発症（腹壁血腫）によるものであり、否定できると判断した。弊社は、併発症（腹壁血腫）による出血に起因したと考え、エノキサパリン及びワルファリンとの因果関係は否定できないと考える。 HYPOVEOLEMIC SHOCK（PT：出血性ショック） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症（腹壁血腫）による出血に起因したと考え、エノキサパリン及びワルファリンとの因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160373007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/69/N.A./FRANCE/YES
Medical history	Appendicectomy, Dizziness, Osteoarthritis, Polyarthritis, Typhoid fever, Varicose vein operation, Sciatica, Postmenopause, Depression
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALTIM, CITALOPRAM, ENOXAPARIN, EUPANTOL, GAVISCON, LEXOMIL, PERFALGAN, PRIMPERAN, VALIUM, WARFARIN
Adverse Events (AE) Preferred term	1. Fatigue 2. Chest pain 3. Oedema 4. Tachypnoea 5. Tachycardia 6. Nausea 7. Intervertebral disc compression 8. Back pain 9. Abdominal pain upper 10. Dyspepsia 11. Hiatus hernia 12. Osteoarthritis 13. Gastrooesophageal reflux disease 14. Dizziness 15. Chest pain 16. Varicose vein 17. Arthralgia 18. Bone pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/YES/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/YES/YES 15. MILD/NO/NO/YES 16. MILD/NO/NO/YES 17. MILD/NO/NO/YES 18. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --OCT2010 (.) - --OCT2010 (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373007

Parameter	Value
	2. 10JAN2010 (65) - --MAR2010 (.)
	3. 10JAN2010 (65) - --MAR2010 (.)
	4. 10JAN2010 (65) - --MAR2010 (.)
	5. 10JAN2010 (65) - --MAR2010 (.)
	6. 11JAN2010 (66) - 11JAN2010 (66)
	7. 11JAN2010 (66) - 12JAN2010 (67)
	8. 11JAN2010 (66) - 12JAN2010 (67)
	9. 02MAR2010 (116) - --------- (.)
	10. 02MAR2010 (116) - --------- (.)
	11. 02MAR2010 (116) - --------- (.)
	12. 02MAR2010 (116) - --MAR2010 (.)
	13. 02MAR2010 (116) - --------- (.)
	14. 01APR2010 (146) - 02APR2010 (147)
	15. 08JUN2010 (214) - --JUN2010 (.)
	16. 09JUL2010 (245) - --------- (.)
	17. 30SEP2010 (328) - --OCT2010 (.)
	18. 30SEP2010 (328) - --OCT2010 (.)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. 1
	7. 2
	8. 2
	9. .
	10. .
	11. .
	12. .
	13. .
	14. 2
	15. .
	16. .
	17. .
	18. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373007

Parameter	Value
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. NONE
	16. OTHER
	17. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373007

Parameter	Value
	18. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. UNCHANGED
	11. UNCHANGED
	12. RESOLVED
	13. UNCHANGED
	14. RESOLVED
	15. RESOLVED
	16. UNCHANGED
	17. RESOLVED
	18. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160373015/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/60/N.A./FRANCE/YES
Medical history	Amyotrophy, Asthenia, Hypertension, Drug hypersensitivity, Clavicle fracture, Haemorrhoids, Musculoskeletal pain, Oesophagitis, Dyspnoea exertional, Gastric disorder, Skeletal injury, Dyslipidaemia, Spinal column injury
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACUPAN, BIPROFENID, COLTRAMYL, CONTRAMAL, DAPHALGAN, EFFERALGAN CODEINE, EUPANTOL, FLAGYL, FORLAX, INEXIUM, LANSOYL, LERCAN, LOVENOX, MICARDIS, MICARDIS PLUS, PARACETAMOL, PERFALGAN, PROCTOLOG, SEPTIVON [CHLORHEXIDINE GLUCONATE], VOLTARENE, ZAMUDOL
Adverse Events (AE) Preferred term	1. Vertigo 2. Ligament sprain 3. Constipation 4. Pain in extremity 5. Vein pain 6. Oedema peripheral 7. Dyspnoea 8. Cough 9. Haemorrhoidal haemorrhage 10. Pain in extremity 11. Haemorrhoids 12. Pain in extremity
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/YES/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/YES/YES 12. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --OCT2010 (.) - 02FEB2011 (268) 2. --DEC2010 (.) - 02FEB2011 (268) 3. 13MAY2010 (3) - 09JUN2010 (30) 4. 19MAY2010 (9) - 25MAY2010 (15) 5. 19MAY2010 (9) - 25MAY2010 (15) 6. 19MAY2010 (9) - 25MAY2010 (15) 7. 25MAY2010 (15) - 07JUL2010 (58) 8. 25MAY2010 (15) - 09JUN2010 (30) 9. 01JUL2010 (52) - 05NOV2010 (179) 10. 07JUL2010 (58) - 13AUG2010 (95) 11. 05NOV2010 (179) - 06NOV2010 (180)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373015

Parameter	Value
	12. 01JUN2011 (387) - --------- (.)
Duration of AE	1. .
	2. .
	3. 28
	4. 7
	5. 7
	6. 7
	7. 44
	8. 16
	9. 128
	10. 38
	11. 2
	12. .
Dose on AE onset	1.
	2.
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. I
	12. F
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373015

Parameter	Value
	8. NONE
	9. REMEDIAL DRUG THERAPY,OTHER
	10. NONE
	11. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	12. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160373017/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/41/N.A./FRANCE/YES
Medical history	Anxiety, Depression, Insomnia, Metrorrhagia, Microcytic anaemia, Ligament sprain, Stress, Tendonitis, Uterine leiomyoma, Cytolytic hepatitis, Sympathetic posterior cervical syndrome
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILINE, ATARAX, ENOXAPARIN, LISOPAINE, PARACETAMOL, STILNOX, TARDYFERON, VITAMIN K, WARFARIN, XANAX
Adverse Events (AE) Preferred term	1. Menorrhagia 2. Dyspnoea 3. Alcohol use 4. International normalised ratio increased 5. Palpitations 6. Pain in extremity 7. Dyspnoea 8. Chest pain 9. Metrorrhagia 10. Tachycardia 11. Uterine leiomyoma 12. Toothache 13. Rectal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/YES/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/YES/YES 12. MILD/NO/NO/YES 13. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 23AUG2010 (5) - 26APR2011 (251) 2. 31AUG2010 (13) - 01SEP2010 (14) 3. 31AUG2010 (13) - 01SEP2010 (14) 4. 31AUG2010 (13) - 02SEP2010 (15) 5. 22NOV2010 (96) - 22MAR2011 (216) 6. 23NOV2010 (97) - 15DEC2010 (119) 7. 23NOV2010 (97) - --JAN2011 (.) 8. 23NOV2010 (97) - 11JAN2011 (146) 9. 28DEC2010 (132) - 26APR2011 (251) 10. 15FEB2011 (181) - 22MAR2011 (216) 11. 22APR2011 (247) - 28APR2011 (253)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373017

Parameter	Value
	12. 07JUN2011 (293) - --JUN2011 (.)
	13. 14JUN2011 (300) - 14JUN2011 (300)
Duration of AE	1. 247
	2. 2
	3. 2
	4. 3
	5. 121
	6. 23
	7. .
	8. 50
	9. 120
	10. 36
	11. 7
	12. .
	13. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Action taken	1. OTHER
	2. NONE
	3. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160373017

Parameter	Value
	4. DOSE OF STUDY DRUG REDUCED,STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. OTHER
	10. NONE
	11. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160383002/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/61/N.A./FRANCE/YES
Medical history	Anaemia, Angina pectoris, Bronchitis chronic, Gastrooesophageal reflux disease, Haemorrhoids, Hypercholesterolaemia, Hypertension, Obesity, Uterine leiomyoma, Tobacco user, Postmenopause, Spinal osteoarthritis, Rectal haemorrhage, Age-related macular degeneration
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BURINEX, DAFALGAN, FERRISAT, INEXIUM, LECTIL, LOVENOX, NATISPRAY, NEBILOX, NITRIDERM, OGAST, PARACETAMOL, SPECIAFOLDINE, SPIRIVA, TAHOR, TARDIFERON, TARDIFERON B9, TARDYFERON, TEMERIT, TOPALGIC [TRAMADOL], TRIATEC
Adverse Events (AE) Preferred term	1. Rectal haemorrhage 2. Hypoglycaemia 3. Angina unstable 4. Anaemia 5. Anaemia 6. Blood bilirubin increased 7. Meniere's disease
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/YES/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/YES/YES 4. SEVERE/YES/YES/YES 5. SEVERE/YES/YES/YES 6. MODERATE/YES/NO/YES 7. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 17SEP2009 (30) - 17MAY2010 (272) 2. 03NOV2009 (77) - 03NOV2009 (77) 3. 04NOV2009 (78) - 23NOV2009 (97) 4. 17NOV2009 (91) - 19NOV2009 (93) 5. 13JAN2010 (148) - 19JAN2010 (154) 6. 14JAN2010 (149) - 21JAN2010 (156) 7. 21APR2010 (246) - 23APR2010 (248)
Duration of AE	1. 243 2. 1 3. 20 4. 3 5. 7 6. 8 7. 3
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383002

Parameter	Value
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. . 7. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 2. NONE 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 4. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 5. REMEDIAL DRUG THERAPY 6. OTHER 7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED 4. RESOLVED 5. RESOLVED 6. RESOLVED 7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160383003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/54/N.A./FRANCE/YES
Medical history	Anxiety, Anxiety, Anxiety, Ligament sprain, Obesity, Dermal cyst, Tachycardia, Urticaria, Urticaria, Urticaria, Spinal compression fracture, Meniscus removal, Cryptorchism
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARNICAN 4%, CORDARONE, DAFALGAN, DAFALGAN CODEINE, DAFALGAN CODÉINÉ, DETENSIEL, ENOXAPARIN, FLECAINE LP, GLUCOSÉ 5%, PERFALGAN, TETRAZEPAM, UNFRACTIONED HEPARINE, WARFARIN
Adverse Events (AE) Preferred term	1. Tachycardia 2. Back pain 3. Ecchymosis 4. Haematoma 5. Atrial fibrillation 6. Headache 7. Back pain 8. Left atrial dilatation 9. Mitral valve incompetence 10. Oedema peripheral 11. Back pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/YES/NO/YES 4. MODERATE/YES/NO/YES 5. SEVERE/NO/YES/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --SEP2009 (.) - --SEP2009 (.) 2. 02SEP2009 (10) - 04SEP2009 (12) 3. 03OCT2009 (41) - 04OCT2009 (42) 4. 08MAR2010 (197) - 30MAR2010 (219) 5. 18APR2010 (238) - 01JUN2010 (282) 6. 18APR2010 (238) - 18APR2010 (238) 7. 16MAY2010 (266) - 20MAY2010 (270) 8. 03JUL2010 (314) - --------- (.) 9. 03JUL2010 (314) - --------- (.) 10. 07JUL2010 (318) - --------- (.) 11. 10JUL2010 (321) - 10JUL2010 (321)
Duration of AE	1. . 2. 3 3. 2

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383003

Parameter	Value
	4. 23
	5. 45
	6. 1
	7. 5
	8. .
	9. .
	10. .
	11. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. OTHER
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. OTHER
	5. DOSE OF STUDY DRUG REDUCED,REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. OTHER
	9. NONE
	10. NONE
	11. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383003

Parameter	Value
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. UNCHANGED
	10. UNCHANGED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160383004/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/40/N.A./FRANCE/YES
Medical history	Anxiety, Appendicectomy, Epicondylitis, Headache, Dystonia, Overweight, Salpingectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLINE, ANACARDIUM ORIENTALE 5CH, ANTIMONIUM CRUDUM 5CH, BIOGARAN [SPIRAMICINE, METRONIDAZOLE], CARBOCYSTEINE 5%, DAFALGAN, DIANTALVIC, DOLIPRANE, EFFERALGAN CODEINÉ, FLAGYL, FOENUM GRAECUM 5CH, IDARAC, IGNATIA AMARA 7 CH, IXPRIM, KLIPAL, MEGAMAG, MICROVAL, OFLOCET, PNEUMOREL, SPASFON LYOC, SPIRAMICINE/METRONIDAZOLE 1.5MUI /250MG BIOGARAN, TOPALGIC (TRAMADOL HYDROCHLORIDE), XANAX, ZOVIRAX
Adverse Events (AE) Preferred term	1. Tendon disorder 2. Chest pain 3. Pain in extremity 4. Oedema 5. Tachypnoea 6. Hot flush 7. Torticollis 8. Gingival bleeding 9. Myalgia 10. Oedema peripheral 11. Transaminases increased 12. Pruritus 13. Gingival bleeding 14. Abdominal pain 15. Gingival bleeding 16. Oral herpes 17. Fatigue 18. Oedema 19. Gingival bleeding 20. Gingival bleeding 21. Subcutaneous haematoma 22. Synovial cyst 23. Bronchitis 24. Post procedural haemorrhage 25. Myalgia 26. Tooth abscess 27. Gingival bleeding 28. Cholelithiasis 29. Cholelithiasis 30. Cholelithiasis 31. Groin pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383004

Parameter	Value
	4. MILD/NO/NO/YES
	5. MILD/NO/NO/YES
	6. MODERATE/NO/NO/YES
	7. MODERATE/NO/NO/YES
	8. MODERATE/YES/NO/YES
	9. MODERATE/NO/NO/YES
	10. MILD/NO/NO/YES
	11. MILD/YES/NO/YES
	12. MILD/NO/NO/YES
	13. MODERATE/YES/NO/YES
	14. MODERATE/NO/NO/YES
	15. MILD/YES/NO/YES
	16. MODERATE/NO/NO/YES
	17. MODERATE/NO/NO/YES
	18. MODERATE/NO/NO/YES
	19. MODERATE/YES/NO/YES
	20. MODERATE/YES/NO/YES
	21. MODERATE/YES/NO/YES
	22. MODERATE/NO/NO/YES
	23. MODERATE/NO/NO/YES
	24. MODERATE/YES/NO/YES
	25. MODERATE/NO/NO/YES
	26. MODERATE/NO/NO/YES
	27. MODERATE/YES/NO/YES
	28. MODERATE/NO/NO/YES
	29. MODERATE/NO/YES/YES
	30. MODERATE/NO/NO/YES
	31. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --FEB2010 (.) - 18MAY2010 (239)
	2. --SEP2009 (.) - --OCT2009 (.)
	3. --SEP2009 (.) - --OCT2009 (.)
	4. --NOV2009 (.) - --DEC2009 (.)
	5. --SEP2009 (.) - --OCT2009 (.)
	6. 23SEP2009 (2) - 03OCT2009 (12)
	7. 03OCT2009 (12) - 13OCT2009 (22)
	8. 04OCT2009 (13) - 05OCT2009 (14)
	9. 09OCT2009 (18) - --------- (.)
	10. 09OCT2009 (18) - --NOV2009 (.)
	11. 20OCT2009 (29) - 29OCT2009 (38)
	12. 26OCT2009 (35) - 26OCT2009 (35)
	13. 10NOV2009 (50) - 10NOV2009 (50)
	14. 15NOV2009 (55) - 15JAN2010 (116)
	15. 18DEC2009 (88) - 18DEC2009 (88)
	16. 09JAN2010 (110) - 16JAN2010 (117)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383004

Parameter	Value
	17. 12JAN2010 (113) - 15FEB2010 (147)
	18. 15JAN2010 (116) - --------- (.)
	19. 01FEB2010 (133) - 13SEP2010 (357)
	20. 12FEB2010 (144) - 12FEB2010 (144)
	21. 21FEB2010 (153) - 08MAR2010 (168)
	22. 27FEB2010 (159) - --------- (.)
	23. 27MAY2010 (248) - 06JUN2010 (258)
	24. 11JUN2010 (263) - 11JUN2010 (263)
	25. 15JUN2010 (267) - 11JUL2010 (293)
	26. 23JUN2010 (275) - 09SEP2010 (353)
	27. 14JUL2010 (296) - 14JUL2010 (296)
	28. 15AUG2010 (328) - 16AUG2010 (329)
	29. 16AUG2010 (329) - 17AUG2010 (330)
	30. 18AUG2010 (331) - --------- (.)
	31. 26SEP2010 (370) - 07OCT2010 (381)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. 11
	7. 11
	8. 2
	9. .
	10. .
	11. 10
	12. 1
	13. 1
	14. 62
	15. 1
	16. 8
	17. 35
	18. .
	19. 225
	20. 1
	21. 16
	22. .
	23. 11
	24. 1
	25. 27
	26. 79
	27. 1
	28. 2
	29. 2

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383004

Parameter	Value
	30. .
	31. 12
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
	22. 20 mg
	23. 20 mg
	24. 20 mg
	25. 20 mg
	26. 20 mg
	27. 20 mg
	28. 20 mg
	29. 20 mg
	30. 20 mg
	31. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383004

Parameter	Value
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
	18. .
	19. .
	20. .
	21. .
	22. .
	23. .
	24. .
	25. .
	26. .
	27. .
	28. .
	29. .
	30. .
	31. F
Action taken	1. OTHER
	2. NONE
	3. NONE
	4. NONE
	5. OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. OTHER
	9. OTHER
	10. NONE
	11. OTHER
	12. REMEDIAL DRUG THERAPY
	13. NONE
	14. NONE
	15. NONE
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. OTHER
	19. NONE
	20. NONE
	21. NONE
	22. NONE
	23. REMEDIAL DRUG THERAPY
	24. OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383004

Parameter	Value
	25. REMEDIAL DRUG THERAPY
	26. REMEDIAL DRUG THERAPY,OTHER
	27. NONE
	28. REMEDIAL DRUG THERAPY
	29. REMEDIAL DRUG THERAPY
	30. REMEDIAL DRUG THERAPY
	31. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. UNCHANGED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. UNCHANGED
	23. RESOLVED
	24. RESOLVED
	25. RESOLVED
	26. RESOLVED
	27. RESOLVED
	28. WORSENED
	29. RESOLVED
	30. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383004

Parameter	Value
	31. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160383009/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/76/N.A./FRANCE/YES
Medical history	Osteoarthritis, Cataract, Cholecystectomy, Chronic sinusitis, Dry eye, Eczema, Gastrooesophageal reflux disease, Hypothyroidism, Insomnia, Ligament sprain, Pulmonary tuberculosis, Tendon disorder, Varicose vein, Postmenopause, Iodine allergy, Gastric disorder, Chondrocalcinosis, Constipation, House dust allergy, Depression
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AERIUS, AIROMIR, ARTELAC, ATARAX, AUGMENTIN, CARBOSYMAG, CELLUVISC, CHONDROSULF, DAFALGAN, DIANTALVIC, FICUS CARICA, FOENICULUM VULG, FORLAX, GAVISCON, GINKOR FORT, HYALGAN, IGNATIA AMARA, IMOVANE, IPECA 5 CH, IRIS VERSICOLOR, LEVOTHYROX, LOCOID, LYCOPODIUM 7 CH, METEOSPASMYL, METEOXANE, MONOZECLAR, NASACORT, NORFLOXACINE, OMEPRAZOLE, RHINOTROPHYL, ROBINIA PSEUDO-AC 5CH, SERETIDE, SEROPLEX, TUSSIDANE SANS SUCRE, VACCINIUM VITIS IDAEA
Adverse Events (AE) Preferred term	1. Pain in extremity 2. Hyperkeratosis 3. Articular calcification 4. Ecchymosis 5. Pain in extremity 6. Arthralgia 7. Eczema 8. Bronchitis 9. Rhinitis 10. Gastrooesophageal reflux disease 11. Haematoma 12. Hypothyroidism 13. Urinary tract infection 14. Skin haemorrhage 15. Haematemesis 16. Syncope 17. Headache 18. Hypokalaemia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/YES/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MODERATE/YES/NO/YES 12. MODERATE/NO/NO/YES 13. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383009

Parameter	Value
	14. MODERATE/NO/NO/NO
	15. MILD/NO/NO/NO
	16. SEVERE/NO/YES/NO
	17. MODERATE/NO/NO/NO
	18. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --DEC2010 (.) - --------- (.)
	2. --------- (.) - 04JAN2011 (292)
	3. --JAN2011 (.) - 05MAR2011 (352)
	4. 05APR2010 (18) - 12APR2010 (25)
	5. 15MAY2010 (58) - 14JUL2010 (118)
	6. 10AUG2010 (145) - --------- (.)
	7. 08SEP2010 (174) - 01FEB2011 (320)
	8. 10DEC2010 (267) - 15FEB2011 (334)
	9. 10DEC2010 (267) - 15FEB2011 (334)
	10. 12DEC2010 (269) - --------- (.)
	11. 07JAN2011 (295) - 21JAN2011 (309)
	12. 31JAN2011 (319) - --------- (.)
	13. 01FEB2011 (320) - 10FEB2011 (329)
	14. 29MAR2011 (376) - 29MAR2011 (376)
	15. 29MAR2011 (376) - 29MAR2011 (376)
	16. 29MAR2011 (376) - 29MAR2011 (376)
	17. 29MAR2011 (376) - --------- (.)
	18. 31MAR2011 (378) - 05APR2011 (383)
Duration of AE	1. .
	2. .
	3. .
	4. 8
	5. 61
	6. .
	7. 147
	8. 68
	9. 68
	10. .
	11. 15
	12. .
	13. 10
	14. 1
	15. 1
	16. 1
	17. .
	18. 6
Dose on AE onset	1.
	2.
	3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383009

Parameter	Value
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. F
	15. F
	16. F
	17. F
	18. F
Action taken	1. OTHER
	2. OTHER
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY,OTHER
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383009

Parameter	Value
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. OTHER
	15. OTHER
	16. OTHER
	17. REMEDIAL DRUG THERAPY
	18. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. IMPROVED
	11. RESOLVED
	12. UNCHANGED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. UNCHANGED
	18. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160383010/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/26/N.A./FRANCE/YES
Medical history	Ear infection, Caesarean section, Factor V Leiden mutation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLINE, BACTRIM FORTE, CERAZETTE, COLTRAMYL 4MG, CYTOTEC, DAFALGAN, ENOXAPARIN, ENOXAPARINE, GENTAMICINE, HELICIDINE, HELICIDINE 10 %, KASKADIL, LOVENOX, MIFEGYNE, NACL 0,9%, OFLOCET, PERFALGAN, RHINOFLUIMUCIL, ROCEPHINE, TOPALGIC [TRAMADOL CHLORHYDRATE], TOPLEXIL [OXOMEMAZINE], WARFARIN
Adverse Events (AE) Preferred term	1. Sensation of heaviness 2. Pain in extremity 3. Gingival bleeding 4. Pyelonephritis 5. Epistaxis 6. Laryngitis 7. Pregnancy 8. Abortion induced 9. Vaginal haemorrhage 10. Metrorrhagia 11. Gingival bleeding 12. Epistaxis 13. Urinary tract infection 14. Chest pain 15. Chest pain 16. Influenza
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/YES/NO/YES 4. SEVERE/NO/YES/YES 5. MODERATE/YES/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/YES/YES 8. SEVERE/NO/YES/YES 9. MILD/NO/NO/YES 10. SEVERE/YES/YES/YES 11. MODERATE/YES/NO/YES 12. MILD/YES/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES 15. MILD/NO/NO/YES 16. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --DEC2010 (.) - --------- (.) 2. --JUN2010 (.) - --JUN2010 (.) 3. 02APR2010 (11) - 02APR2010 (11) 4. 06APR2010 (15) - 09APR2010 (18)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383010

Parameter	Value
	5. 13APR2010 (22) - 15APR2010 (24)
	6. 27APR2010 (36) - 03MAY2010 (42)
	7. 11MAY2010 (50) - 25MAY2010 (64)
	8. 23MAY2010 (62) - 25MAY2010 (64)
	9. 01JUN2010 (71) - --------- (.)
	10. 17JUN2010 (87) - 28JUN2010 (98)
	11. 12JUL2010 (112) - 13JUL2010 (113)
	12. 01SEP2010 (163) - 20DEC2010 (273)
	13. 21DEC2010 (274) - 31DEC2010 (284)
	14. 31DEC2010 (284) - 31DEC2010 (284)
	15. 04FEB2011 (319) - 04FEB2011 (319)
	16. 04FEB2011 (319) - 08FEB2011 (323)
Duration of AE	1. .
	2. .
	3. 1
	4. 4
	5. 3
	6. 7
	7. 15
	8. 3
	9. .
	10. 12
	11. 2
	12. 111
	13. 11
	14. 1
	15. 1
	16. 5
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383010

Parameter	Value
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
Action taken	1. OTHER
	2. OTHER
	3. NONE
	4. DOSE OF STUDY DRUG REDUCED,STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	8. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	9. NONE
	10. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	11. NONE
	12. OTHER
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. NONE
	16. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160383010

Parameter	Value
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160383010[1)]	PREGNANCY（PT：妊娠） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリン投与前の発現であるため、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160403001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160403001/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/79/N.A./FRANCE/YES
Medical history	Anxiety, Drug hypersensitivity, Hypertension, Overweight, Pulmonary embolism, Pulmonary hypertension, Dyslipidaemia, Varicose vein operation, Oophorectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPRAZOLAM, DIFFU K, ENDOTELON, FENOFIBRATE, FLUINDIONE, INEXIUM, INIPOMP, METOPROLOL, SPIRONOLACTONE, STRUCTUM, UFH, UNFRACTIONATED HEPARIN, VOLTARENE
Adverse Events (AE) Preferred term	1. Syncope 2. Syncope 3. Dyspnoea 4. Oedema peripheral 5. Right ventricular failure
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 02JUL2009 (7) - 02JUL2009 (7) 2. 08AUG2009 (44) - 08AUG2009 (44) 3. 30SEP2009 (97) - 26JAN2010 (215) 4. 30SEP2009 (97) - 26JAN2010 (215) 5. 18DEC2009 (176) - 26JAN2010 (215)
Duration of AE	1. 1 2. 1 3. 119 4. 119 5. 40
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. NONE 2. NONE 3. NONE 4. NONE 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160403001

Parameter	Value
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-160403001[2)]	RIGHT HEART FAILURE（PT：右室不全） 治験担当医はリバーロキサバンと報告事象との関連性があると判断した。弊社は、合併症（肥満、高血圧、脂質異常）によるものであり、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160403002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160403002/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/83/N.A./FRANCE/YES
Medical history	Aortic aneurysm, Arteritis, Glaucoma, Haemoptysis, Hypercholesterolaemia, Hypertension, Kyphosis, Ankle fracture, Venous insufficiency, Cataract operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CANDERDARTAN, ESOMEPRAZOL, PARACETAMOL, SIMVASTATINE, VITAMIN K
Adverse Events (AE) Preferred term	1. International normalised ratio increased 2. Lung infection 3. Epistaxis 4. Syncope
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/NO 4. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 04JUL2009 (2) - 04JUL2009 (2) 2. 05JUL2009 (3) - 17JUL2009 (15) 3. 10JUL2009 (8) - 10JUL2009 (8) 4. 10JUL2009 (8) - 10JUL2009 (8)
Duration of AE	1. 1 2. 13 3. 1 4. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg
Dose status on AE onset	1. . 2. F 3. F 4. F
Action taken	1. DOSE OF STUDY DRUG REDUCED,STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. NONE 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160403002

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160403003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160403003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/58/N.A./FRANCE/YES
Medical history	Appendicectomy, Depression, Skin lesion, Sleep apnoea syndrome, Abdominal hernia repair, Shoulder operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, INEXIUM, PARACETAMOL, PYOSTACINE, WARFARIN
Adverse Events (AE) Preferred term	1. Skin lesion
	2. Skin lesion
	3. Dyspnoea
	4. Emphysema
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MILD/NO/YES/YES
	3. MILD/NO/NO/YES
	4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 13NOV2009 (30) - 16NOV2009 (33)
	2. 08DEC2009 (55) - 10DEC2009 (57)
	3. 04FEB2010 (113) - --------- (.)
	4. 16FEB2010 (125) - 16JUN2010 (245)
Duration of AE	1. 4
	2. 3
	3. .
	4. 121
Dose on AE onset	1.
	2.
	3.
	4.
Dose status on AE onset	1.
	2.
	3.
	4.
Action taken	1. OTHER
	2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	3. NONE
	4. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160403003

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 160403006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/160403006/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/60/N.A./FRANCE/YES
Medical history	Right ventricular failure, Thyroidectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATARAX, ENOXAPARIN, LEVOTHYROXINE, UNFRACTIONATED HEPARIN, XYZALL
Adverse Events (AE) Preferred term	1. Urticaria
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 18MAR2010 (7) - 07APR2010 (27)
Duration of AE	1. 21
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/180053001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/POLAND/YES
Medical history	Anaemia, Angina pectoris, Cataract, Ectopic pregnancy, Cardiac failure, Hypertension, VIIIth nerve injury, Cyanosis, Mitral valve incompetence, Myocardial infarction, Nasal obstruction, Nasal obstruction, Pleural adhesion, Ear discomfort, Ear discomfort, Tinnitus, Varicose vein, Lung neoplasm, Obesity, Left atrial dilatation, Aortic calcification, Myocardial ischaemia, Abdominal hernia, Varicose vein operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACARD, ACENOCOUMAROL, ATORIS, CARVEDILOL, CATALIN, ENOXAPARIN, FUROSEMID, HEMOROL, LORISTA, LUCETAM, NITROMINT, POLPRAZOL, SORBIFER DURULES, SPIRONOLAKTON, TIALORID, TRITACE
Adverse Events (AE) Preferred term	1. Rectal haemorrhage 2. Anaemia 3. Haemorrhoids 4. Chest pain 5. Hepatic steatosis 6. Nephrolithiasis 7. Aortic calcification 8. Rectal haemorrhage 9. Rectal neoplasm 10. Rectal haemorrhage 11. Rectal cancer 12. Rectal haemorrhage 13. Herpes zoster 14. Rectal haemorrhage 15. Rectal cancer 16. Rectal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MODERATE/YES/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. SEVERE/YES/YES/YES 9. MODERATE/NO/NO/NO 10. MILD/NO/NO/NO 11. SEVERE/NO/YES/NO 12. MODERATE/NO/NO/NO 13. MODERATE/NO/NO/NO 14. MILD/NO/NO/NO 15. SEVERE/NO/YES/NO 16. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 14MAR2008 (9) - 16JUN2008 (103) 2. 07APR2008 (33) - 19JUN2008 (106)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053001

Parameter	Value
	3. 11APR2008 (37) - --------- (.)
	4. 03MAY2008 (59) - 03MAY2008 (59)
	5. 10JUN2008 (97) - 03FEB2009 (335)
	6. 10JUN2008 (97) - 03FEB2009 (335)
	7. 10JUN2008 (97) - --------- (.)
	8. 17JUN2008 (104) - 25JUN2008 (112)
	9. 23JUN2008 (110) - 07JAN2009 (308)
	10. 26JUN2008 (113) - 30JUN2008 (117)
	11. 30JUN2008 (117) - 05JAN2009 (306)
	12. 13JUL2008 (130) - 28JUL2008 (145)
	13. 19JUL2008 (136) - 15AUG2008 (163)
	14. 16SEP2008 (195) - 07JAN2009 (308)
	15. 06JAN2009 (307) - 14JAN2009 (315)
	16. 13JUN2009 (465) - 15JUN2009 (467)
Duration of AE	1. 95
	2. 74
	3. .
	4. 1
	5. 239
	6. 239
	7. .
	8. 9
	9. 199
	10. 5
	11. 190
	12. 16
	13. 28
	14. 114
	15. 9
	16. 3
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053001

Parameter	Value
	15.
	16.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. NONE
	8. STUDY DRUG DISCONTINUED PERMANENTLY
	9. STUDY DRUG DISCONTINUED PERMANENTLY
	10. NONE
	11. NONE
	12. OTHER
	13. REMEDIAL DRUG THERAPY
	14. OTHER
	15. OTHER
	16. OTHER
Outcome of event	1. WORSENED
	2. RESOLVED
	3. IMPROVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. IMPROVED
	9. RESOLVED
	10. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053001

Parameter	Value
	11. WORSENED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/180053004/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/31/WHITE/POLAND/YES
Medical history	Alanine aminotransferase increased, Aspartate aminotransferase increased, Blood lead increased, Gamma-glutamyltransferase increased, Tachycardia, Thrombocytopenia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ARECHIN, ENOXAPARIN, ESPUMISAN, ESSENTIALE FORTE, HEPATIL, ORNITYNA, PARACETAMOL, SOL.10% GLUCOSE, SOL.10%GLUCOSE, TRAVOCORT CREAM, TRIOXAL
Adverse Events (AE) Preferred term	1. Antiphospholipid antibodies positive 2. Thrombocytopenia 3. Alanine aminotransferase increased 4. Aspartate aminotransferase increased 5. Systemic lupus erythematosus 6. Antiphospholipid syndrome 7. Hyperlipidaemia 8. Systemic lupus erythematosus 9. Antiphospholipid syndrome 10. Headache 11. Psoriasis 12. Seborrhoeic dermatitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. SEVERE/NO/YES/YES 6. SEVERE/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 16APR2008 (2) - --------- (.) 2. 17APR2008 (3) - 20APR2008 (6) 3. 21APR2008 (7) - 12MAY2008 (28) 4. 21APR2008 (7) - 02JUN2008 (49) 5. 27JUN2008 (74) - 04JUL2008 (81) 6. 27JUN2008 (74) - 04JUL2008 (81) 7. 27JUN2008 (74) - --------- (.) 8. 04JUL2008 (81) - --------- (.) 9. 04JUL2008 (81) - --------- (.) 10. 25AUG2008 (133) - 26AUG2008 (134) 11. 20OCT2008 (189) - 17FEB2009 (309) 12. 17FEB2009 (309) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053004

Parameter	Value
Duration of AE	1. .
	2. 4
	3. 22
	4. 43
	5. 8
	6. 8
	7. .
	8. .
	9. .
	10. 2
	11. 121
	12. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. OTHER
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053004

Parameter	Value
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. IMPROVED
	6. IMPROVED
	7. UNCHANGED
	8. UNCHANGED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-180053004[4)]	WORSENING OF ALAT ELEVATION（PT：アラニンアミノトランスフェラーゼ増加） 治験担当医は、併用薬（Hepatil）及び原疾患（肺塞栓症）によるものであり、否定できると判断した。弊社は、エノキサパリン及びアセノクマロール投与と報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/180053011/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/71/WHITE/POLAND/YES
Medical history	Angina pectoris, Arteriosclerosis, Asthma, Atrial fibrillation, Back pain, Carpal tunnel syndrome, Chest pain, Hypercholesterolaemia, Hyperlipidaemia, Hypertension, Hypothyroidism, Obesity, Pneumonia, Urinary incontinence, Osteoarthritis, Lower limb fracture, Spinal osteoarthritis, Duodenogastric reflux
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	0,9%NACL, AMLOPIN, ARTHRON CHONDREX, ATROVENT, BIOFAZOLIN, BUSCOLYSIN, CLEXANE, DIPROPHOS, DOXEPIN, ESSENTIALE FORTE, FEBROFEN GEL, GRIPEX, HYDROXIZINE, HYDROXIZINUM, ISOPTIN SR, KETONAL, LACIPIL, LETROX, LOPERAMIDE, MUCOSOLVAN, MYOLASTAN, NILOGRIN, NIMESIL, NITROMINT, NOSPA, PARACETAMOL, PERAZINE, PIASCLEDINE, POLOCARD, POLPRAZOL, PYRALGIN, PYRALGINUM, RAPHACHOLIN, SAL EMS ARTIFICIALE, SILYMARIN, SOPODORM, SPASMALGON, STIMULOTON, VIANI MITE, VIVACOR [CARVEDILOL], XANAX, ZALDIAR, ZOCOR
Adverse Events (AE) Preferred term	1. Bladder prolapse 2. Rectal prolapse 3. Hepatic cyst 4. Renal cyst 5. Hepatic steatosis 6. Epistaxis 7. Haemoptysis 8. Angina unstable 9. Chest pain 10. Neurosis 11. Chest pain 12. Gastritis 13. Asthenia 14. Diarrhoea 15. Vomiting 16. Asthenia 17. Chest pain 18. Urinary incontinence 19. Abdominal pain 20. Cholelithiasis 21. Abdominal pain 22. Hepatomegaly 23. Nephrolithiasis 24. Atelectasis 25. C-reactive protein increased 26. Osteolysis 27. Ultrasound liver abnormal 28. Hepatitis chronic active 29. Diverticulum intestinal 30. Hiatus hernia 31. Rash

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053011

Parameter	Value
	32. Headache
	33. Tinnitus
	34. Ultrasound liver abnormal
	35. Gingival bleeding
	36. Contusion
	37. Nasopharyngitis
	38. Chest pain
	39. Respiratory tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/NO/YES
	4. MILD/NO/NO/YES
	5. MILD/NO/NO/YES
	6. MILD/YES/NO/YES
	7. MILD/YES/NO/YES
	8. SEVERE/NO/YES/YES
	9. MODERATE/NO/NO/YES
	10. MODERATE/NO/NO/YES
	11. MODERATE/NO/NO/YES
	12. MODERATE/NO/NO/YES
	13. MILD/NO/NO/YES
	14. MODERATE/YES/NO/YES
	15. MODERATE/YES/NO/YES
	16. MILD/NO/NO/YES
	17. MODERATE/NO/NO/YES
	18. MODERATE/NO/NO/YES
	19. SEVERE/NO/YES/YES
	20. MILD/NO/NO/YES
	21. MODERATE/NO/NO/YES
	22. MILD/NO/NO/YES
	23. MILD/NO/NO/YES
	24. MILD/NO/NO/YES
	25. MILD/NO/NO/YES
	26. MILD/NO/NO/YES
	27. SEVERE/YES/YES/YES
	28. SEVERE/YES/YES/YES
	29. MILD/NO/NO/YES
	30. MILD/NO/NO/YES
	31. MILD/NO/NO/YES
	32. MILD/YES/NO/YES
	33. MODERATE/YES/NO/YES
	34. MILD/YES/NO/YES
	35. MILD/YES/NO/YES
	36. MILD/YES/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053011

Parameter	Value
	37. MILD/NO/NO/YES
	38. MODERATE/NO/NO/YES
	39. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 02OCT2008 (4) - --------- (.)
	2. 02OCT2008 (4) - --------- (.)
	3. 03OCT2008 (5) - --------- (.)
	4. 03OCT2008 (5) - --------- (.)
	5. 03OCT2008 (5) - --------- (.)
	6. 05OCT2008 (7) - 06OCT2008 (8)
	7. 06OCT2008 (8) - 06OCT2008 (8)
	8. 10OCT2008 (12) - 17OCT2008 (19)
	9. 10OCT2008 (12) - 11OCT2008 (13)
	10. 10OCT2008 (12) - --------- (.)
	11. 12OCT2008 (14) - 12OCT2008 (14)
	12. 13OCT2008 (15) - --------- (.)
	13. 13OCT2008 (15) - 13OCT2008 (15)
	14. 14OCT2008 (16) - 16OCT2008 (18)
	15. 14OCT2008 (16) - 15OCT2008 (17)
	16. 15OCT2008 (17) - 15OCT2008 (17)
	17. 17OCT2008 (19) - 20OCT2008 (22)
	18. 02DEC2008 (65) - --------- (.)
	19. 26DEC2008 (89) - 27DEC2008 (90)
	20. 26DEC2008 (89) - 29DEC2008 (92)
	21. 27DEC2008 (90) - 29JAN2009 (123)
	22. 29DEC2008 (92) - 16FEB2009 (141)
	23. 29DEC2008 (92) - 16FEB2009 (141)
	24. 29DEC2008 (92) - --------- (.)
	25. 29DEC2008 (92) - 13JAN2009 (107)
	26. 29DEC2008 (92) - --------- (.)
	27. 29DEC2008 (92) - 16FEB2009 (141)
	28. 31DEC2008 (94) - --------- (.)
	29. 31DEC2008 (94) - --------- (.)
	30. 14JAN2009 (108) - --------- (.)
	31. 14JAN2009 (108) - 23JUN2009 (268)
	32. 15JAN2009 (109) - --------- (.)
	33. 01FEB2009 (126) - --------- (.)
	34. 16FEB2009 (141) - --------- (.)
	35. 01MAR2009 (154) - --------- (.)
	36. 14APR2009 (198) - 21JUL2009 (296)
	37. 18JUN2009 (263) - 23JUN2009 (268)
	38. 20AUG2009 (326) - 21AUG2009 (327)
	39. 08SEP2009 (345) - 27SEP2009 (364)
Duration of AE	1. .
	2. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053011

Parameter	Value
	3. .
	4. .
	5. .
	6. 2
	7. 1
	8. 8
	9. 2
	10. .
	11. 1
	12. .
	13. 1
	14. 3
	15. 2
	16. 1
	17. 4
	18. .
	19. 2
	20. 4
	21. 34
	22. 50
	23. 50
	24. .
	25. 16
	26. .
	27. 50
	28. .
	29. .
	30. .
	31. 161
	32. .
	33. .
	34. .
	35. .
	36. 99
	37. 6
	38. 2
	39. 20
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053011

Parameter	Value
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 15 mg
	12. 15 mg
	13. 15 mg
	14. 15 mg
	15. 15 mg
	16. 15 mg
	17. 15 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
	22. 20 mg
	23. 20 mg
	24. 20 mg
	25. 20 mg
	26. 20 mg
	27. 20 mg
	28. 20 mg
	29. 20 mg
	30. 20 mg
	31. 20 mg
	32. 20 mg
	33. 20 mg
	34. 20 mg
	35. 20 mg
	36. 20 mg
	37. 20 mg
	38. 20 mg
	39. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053011

Parameter	Value
	13. .
	14. .
	15. .
	16. .
	17. .
	18. .
	19. .
	20. .
	21. .
	22. .
	23. .
	24. .
	25. .
	26. .
	27. .
	28. I
	29. I
	30. .
	31. .
	32. .
	33. .
	34. .
	35. .
	36. .
	37. .
	38. .
	39. .
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. NONE
	16. NONE
	17. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053011

Parameter	Value
	18. NONE
	19. REMEDIAL DRUG THERAPY
	20. NONE
	21. REMEDIAL DRUG THERAPY
	22. NONE
	23. NONE
	24. NONE
	25. NONE
	26. NONE
	27. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	28. NONE
	29. NONE
	30. NONE
	31. NONE
	32. NONE
	33. REMEDIAL DRUG THERAPY
	34. NONE
	35. NONE
	36. NONE
	37. REMEDIAL DRUG THERAPY
	38. REMEDIAL DRUG THERAPY
	39. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. UNCHANGED
	11. RESOLVED
	12. UNCHANGED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. UNCHANGED
	19. IMPROVED
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053011

Parameter	Value
	23. RESOLVED
	24. UNCHANGED
	25. RESOLVED
	26. UNCHANGED
	27. RESOLVED
	28. UNCHANGED
	29. UNCHANGED
	30. UNCHANGED
	31. RESOLVED
	32. UNCHANGED
	33. UNCHANGED
	34. UNCHANGED
	35. UNCHANGED
	36. RESOLVED
	37. RESOLVED
	38. RESOLVED
	39. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-180053011[2),2)]	CHRONIC ACTIVE HEPATITIS（PT：慢性活動性肝炎） 報告者はリバーロキサバンと報告対象事象との関連性があると判断した。弊社は、合併症（肝嚢胞）を持つことなどから、臨床検査において偶発的に確認された事象であり、発現後も投与継続されていることから、リバーロキサバンとの因果関係を否定できると考える。 HYPOECHOGENIC FOCI OF HEPAR（PT：肝超音波検査異常） 報告者はリバーロキサバンと報告対象事象との関連性があると判断した。弊社は、合併症（肝嚢胞）を持つことなどから、臨床検査において偶発的に確認された事象であり、発現後も投与継続されていることから、リバーロキサバンとの因果関係を否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/180053014/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/67/WHITE/POLAND/YES
Medical history	Blood alkaline phosphatase increased, Anaemia, Bladder cancer, Bladder neoplasm, Chest pain, Colon polypectomy, Cough, Goitre, Hydronephrosis, Hypertension, Hysterectomy, Lymphadenopathy mediastinal, Pleural effusion, Spinal osteoarthritis, Cataract operation, Oophorectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	0,9% NACL, 0,9%NACL, ACENOCOUMAROL, AMIKIN, AUGMENTIN, CEFOTAKSYM, CIPROFLOXACIN, CLEXANE, DEXAVEN, DICLOFENAC, DIPHERGAN, DOXEPIN, DOXYCYCLINE, DUROGESIC, ENOXAPARIN, FENICORT, FLEGAMINA, FRAGMIN, FUROSEMID, GEMCITABINE, GOPTEN, HYDROXYZINUM, KETOCONAZOLE, KETONAL, LACTULOSA, LAKCID, METOCLOPRAMIDE, METRONIDAZOLE, METYPRED, MORPHINUM, MUCOSOLVAN, ONDANSETRON, PARACETAMOL, POLODINA, POLPRAZOL, PROXACIN, PYRALGIN, SEVREDOL, SPIRONOL, THYROZOL, TIALORID, TIALORID MITE, TRAMAL, UNFRACTIONED HEPARIN, VITACON, VIVACOR [CARVEDILOL], ZALDIAR
Adverse Events (AE) Preferred term	1. Pyrexia 2. Aortic calcification 3. Abdominal pain upper 4. Mitral valve incompetence 5. Chest pain 6. Gastritis 7. Back pain 8. Pain in extremity 9. Hiatus hernia 10. Pelvic neoplasm 11. Hepatic cyst 12. Chest pain 13. Vomiting 14. Hiccups 15. Pneumonia 16. Pleural effusion 17. Depression 18. Anaemia 19. Hyperthyroidism 20. Pneumonia 21. Hyperthyroidism 22. Gastritis 23. Back pain 24. Epistaxis 25. Anaemia 26. Extremity necrosis 27. Coagulopathy 28. Pain in extremity 29. Constipation 30. Nausea

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053014

Parameter	Value
	31. Ischaemic stroke
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES
	2. MILD/NO/NO/YES
	3. MODERATE/NO/NO/YES
	4. MILD/NO/NO/YES
	5. MODERATE/NO/NO/YES
	6. MODERATE/NO/NO/YES
	7. MODERATE/NO/NO/YES
	8. MODERATE/NO/NO/YES
	9. MILD/NO/NO/YES
	10. SEVERE/NO/YES/YES
	11. MILD/NO/NO/YES
	12. MODERATE/NO/NO/YES
	13. MODERATE/NO/NO/YES
	14. MODERATE/NO/NO/YES
	15. MODERATE/NO/NO/YES
	16. MODERATE/NO/NO/YES
	17. MODERATE/NO/NO/YES
	18. SEVERE/YES/YES/YES
	19. MILD/NO/NO/YES
	20. SEVERE/NO/YES/YES
	21. MODERATE/NO/NO/YES
	22. MILD/NO/NO/YES
	23. MODERATE/NO/NO/YES
	24. MILD/YES/NO/YES
	25. MILD/YES/NO/YES
	26. MODERATE/NO/NO/YES
	27. SEVERE/YES/YES/YES
	28. MODERATE/NO/NO/YES
	29. MODERATE/NO/NO/YES
	30. MODERATE/NO/NO/YES
	31. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 09OCT2008 (2) - 16NOV2008 (40)
	2. 09OCT2008 (2) - --------- (.)
	3. 10OCT2008 (3) - 11OCT2008 (4)
	4. 10OCT2008 (3) - --------- (.)
	5. 11OCT2008 (4) - 11OCT2008 (4)
	6. 13OCT2008 (6) - 19NOV2008 (43)
	7. 14OCT2008 (7) - 14OCT2008 (7)
	8. 14OCT2008 (7) - 20OCT2008 (13)
	9. 15OCT2008 (8) - --------- (.)
	10. 16OCT2008 (9) - 13JAN2009 (98)
	11. 16OCT2008 (9) - --------- (.)
	12. 19OCT2008 (12) - 19NOV2008 (43)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053014

Parameter	Value
	13. 21OCT2008 (14) - 21OCT2008 (14)
	14. 21OCT2008 (14) - 27OCT2008 (20)
	15. 21OCT2008 (14) - 28OCT2008 (21)
	16. 21OCT2008 (14) - 10DEC2008 (64)
	17. 23OCT2008 (16) - --------- (.)
	18. 26OCT2008 (19) - 28OCT2008 (21)
	19. 27OCT2008 (20) - 18NOV2008 (42)
	20. 28OCT2008 (21) - 19NOV2008 (43)
	21. 18NOV2008 (42) - --------- (.)
	22. 20NOV2008 (44) - --------- (.)
	23. 02DEC2008 (56) - 02DEC2008 (56)
	24. 04DEC2008 (58) - 05DEC2008 (59)
	25. 04DEC2008 (58) - --------- (.)
	26. 04DEC2008 (58) - --------- (.)
	27. 05DEC2008 (59) - 15DEC2008 (69)
	28. 05DEC2008 (59) - --------- (.)
	29. 06DEC2008 (60) - 11DEC2008 (65)
	30. 08DEC2008 (62) - 08DEC2008 (62)
	31. 26DEC2008 (80) - 31DEC2008 (85)
Duration of AE	1. 39
	2. .
	3. 2
	4. .
	5. 1
	6. 38
	7. 1
	8. 7
	9. .
	10. 90
	11. .
	12. 32
	13. 1
	14. 7
	15. 8
	16. 51
	17. .
	18. 3
	19. 23
	20. 23
	21. .
	22. .
	23. 1
	24. 2
	25. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053014

Parameter	Value
	26. .
	27. 11
	28. .
	29. 6
	30. 1
	31. 6
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
	27.
	28.
	29.
	30.
	31.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053014

Parameter	Value
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
	27.
	28.
	29.
	30.
	31.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. NONE
	10. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. OTHER
	19. NONE
	20. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053014

Parameter	Value
	21. REMEDIAL DRUG THERAPY
	22. REMEDIAL DRUG THERAPY
	23. REMEDIAL DRUG THERAPY
	24. STUDY DRUG DISCONTINUED AND RESTARTED
	25. STUDY DRUG DISCONTINUED AND RESTARTED
	26. REMEDIAL DRUG THERAPY
	27. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	28. REMEDIAL DRUG THERAPY
	29. REMEDIAL DRUG THERAPY
	30. REMEDIAL DRUG THERAPY
	31. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. IMPROVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. DEATH
	11. UNCHANGED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. WORSENED
	16. RESOLVED
	17. UNCHANGED
	18. IMPROVED
	19. WORSENED
	20. RESOLVED
	21. UNCHANGED
	22. UNCHANGED
	23. RESOLVED
	24. RESOLVED
	25. UNCHANGED
	26. UNCHANGED
	27. RESOLVED
	28. UNCHANGED
	29. RESOLVED
	30. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053014

Parameter	Value
	31. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-180053014[1)]	COAGULATION DISORDERS（PT：凝血異常） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリン投与終了 7 週間後の発現であり、時間的関連性がないため、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/180053017/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/POLAND/YES
Medical history	Appendicectomy, Atelectasis, Atrioventricular block second degree, Bronchiectasis, Bronchitis, Cardiac pacemaker insertion, Cholecystectomy, Cough, Dyspnoea, Pulmonary fibrosis, Hypertension, Hypokalaemia, Hypokalaemia, Hypotonia, Obesity, Oedema peripheral, Rheumatoid arthritis, Skin hyperpigmentation, Tachycardia, Venous insufficiency, Asthenia, Polycystic liver disease, Angiomyolipoma, Aortic calcification, Myocardial ischaemia, Spinal osteoarthritis, Skin ulcer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	0,9%NACL, ACC, ALANTAN, ATROVENT, AVEDOL, BERODUAL, BISOCARD, DOXYCYCLINE, FLEGAMINA, FUROSEMIDUM, KALDYUM, METOCLOPRAMIDE, METYPRED, MUCOSOLVAN, MULTIELECTROLYTE LIQUID, OCTENISEPT, POLODINA R, POLPRAZOL, PROXACIN, SPIRONOL, THEOPHYLLINE, THEOSPIREX, THIOCODIN, TIALORID, TIALORID MITE, VIVACOR [CARVEDILOL]
Adverse Events (AE) Preferred term	1. Hypokalaemia 2. Dyspnoea 3. Cardiac aneurysm 4. Mitral valve incompetence 5. Aortic valve incompetence 6. Pleural effusion 7. Pleural adhesion 8. Asthenia 9. Nausea 10. Cough 11. Dyspnoea 12. Respiratory tract infection 13. Glucose tolerance impaired 14. Pleural fibrosis 15. Chest pain 16. Circulatory collapse 17. Dermatitis 18. Circulatory collapse 19. Contusion 20. Neuropathy peripheral 21. Cervicobrachial syndrome 22. Ventricular hypertrophy 23. Renal cyst 24. Pancreatic atrophy 25. Hepatic cirrhosis 26. Circulatory collapse 27. Circulatory collapse 28. Circulatory collapse 29. Erysipelas 30. Cerebrovascular insufficiency 31. Chronic sinusitis

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053017

Parameter	Value
	32. International normalised ratio increased
	33. Emphysema
	34. Cerebral atrophy
	35. Circulatory collapse
	36. Circulatory collapse
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES
	2. MODERATE/NO/NO/YES
	3. MILD/NO/NO/YES
	4. MILD/NO/NO/YES
	5. MILD/NO/NO/YES
	6. MILD/NO/NO/YES
	7. MILD/NO/NO/YES
	8. MODERATE/NO/NO/YES
	9. MODERATE/NO/NO/YES
	10. MODERATE/NO/NO/YES
	11. MODERATE/NO/NO/YES
	12. SEVERE/NO/YES/YES
	13. MODERATE/NO/NO/YES
	14. MILD/NO/NO/YES
	15. MODERATE/NO/NO/YES
	16. MODERATE/NO/NO/YES
	17. MODERATE/NO/NO/YES
	18. SEVERE/NO/YES/YES
	19. MODERATE/YES/NO/YES
	20. MODERATE/NO/NO/YES
	21. MODERATE/NO/NO/YES
	22. MILD/NO/NO/YES
	23. MILD/NO/NO/YES
	24. MILD/NO/NO/YES
	25. MILD/NO/NO/YES
	26. MILD/NO/NO/NO
	27. MODERATE/NO/NO/NO
	28. MILD/NO/NO/NO
	29. MODERATE/NO/NO/NO
	30. SEVERE/NO/YES/NO
	31. MODERATE/NO/NO/NO
	32. MODERATE/NO/NO/NO
	33. MILD/NO/NO/NO
	34. MILD/NO/NO/NO
	35. MODERATE/NO/NO/NO
	36. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 14FEB2009 (3) - 16FEB2009 (5)
	2. 15FEB2009 (4) - 19FEB2009 (8)
	3. 16FEB2009 (5) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053017

Parameter	Value
	4. 16FEB2009 (5) - --------- (.)
	5. 16FEB2009 (5) - --------- (.)
	6. 19FEB2009 (8) - 02OCT2009 (233)
	7. 19FEB2009 (8) - 02OCT2009 (233)
	8. 19FEB2009 (8) - 19FEB2009 (8)
	9. 20FEB2009 (9) - 24FEB2009 (13)
	10. 25FEB2009 (14) - 27FEB2009 (16)
	11. 09MAR2009 (26) - 19MAR2009 (36)
	12. 13MAR2009 (30) - 19MAR2009 (36)
	13. 13MAR2009 (30) - --------- (.)
	14. 13MAR2009 (30) - --------- (.)
	15. 01APR2009 (49) - 20APR2009 (68)
	16. 10APR2009 (58) - 20APR2009 (68)
	17. 10APR2009 (58) - 29APR2009 (77)
	18. 20APR2009 (68) - 30APR2009 (78)
	19. 21APR2009 (69) - 05JUN2009 (114)
	20. 22APR2009 (70) - --------- (.)
	21. 22APR2009 (70) - --------- (.)
	22. 24APR2009 (72) - --------- (.)
	23. 24APR2009 (72) - 29APR2009 (77)
	24. 28APR2009 (76) - 07OCT2009 (238)
	25. 28APR2009 (76) - 07OCT2009 (238)
	26. 30APR2009 (78) - 10MAY2009 (88)
	27. 11MAY2009 (89) - 16JUL2009 (155)
	28. 17JUL2009 (156) - 15NOV2009 (277)
	29. 08SEP2009 (209) - 23SEP2009 (224)
	30. 30SEP2009 (231) - 08OCT2009 (239)
	31. 02OCT2009 (233) - --------- (.)
	32. 02OCT2009 (233) - 04OCT2009 (235)
	33. 02OCT2009 (233) - --------- (.)
	34. 02OCT2009 (233) - --------- (.)
	35. 16NOV2009 (278) - 20NOV2009 (282)
	36. 20NOV2009 (282) - 22NOV2009 (284)
Duration of AE	1. 3
	2. 5
	3. .
	4. .
	5. .
	6. 226
	7. 226
	8. 1
	9. 5
	10. 3
	11. 11

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053017

Parameter	Value
	12. 7
	13. .
	14. .
	15. 20
	16. 11
	17. 20
	18. 11
	19. 46
	20. .
	21. .
	22. .
	23. 6
	24. 163
	25. 163
	26. 11
	27. 67
	28. 122
	29. 16
	30. 9
	31. .
	32. 3
	33. .
	34. .
	35. 5
	36. 3
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053017

Parameter	Value
	20. 20 mg
	21. 20 mg
	22. 20 mg
	23. 20 mg
	24. 20 mg
	25. 20 mg
	26. 20 mg
	27. 20 mg
	28. 20 mg
	29. 20 mg
	30. 20 mg
	31. 20 mg
	32. 20 mg
	33. 20 mg
	34. 20 mg
	35. 20 mg
	36. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
	18. .
	19. .
	20. .
	21. .
	22. .
	23. .
	24. F
	25. F
	26. F
	27. F

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053017

Parameter	Value
	28. F
	29. F
	30. F
	31. F
	32. F
	33. F
	34. F
	35. F
	36. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. OTHER
	14. NONE
	15. NONE
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. REMEDIAL DRUG THERAPY
	19. NONE
	20. NONE
	21. NONE
	22. NONE
	23. NONE
	24. NONE
	25. REMEDIAL DRUG THERAPY
	26. REMEDIAL DRUG THERAPY
	27. REMEDIAL DRUG THERAPY
	28. REMEDIAL DRUG THERAPY
	29. REMEDIAL DRUG THERAPY
	30. REMEDIAL DRUG THERAPY
	31. REMEDIAL DRUG THERAPY
	32. REMEDIAL DRUG THERAPY
	33. NONE
	34. NONE
	35. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053017

Parameter	Value
	36. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. UNCHANGED
	14. UNCHANGED
	15. RESOLVED
	16. WORSENED
	17. RESOLVED
	18. IMPROVED
	19. RESOLVED
	20. UNCHANGED
	21. UNCHANGED
	22. UNCHANGED
	23. RESOLVED
	24. RESOLVED
	25. RESOLVED
	26. WORSENED
	27. IMPROVED
	28. WORSENED
	29. RESOLVED
	30. RESOLVED
	31. UNCHANGED
	32. RESOLVED
	33. UNCHANGED
	34. UNCHANGED
	35. WORSENED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053017

Parameter	Value
	36. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053018

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/180053018/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/35/WHITE/POLAND/YES
Medical history	Headache, Hypertension, Obesity, Thrombophlebitis superficial, Tachycardia, Venous insufficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOKUMAROL, BETALOC ZOK, BISOCARD, DETRALEX, ERFIN, FENTANYL, HYDROXIZINUM, LANZUL, PANADOL, PARACETAMOL, PIROLAM GEL, PRESTARIUM
Adverse Events (AE) Preferred term	1. Hypertriglyceridaemia 2. Oropharyngeal pain 3. Antiphospholipid antibodies positive 4. Abdominal pain upper 5. Hepatic steatosis 6. Splenomegaly 7. Ventricular hypertrophy 8. Gastritis erosive 9. Erosive duodenitis 10. Alanine aminotransferase increased 11. Onychomycosis 12. Headache 13. Type V hyperlipidaemia 14. Irritable bowel syndrome 15. Diverticulum intestinal 16. Hypercoagulation 17. Hepatomegaly 18. Renal cyst 19. Hypercoagulation 20. Chest pain 21. Hiatus hernia 22. Left atrial dilatation
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MILD/YES/NO/YES 11. MILD/NO/NO/YES 12. MODERATE/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MILD/NO/NO/YES 15. MILD/NO/NO/YES 16. SEVERE/NO/YES/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053018

Parameter	Value
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MILD/NO/NO/YES
	20. MILD/NO/NO/YES
	21. MILD/NO/NO/YES
	22. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --SEP2009 (.) - --------- (.)
	2. 17MAR2009 (6) - 17MAR2009 (6)
	3. 17MAR2009 (6) - --------- (.)
	4. 18MAR2009 (7) - 18MAR2009 (7)
	5. 18MAR2009 (7) - 09SEP2009 (182)
	6. 18MAR2009 (7) - --------- (.)
	7. 18MAR2009 (7) - --------- (.)
	8. 19MAR2009 (8) - 27NOV2009 (261)
	9. 19MAR2009 (8) - 27NOV2009 (261)
	10. 25MAR2009 (14) - 15MAY2009 (65)
	11. 03APR2009 (23) - 15JUL2009 (126)
	12. 08MAY2009 (58) - 08MAY2009 (58)
	13. 02JUN2009 (83) - --SEP2009 (.)
	14. 16JUN2009 (97) - --------- (.)
	15. 16JUN2009 (97) - --------- (.)
	16. 08SEP2009 (181) - 11SEP2009 (184)
	17. 09SEP2009 (182) - --------- (.)
	18. 09SEP2009 (182) - --------- (.)
	19. 11SEP2009 (184) - 16NOV2009 (250)
	20. 10NOV2009 (244) - 28DEC2009 (292)
	21. 27NOV2009 (261) - --------- (.)
	22. 04DEC2009 (268) - --------- (.)
Duration of AE	1. .
	2. 1
	3. .
	4. 1
	5. 176
	6. .
	7. .
	8. 254
	9. 254
	10. 52
	11. 104
	12. 1
	13. .
	14. .
	15. .
	16. 4

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053018

Parameter	Value
	17. .
	18. .
	19. 67
	20. 49
	21. .
	22. .
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
	22. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053018

Parameter	Value
	17. .
	18. .
	19. .
	20. .
	21. .
	22. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. OTHER
	5. NONE
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. NONE
	14. NONE
	15. NONE
	16. OTHER
	17. NONE
	18. NONE
	19. NONE
	20. OTHER
	21. NONE
	22. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. UNCHANGED
	15. UNCHANGED
	16. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053018

Parameter	Value
	17. UNCHANGED
	18. UNCHANGED
	19. RESOLVED
	20. RESOLVED
	21. UNCHANGED
	22. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/180053023/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/POLAND/YES
Medical history	Lung adenocarcinoma stage I, Appendicectomy, Blood bilirubin increased, Chronic obstructive pulmonary disease, Pyrexia, Pulmonary fibrosis, Goitre, Hemiparesis, Hyperlipidaemia, Hypertension, Lung lobectomy, Mitral valve incompetence, Pericardial effusion, Pleural adhesion, Sjogren's syndrome, Tachycardia, Blood uric acid increased, Renal hypoplasia, Postmenopause, Aortic valve incompetence, Aortic calcification, Ischaemic stroke, Ischaemic stroke, Ventricular hypertrophy, Spinal osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	0.9% NACL, ACC, AGEN, ALLUPOL, ASPARGIN, ATROVENT, ATROX, BESTPIRIN, BISOCARD, BISOPROMERCK, CALPEROS, DIURESIN SR, ENARENAL, ESPUTICON, FLUCOFAST, KALIPOZ, NICERGOLIN, NOOTROPIL, POLOPIRYNA C, ROVAMYCINE, TERTENSIF SR, TRITACE, VINORELBINA, VIVACE [RAMIPRIL]
Adverse Events (AE) Preferred term	1. Renal cyst 2. Rhinitis 3. Hypertension 4. Epistaxis 5. Respiratory tract infection 6. Contusion 7. Muscle spasms 8. Lung carcinoma cell type unspecified recurrent 9. Bronchitis chronic 10. Weight decreased 11. Skin ulcer 12. Anaemia 13. Leukopenia 14. Anaemia 15. Anaemia 16. Leukopenia 17. Thrombocytopenia 18. Vertigo 19. Breast mass
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/YES/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/YES/NO/YES 7. MILD/NO/NO/YES 8. SEVERE/NO/YES/YES 9. MILD/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MILD/NO/NO/NO 12. MILD/NO/NO/NO 13. MODERATE/NO/NO/NO

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053023

Parameter	Value
	14. SEVERE/NO/YES/NO
	15. MILD/NO/NO/NO
	16. MODERATE/NO/NO/NO
	17. MILD/NO/NO/NO
	18. MILD/NO/NO/NO
	19. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 18DEC2009 (4) - --------- (.)
	2. 21DEC2009 (7) - 27DEC2009 (13)
	3. 21DEC2009 (7) - 21DEC2009 (7)
	4. 18JAN2010 (35) - --------- (.)
	5. 03FEB2010 (51) - 09FEB2010 (57)
	6. 08MAR2010 (84) - 24MAR2010 (100)
	7. 20APR2010 (127) - --------- (.)
	8. 26APR2010 (133) - --------- (.)
	9. 26APR2010 (133) - --------- (.)
	10. 18MAY2010 (155) - --------- (.)
	11. 24JUN2010 (192) - 27JUL2010 (225)
	12. 30JUN2010 (198) - 30JUL2010 (228)
	13. 28JUL2010 (226) - 30JUL2010 (228)
	14. 30JUL2010 (228) - 12AUG2010 (241)
	15. 12AUG2010 (241) - 08DEC2010 (359)
	16. 18AUG2010 (247) - 19AUG2010 (248)
	17. 18AUG2010 (247) - 08DEC2010 (359)
	18. 03NOV2010 (324) - --------- (.)
	19. 26NOV2010 (347) - --------- (.)
Duration of AE	1. .
	2. 7
	3. 1
	4. .
	5. 7
	6. 17
	7. .
	8. .
	9. .
	10. .
	11. 34
	12. 31
	13. 3
	14. 14
	15. 119
	16. 2
	17. 113
	18. .
	19. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053023

Parameter	Value
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. F
	12. F
	13. F
	14. F
	15. F
	16. F
	17. F
	18. F
	19. F
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053023

Parameter	Value
	7. REMEDIAL DRUG THERAPY
	8. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. NONE
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. OTHER
	15. NONE
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. NONE
	19. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. UNCHANGED
	9. UNCHANGED
	10. UNCHANGED
	11. RESOLVED
	12. WORSENED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. UNCHANGED
	19. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053026

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/180053026/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/49/WHITE/POLAND/YES
Medical history	Bone pain, Contusion, Chest pain, Constipation, Cough, Cough, Dyspnoea, Ear pain, Oedema peripheral, Epistaxis, Pyrexia, Pyrexia, Glaucoma, Hyperhidrosis, Hypertension, Pulmonary fibrosis, Nasal septum deviation, Psoriasis, Depression, Thyroid neoplasm, Uterine leiomyoma, Asthenia, Obesity, Bone pain, Spinal osteoarthritis, Dyssomnia, Respiratory tract infection, Headache, Chest pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	0,9% NACL, 0.9% NATRIUM CHLORATUM, ACENOCOUMAROL, ALTHEAE SYRUP, AVAMYS, AZOPT, BETALOC ZOK, BROMIDES, CAPTOPRIL, CIPRINOL, EFFOX LONG, ENOXAPARIN, FLUCINAR, GROPRINOSINE, HEPATIL, HYDROXIZINUM, IODINE, IPP, KETONAL, LACIDOFIL, LACTOLOSE, LORATADYNA, LORISTA, MUCOSOLVAN, PERFALGAN, POLPRAZOL, PRAMOLAN, PRESTARIUM, PROXACIN, SINUPRET, TERPICHOL, THIOCODIN, UNIDOX, VITARAL
Adverse Events (AE) Preferred term	1. Methylenetetrahydrofolate reductase polymorphism 2. Pleural adhesion 3. Hepatomegaly 4. Pancreas lipomatosis 5. Aortic arteriosclerosis 6. Hypotension 7. Nervousness 8. Dyspnoea 9. Chest pain 10. Paraesthesia 11. Gastrooesophageal reflux disease 12. Paranasal cyst 13. Paranasal sinus hypersecretion 14. Paranasal sinus mucosal hypertrophy 15. Hypertension 16. Epistaxis 17. Epistaxis 18. Spinal osteoarthritis 19. Neuralgia 20. Contusion 21. Epistaxis 22. Abdominal pain 23. Herpes simplex 24. Asthenia 25. Dyspnoea 26. Cough 27. Chills 28. Neurosis 29. Tremor 30. Telangiectasia 31. Traumatic haemorrhage 32. Contusion

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053026

Parameter	Value
	33. Syncope
	34. Excoriation
	35. Hypertension
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/NO/YES
	4. MILD/NO/NO/YES
	5. MILD/NO/NO/YES
	6. MILD/NO/NO/YES
	7. MODERATE/NO/NO/YES
	8. MODERATE/NO/NO/YES
	9. MODERATE/NO/NO/YES
	10. MILD/NO/NO/YES
	11. MODERATE/NO/NO/YES
	12. MILD/NO/NO/YES
	13. MILD/NO/NO/YES
	14. MILD/NO/NO/YES
	15. MODERATE/NO/NO/YES
	16. MILD/YES/NO/YES
	17. MILD/YES/NO/YES
	18. SEVERE/NO/YES/YES
	19. MODERATE/NO/NO/YES
	20. MILD/YES/NO/YES
	21. MODERATE/YES/NO/YES
	22. MILD/NO/NO/YES
	23. MODERATE/NO/NO/YES
	24. MILD/NO/NO/YES
	25. MODERATE/NO/NO/YES
	26. MODERATE/NO/NO/YES
	27. MODERATE/NO/NO/YES
	28. MODERATE/NO/NO/YES
	29. MODERATE/NO/NO/YES
	30. MILD/NO/NO/YES
	31. MODERATE/NO/NO/YES
	32. MILD/YES/NO/YES
	33. MODERATE/NO/NO/YES
	34. MILD/NO/NO/YES
	35. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 14JUL2010 (3) - --------- (.)
	2. 15JUL2010 (4) - --------- (.)
	3. 16JUL2010 (5) - --------- (.)
	4. 16JUL2010 (5) - --------- (.)
	5. 16JUL2010 (5) - --------- (.)
	6. 16JUL2010 (5) - 19JUL2010 (8)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053026

Parameter	Value
	7. 17JUL2010 (6) - 17JUL2010 (6)
	8. 17JUL2010 (6) - 17JUL2010 (6)
	9. 17JUL2010 (6) - 17JUL2010 (6)
	10. 26AUG2010 (46) - --------- (.)
	11. 02SEP2010 (53) - --------- (.)
	12. 02SEP2010 (53) - --------- (.)
	13. 02SEP2010 (53) - --------- (.)
	14. 02SEP2010 (53) - --------- (.)
	15. 03SEP2010 (54) - 15SEP2010 (66)
	16. 06SEP2010 (57) - 06SEP2010 (57)
	17. 01OCT2010 (82) - 01OCT2010 (82)
	18. 07NOV2010 (119) - 28NOV2010 (140)
	19. 07NOV2010 (119) - --------- (.)
	20. 23NOV2010 (135) - 07DEC2010 (149)
	21. 26DEC2010 (168) - --------- (.)
	22. 05JAN2011 (178) - 06MAY2011 (299)
	23. 19JAN2011 (192) - --------- (.)
	24. 22FEB2011 (226) - 01MAR2011 (233)
	25. 02APR2011 (265) - 02APR2011 (265)
	26. 02APR2011 (265) - 03APR2011 (266)
	27. 02APR2011 (265) - 02APR2011 (265)
	28. 02APR2011 (265) - 02APR2011 (265)
	29. 02APR2011 (265) - 02APR2011 (265)
	30. 24MAY2011 (317) - --------- (.)
	31. 21JUN2011 (345) - 21JUN2011 (345)
	32. 21JUN2011 (345) - 08JUL2011 (362)
	33. 21JUN2011 (345) - 21JUN2011 (345)
	34. 21JUN2011 (345) - 05JUL2011 (359)
	35. 14JUL2011 (368) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. 4
	7. 1
	8. 1
	9. 1
	10. .
	11. .
	12. .
	13. .
	14. .
	15. 13

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053026

Parameter	Value
	16. 1
	17. 1
	18. 22
	19. .
	20. 15
	21. .
	22. 122
	23. .
	24. 8
	25. 1
	26. 2
	27. 1
	28. 1
	29. 1
	30. .
	31. 1
	32. 18
	33. 1
	34. 15
	35. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053026

Parameter	Value
	25.
	26.
	27.
	28.
	29.
	30.
	31.
	32.
	33.
	34.
	35.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
	27.
	28.
	29.
	30.
	31.
	32.
	33.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053026

Parameter	Value
	34.
	35.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. NONE
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. NONE
	17. NONE
	18. OTHER
	19. NONE
	20. NONE
	21. STUDY DRUG DISCONTINUED AND RESTARTED
	22. REMEDIAL DRUG THERAPY
	23. REMEDIAL DRUG THERAPY
	24. NONE
	25. NONE
	26. NONE
	27. NONE
	28. NONE
	29. NONE
	30. NONE
	31. NONE
	32. NONE
	33. NONE
	34. NONE
	35. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053026

Parameter	Value
	8. RESOLVED
	9. RESOLVED
	10. UNCHANGED
	11. UNCHANGED
	12. UNCHANGED
	13. UNCHANGED
	14. UNCHANGED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. UNCHANGED
	20. RESOLVED
	21. UNCHANGED
	22. RESOLVED
	23. UNCHANGED
	24. RESOLVED
	25. RESOLVED
	26. RESOLVED
	27. RESOLVED
	28. RESOLVED
	29. RESOLVED
	30. UNCHANGED
	31. RESOLVED
	32. RESOLVED
	33. RESOLVED
	34. RESOLVED
	35. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/180053029/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/74/WHITE/POLAND/YES
Medical history	Appendicectomy, Cardiac murmur, Cough, Dyspnoea, Dyspnoea, Cardiomegaly, Dyspepsia, Joint dislocation, Hypertension, Hyponatraemia, Injection site haematoma, Pulmonary fibrosis, Menopause, Muscle spasms, Nephrolithiasis, Oedema peripheral, Joint dislocation, Varicose vein, Osteoarthritis, Rales, Aortic calcification, Myocardial ischaemia, Spinal osteoarthritis, Dyssomnia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	0.9% NACL, 10% NACL, ACARD, ARTHROSTOP, ARTHRYL, ATORIS, AUGMENTIN, BISOCARD, CLEMASTINUM, CLEXANE, DIAPREL MR, FASTUM, GLUCOPHAGE, GLUCOPHAGE XR 500, HYDROCORTISON, HYDROCORTISONUM, INDIX SR, INSULINUM ACTRAPID, IPP, LORISTA, MAGNEB6, MELOBAX, MYDOCALM, NATRIUM CHLORATUM, PIASCLEDINE, POLOCARD, POLPRAZOL, SKRZYP VIT, TIALORID MITE, TRITACE, ZALDIAR
Adverse Events (AE) Preferred term	1. Diabetes mellitus 2. Mitral valve incompetence 3. Scoliosis 4. Pleural fibrosis 5. Cystocele 6. Atrophic vulvovaginitis 7. Purpura 8. Gallbladder polyp 9. Respiratory tract infection 10. Oedema peripheral 11. Purpura 12. Purpura 13. Aortic valve incompetence 14. Constipation 15. Musculoskeletal pain 16. Arthralgia 17. Epistaxis 18. Blood alkaline phosphatase increased 19. Rash 20. Non-cardiac chest pain 21. Osteolysis 22. Gamma-glutamyltransferase increased 23. Scoliosis 24. Myalgia 25. Alopecia 26. Osteoarthritis 27. Osteoarthritis 28. Arthritis 29. Arthritis 30. Hypertriglyceridaemia 31. Breast disorder 32. Lymph node fibrosis

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053029

Parameter	Value
	33. Epistaxis
	34. Rash
	35. Blood glucose increased
	36. Pain in extremity
	37. Blood glucose increased
	38. Blood glucose increased
	39. Fatigue
	40. Headache
	41. Blood glucose increased
	42. Left atrial dilatation
	43. Blood glucose increased
	44. Cervical root pain
	45. Rash
	46. Musculoskeletal pain
	47. Chest pain
	48. Type V hyperlipidaemia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/NO/YES
	4. MILD/NO/NO/YES
	5. MILD/NO/NO/YES
	6. MILD/NO/NO/YES
	7. MODERATE/YES/NO/YES
	8. MILD/NO/NO/YES
	9. MODERATE/NO/NO/YES
	10. MILD/NO/NO/YES
	11. SEVERE/YES/YES/YES
	12. MILD/YES/NO/YES
	13. MILD/NO/NO/YES
	14. MILD/NO/NO/YES
	15. MODERATE/NO/NO/YES
	16. MODERATE/NO/NO/YES
	17. MILD/YES/NO/YES
	18. MILD/YES/NO/YES
	19. MILD/NO/NO/YES
	20. MODERATE/NO/NO/YES
	21. SEVERE/NO/YES/YES
	22. MILD/NO/NO/YES
	23. MODERATE/NO/NO/YES
	24. MODERATE/NO/NO/YES
	25. MODERATE/YES/NO/YES
	26. MODERATE/NO/NO/YES
	27. MODERATE/NO/NO/YES
	28. MODERATE/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053029

Parameter	Value
	29. MODERATE/NO/NO/YES
	30. MILD/NO/NO/YES
	31. MILD/NO/NO/YES
	32. MILD/NO/NO/YES
	33. MILD/YES/NO/YES
	34. MILD/YES/NO/YES
	35. MILD/NO/NO/YES
	36. MODERATE/NO/NO/YES
	37. MODERATE/NO/NO/YES
	38. MODERATE/NO/NO/YES
	39. MODERATE/NO/NO/YES
	40. MILD/NO/NO/YES
	41. MODERATE/NO/NO/YES
	42. MILD/NO/NO/YES
	43. MODERATE/NO/NO/YES
	44. MODERATE/NO/NO/YES
	45. MODERATE/NO/NO/YES
	46. MODERATE/NO/NO/YES
	47. MODERATE/NO/NO/YES
	48. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 05AUG2010 (1) - --------- (.)
	2. 06AUG2010 (2) - --------- (.)
	3. 09AUG2010 (5) - --------- (.)
	4. 09AUG2010 (5) - --------- (.)
	5. 10AUG2010 (6) - --------- (.)
	6. 10AUG2010 (6) - --------- (.)
	7. 11AUG2010 (7) - 15AUG2010 (11)
	8. 12AUG2010 (8) - --------- (.)
	9. 12AUG2010 (8) - 18AUG2010 (14)
	10. 15AUG2010 (11) - 16AUG2010 (12)
	11. 16AUG2010 (12) - 20AUG2010 (16)
	12. 20AUG2010 (16) - 24AUG2010 (20)
	13. 20AUG2010 (16) - --------- (.)
	14. 20AUG2010 (16) - --------- (.)
	15. 20AUG2010 (16) - --------- (.)
	16. 20AUG2010 (16) - --------- (.)
	17. 25AUG2010 (21) - 07SEP2010 (34)
	18. 03SEP2010 (30) - --------- (.)
	19. 14SEP2010 (41) - 12OCT2010 (69)
	20. 20SEP2010 (47) - 22SEP2010 (49)
	21. 20OCT2010 (77) - 02NOV2010 (90)
	22. 20OCT2010 (77) - --------- (.)
	23. 20OCT2010 (77) - --------- (.)
	24. 30OCT2010 (87) - 13NOV2010 (101)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053029

Parameter	Value
	25. 01NOV2010 (89) - 01MAR2011 (209)
	26. 02NOV2010 (90) - --------- (.)
	27. 02NOV2010 (90) - --------- (.)
	28. 02NOV2010 (90) - --------- (.)
	29. 02NOV2010 (90) - --------- (.)
	30. 09NOV2010 (97) - 21AUG2011 (382)
	31. 09NOV2010 (97) - --------- (.)
	32. 09NOV2010 (97) - --------- (.)
	33. 14DEC2010 (132) - 15DEC2010 (133)
	34. 15DEC2010 (133) - 18JAN2011 (167)
	35. 26JAN2011 (175) - 26JAN2011 (175)
	36. 03FEB2011 (183) - 17FEB2011 (197)
	37. 17FEB2011 (197) - 18FEB2011 (198)
	38. 22FEB2011 (202) - 22FEB2011 (202)
	39. 01MAR2011 (209) - --------- (.)
	40. 09MAR2011 (217) - --------- (.)
	41. 20APR2011 (259) - 24APR2011 (263)
	42. 27APR2011 (266) - 22AUG2011 (383)
	43. 28APR2011 (267) - 25MAY2011 (294)
	44. 14MAY2011 (283) - --------- (.)
	45. 08JUN2011 (308) - 10JUN2011 (310)
	46. 14JUN2011 (314) - 01JUL2011 (331)
	47. 24JUN2011 (324) - 27JUN2011 (327)
	48. 22AUG2011 (383) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. 5
	8. .
	9. 7
	10. 2
	11. 5
	12. 5
	13. .
	14. .
	15. .
	16. .
	17. 14
	18. .
	19. 29
	20. 3

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053029

Parameter	Value
	21. 14
	22. .
	23. .
	24. 15
	25. 121
	26. .
	27. .
	28. .
	29. .
	30. 286
	31. .
	32. .
	33. 2
	34. 35
	35. 1
	36. 15
	37. 2
	38. 1
	39. .
	40. .
	41. 5
	42. 118
	43. 28
	44. .
	45. 3
	46. 18
	47. 4
	48. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 15 mg
	12. 15 mg
	13. 15 mg
	14. 15 mg
	15. 15 mg
	16. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053029

Parameter	Value
	17. 15 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
	22. 20 mg
	23. 20 mg
	24. 20 mg
	25. 20 mg
	26. 20 mg
	27. 20 mg
	28. 20 mg
	29. 20 mg
	30. 20 mg
	31. 20 mg
	32. 20 mg
	33. 20 mg
	34. 20 mg
	35. 20 mg
	36. 20 mg
	37. 20 mg
	38. 20 mg
	39. 20 mg
	40. 20 mg
	41. 20 mg
	42. 20 mg
	43. 20 mg
	44. 20 mg
	45. 20 mg
	46. 20 mg
	47. 20 mg
	48. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. I
	12. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053029

Parameter	Value
	13. .
	14. .
	15. .
	16. .
	17. .
	18. .
	19. .
	20. .
	21. .
	22. .
	23. .
	24. .
	25. .
	26. .
	27. .
	28. .
	29. .
	30. .
	31. .
	32. .
	33. .
	34. .
	35. .
	36. .
	37. .
	38. .
	39. .
	40. .
	41. .
	42. .
	43. .
	44. .
	45. .
	46. .
	47. .
	48. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053029

Parameter	Value
	9. REMEDIAL DRUG THERAPY
	10. OTHER
	11. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. NONE
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. NONE
	18. NONE
	19. REMEDIAL DRUG THERAPY
	20. NONE
	21. OTHER
	22. NONE
	23. NONE
	24. OTHER
	25. REMEDIAL DRUG THERAPY,OTHER
	26. NONE
	27. NONE
	28. NONE
	29. NONE
	30. NONE
	31. NONE
	32. NONE
	33. NONE
	34. NONE
	35. REMEDIAL DRUG THERAPY
	36. NONE
	37. REMEDIAL DRUG THERAPY
	38. REMEDIAL DRUG THERAPY
	39. NONE
	40. NONE
	41. NONE
	42. NONE
	43. REMEDIAL DRUG THERAPY
	44. REMEDIAL DRUG THERAPY
	45. REMEDIAL DRUG THERAPY
	46. NONE
	47. NONE
	48. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053029

Parameter	Value
	5. UNCHANGED
	6. UNCHANGED
	7. WORSENED
	8. UNCHANGED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. UNCHANGED
	14. UNCHANGED
	15. UNCHANGED
	16. UNCHANGED
	17. RESOLVED
	18. UNCHANGED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. UNCHANGED
	23. UNCHANGED
	24. RESOLVED
	25. RESOLVED
	26. UNCHANGED
	27. UNCHANGED
	28. UNCHANGED
	29. UNCHANGED
	30. RESOLVED
	31. UNCHANGED
	32. UNCHANGED
	33. RESOLVED
	34. RESOLVED
	35. RESOLVED
	36. RESOLVED
	37. RESOLVED
	38. RESOLVED
	39. UNCHANGED
	40. UNCHANGED
	41. RESOLVED
	42. RESOLVED
	43. RESOLVED
	44. UNCHANGED
	45. RESOLVED
	46. RESOLVED
	47. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053029

Parameter	Value
	48. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053032

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/180053032/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/52/WHITE/POLAND/YES
Medical history	Alanine aminotransferase increased, Aspartate aminotransferase increased, Cardiac hypertrophy, Cardiac failure chronic, Cough, Dyspnoea, Dyspnoea, Hypertension, Flatulence, Mitral valve incompetence, Obesity, Pleural effusion, Tachycardia, Renal failure acute, Gamma-glutamyltransferase increased
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	0.9% NACL, 5 % GLUCOSE, AMOKSIKLAV, BISOCARD, CONTROLOC, ESPUMISAN, FUROSEMIDUM, IPP, UNFRACTIONED HEPARIN
Adverse Events (AE) Preferred term	1. Subcutaneous haematoma 2. Head injury 3. Syncope 4. Haematuria 5. Atelectasis 6. Lung neoplasm 7. Carbohydrate antigen 125 increased 8. Respiratory arrest 9. Soft tissue mass 10. Methylenetetrahydrofolate reductase polymorphism 11. Contusion 12. Menorrhagia 13. Cardiac failure 14. Uterine enlargement 15. Cervical cyst 16. Hepatic steatosis 17. Pancreas lipomatosis 18. Respiratory tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. SEVERE/NO/YES/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MODERATE/NO/NO/NO 14. MILD/NO/NO/NO 15. MILD/NO/NO/NO 16. MILD/NO/NO/NO 17. MILD/NO/NO/NO 18. MODERATE/NO/NO/NO

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053032

Parameter	Value
Start/stop date of event with relative date	1. 31DEC2010 (2) - 13JAN2011 (15) 2. 31DEC2010 (2) - 31DEC2010 (2) 3. 31DEC2010 (2) - 31DEC2010 (2) 4. 31DEC2010 (2) - 06JAN2011 (8) 5. 31DEC2010 (2) - --------- (.) 6. 31DEC2010 (2) - --------- (.) 7. 31DEC2010 (2) - --------- (.) 8. 31DEC2010 (2) - 31DEC2010 (2) 9. 31DEC2010 (2) - --------- (.) 10. 31DEC2010 (2) - --------- (.) 11. 01JAN2011 (3) - 13JAN2011 (15) 12. 01JAN2011 (3) - 05JAN2011 (7) 13. 04JAN2011 (6) - 11JAN2011 (13) 14. 04JAN2011 (6) - --------- (.) 15. 04JAN2011 (6) - --------- (.) 16. 05JAN2011 (7) - --------- (.) 17. 05JAN2011 (7) - --------- (.) 18. 22JAN2011 (24) - 07FEB2011 (40)
Duration of AE	1. 14 2. 1 3. 1 4. 7 5. . 6. . 7. . 8. 1 9. . 10. . 11. 13 12. 5 13. 8 14. . 15. . 16. . 17. . 18. 17
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 15 mg 6. 15 mg 7. 15 mg 8. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053032

Parameter	Value
	9. 15 mg
	10. 15 mg
	11. 15 mg
	12. 15 mg
	13. 15 mg
	14. 15 mg
	15. 15 mg
	16. 15 mg
	17. 15 mg
	18. 15 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. F
	12. F
	13. F
	14. F
	15. F
	16. F
	17. F
	18. F
Action taken	1. OTHER
	2. OTHER
	3. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
	9. NONE
	10. NONE
	11. NONE
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. NONE
	16. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180053032

Parameter	Value
	17. NONE
	18. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. UNCHANGED
	7. UNCHANGED
	8. RESOLVED
	9. UNCHANGED
	10. UNCHANGED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. UNCHANGED
	15. UNCHANGED
	16. UNCHANGED
	17. UNCHANGED
	18. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-180053032[3)]	HEMATOMA OF THE FOREHEAD REGION（PT：血腫） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、リバーロキサバンの抗凝固作用を考慮し、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180063008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/180063008/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/23/WHITE/POLAND/YES
Medical history	Depression, Migraine with aura, Neurosis, Prurigo, Supraventricular tachycardia, Viral upper respiratory tract infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ACICLOVIR, ALAX, AMBROXOL, ATARAX, DIVASCAN, ENOXAPARIN, ESPUMISAN, HELICID, HYDROKSYZYNA, KETONAL, KETONAL FORTE, METINDOL, PARACETAMOL, PARACETMOL, PAROGEN, PERFALGAN, PERNAZINE, POLPRAZOL, PROPRANOLOL, PROXACIN, REXETIN, SULPIRYD, TRAMAL, TRANXENE, ZALDIAR
Adverse Events (AE) Preferred term	1. Haemoptysis 2. Syncope 3. Urinary tract infection 4. Somnolence 5. Tremor 6. Upper respiratory tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 25NOV2009 (7) - 14DEC2009 (26) 2. 09MAR2010 (111) - 16MAR2010 (118) 3. 10MAR2010 (112) - 23MAR2010 (125) 4. 10MAR2010 (112) - --MAR2010 (.) 5. 12MAR2010 (114) - 12MAR2010 (114) 6. 18JUN2010 (212) - 25JUN2010 (219)
Duration of AE	1. 20 2. 8 3. 14 4. . 5. 1 6. 8
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180063008

Parameter	Value
	6.
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180063009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/180063009/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/POLAND/YES
Medical history	Colon polypectomy, Chronic obstructive pulmonary disease, Depression, Hypertension, Lung neoplasm malignant, Benign prostatic hyperplasia, Spinal osteoarthritis, Limb injury, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	0,9% NACL, AMLOZEK, ATROVENT, AUGMENTIN, BUDESONID, CAPTOPRIL, CIPROFLOXACIN, CIPROPOL, CISPLATYNA, DICLOBERL, DOXYCYKLINA, DOXYRATIO, ESTAZOLAM, FLUKONAZOL, FOKUSIN, FURAGIN, FUROSEMID, GELATUM ALUMINII PHOSPHORICI, GENSULIN N, GENSULIN R, GLIMEHEXAL, INDAPEN, INSULIN MIXTARD 30, IPOREL, KALIUM EFFERVESCENS, KALIUM EFFEVESCENS, KCL, LAKCID, LORAFEN, MAGNEZIN, MAGNEZIUM SULFATE, MANNITOL 20%, METOCARD, METOCLOPRAMID, MGSO4, MIFLONIDE, NAVELBINA, NEUPOGEN, NO-SPA, NOLICIN, NOLPAZA, PENESTER, SEREVENT DYSK, SPIRIVA, SPIRONOL, TARCEFOKSYM, WINORELBINA, XARTAN, ZINNAT, ZOFRAN, ZOFRAN ZYDIS, ZOXON
Adverse Events (AE) Preferred term	1. Lung adenocarcinoma 2. Prostatitis 3. Urosepsis 4. Diabetes mellitus inadequate control 5. Urinary tract infection 6. Urinary tract infection 7. Urethritis
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 14JAN2010 (7) - --------- (.) 2. 16FEB2010 (40) - 03MAR2010 (55) 3. 19FEB2010 (43) - 03MAR2010 (55) 4. 19FEB2010 (43) - 26FEB2010 (50) 5. 07APR2010 (90) - 16APR2010 (99) 6. 13MAY2010 (126) - --------- (.) 7. 20JUN2010 (164) - --AUG2010 (.)
Duration of AE	1. . 2. 16 3. 13 4. 8 5. 10 6. . 7. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180063009

Parameter	Value
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180103004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/180103004/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/76/WHITE/POLAND/YES
Medical history	Hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ADVANTAN, AMLOPIN, CARDIOLIPIN [CARDIOLIPIN IS AMLODYPINE. INDICATION FOR CARDIOLIPIN IS HYPERTESIO, CAVINTON, ENARENAL, ENOXAPARIN, GOPTEN, HYDROCORTISON, KALIPOZ, MAGNEZIN, NILOGRIN, OMEPRAZOL, TERTENSIF, TULIP [ATORVASTATIN]
Adverse Events (AE) Preferred term	1. Pulmonary hypertension 2. Stasis dermatitis 3. Cough 4. Vertigo 5. Hypokalaemia 6. Vertigo 7. Carotid arteriosclerosis 8. Spondylitis 9. Vertigo
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/YES/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 14MAR2008 (1) - --------- (.) 2. 19MAR2008 (6) - --AUG2008 (.) 3. 10JUL2008 (119) - --SEP2008 (.) 4. 29NOV2008 (261) - 03DEC2008 (265) 5. 04DEC2008 (266) - 08DEC2008 (270) 6. 04DEC2008 (266) - 09DEC2008 (271) 7. 05DEC2008 (267) - --------- (.) 8. 05DEC2008 (267) - --------- (.) 9. 10DEC2008 (272) - 31MAR2009 (383)
Duration of AE	1. . 2. . 3. . 4. 5 5. 5 6. 6 7. . 8. . 9. 112

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180103004

Parameter	Value
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. WORSENED
	5. RESOLVED
	6. IMPROVED
	7. UNCHANGED
	8. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180103004

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 180103007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/180103007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/72/WHITE/POLAND/YES
Medical history	Hypertension, Hypothyroidism, Mastectomy, Obesity, Vascular graft, Coronary artery disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AMLOPIN, BISOCARD, CAPTOPRIL, ELTROXIN, ENOXAPARIN, HYDROCHOLOROTHIAZYD, PERLINGANIT, PRININVIL, PRINIVIL, WALSARTAN, ZOCOR
Adverse Events (AE) Preferred term	1. Chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 28JUL2008 (109) - 30JUL2008 (111)
Duration of AE	1. 3
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220013020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220013020/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/76/WHITE/ITALY/YES
Medical history	Metastases to liver, Hypertension, Hysterectomy, Ovarian cancer, Metastases to lung
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDOMET, CATAPRESAN, COEFFERALGAN, LANSOX, LASITONE, MEGACE, OMEPRAZOL, PERFALGAN, PLASIL, PORTOLAC, TAVOR [LORAZEPAM], TRANSTEC
Adverse Events (AE) Preferred term	1. Hypertension 2. Anxiety 3. Ascites 4. Ovarian cancer
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 08APR2008 (7) - 08APR2008 (7) 2. 11APR2008 (10) - 15APR2008 (14) 3. 21APR2008 (20) - --------- (.) 4. 02MAY2008 (31) - 02MAY2008 (31)
Duration of AE	1. 1 2. 5 3. . 4. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220013020

Parameter	Value
	4. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220013035

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220013035/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/74/WHITE/ITALY/YES
Medical history	Hypercholesterolaemia, Osteoporosis, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADRENALIN, CEFTRIAXONE, ENOXAPARIN, FLUIMUCIL, FUROSEMIDE, INSULIN, MORFINA, OMEPRAZOL
Adverse Events (AE) Preferred term	1. Hyperglycaemia 2. Cardiac failure 3. Hypotension 4. Cerebral haemorrhage 5. Oliguria 6. Hypophosphataemia 7. Candidiasis 8. Hypertension 9. Respiratory failure 10. Convulsion 11. Urinary tract infection 12. Flatulence 13. Hypoalbuminaemia 14. Diarrhoea 15. Enterocolitis 16. Depression 17. Anuria 18. Hypotension
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/NO 7. MILD/NO/NO/NO 8. MODERATE/NO/NO/NO 9. SEVERE/NO/YES/NO 10. MILD/NO/NO/NO 11. MILD/NO/NO/NO 12. MILD/NO/NO/NO 13. MODERATE/NO/NO/NO 14. MODERATE/NO/NO/NO 15. MODERATE/NO/NO/NO 16. MODERATE/NO/NO/NO 17. MODERATE/NO/NO/NO 18. SEVERE/NO/NO/NO
Start/stop date of event with relative date	1. 15NOV2008 (2) - 24NOV2008 (11) 2. 15NOV2008 (2) - 20NOV2008 (7)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220013035

Parameter	Value
	3. 15NOV2008 (2) - 16NOV2008 (3)
	4. 16NOV2008 (3) - 25NOV2008 (12)
	5. 16NOV2008 (3) - 16NOV2008 (3)
	6. 18NOV2008 (5) - 20NOV2008 (7)
	7. 24NOV2008 (11) - 23DEC2008 (40)
	8. 24NOV2008 (11) - 25NOV2008 (12)
	9. 10DEC2008 (27) - 25JAN2009 (73)
	10. 12DEC2008 (29) - 25JAN2009 (73)
	11. 30DEC2008 (47) - 08JAN2009 (56)
	12. 07JAN2009 (55) - 22JAN2009 (70)
	13. 08JAN2009 (56) - 21JAN2009 (69)
	14. 16JAN2009 (64) - 16JAN2009 (64)
	15. 16JAN2009 (64) - 25JAN2009 (73)
	16. 22JAN2009 (70) - 23JAN2009 (71)
	17. 23JAN2009 (71) - 25JAN2009 (73)
	18. 25JAN2009 (73) - 25JAN2009 (73)
Duration of AE	1. 10
	2. 6
	3. 2
	4. 10
	5. 1
	6. 3
	7. 30
	8. 2
	9. 47
	10. 45
	11. 10
	12. 16
	13. 14
	14. 1
	15. 10
	16. 2
	17. 3
	18. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220013035

Parameter	Value
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220013035

Parameter	Value
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. DEATH
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-220013035[4)]	CEREBRAL HEMORRHAGE（PT：脳出血） 治験担当医は因果関係を否定できると判断した。弊社は、エノキサパリンの抗凝固作用を考慮し、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220013048

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220013048/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/69/WHITE/ITALY/YES
Medical history	Asthma, Bronchitis chronic, Hepatitis B, Gastrooesophageal reflux disease, Hip arthroplasty, Hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	B 12 VITAMIN, C VITAMIN 100/10 MG, CLEXANE, ENOXAPARIN, ENOXAPARINE, FOLIC ACID, INDOMETHACIN, IRON, IRON /FOLIC ACID/ASCORBIC ACID, LANSOPRASOL, RIFAMPICINA, TRIMETROPIM/SULFOMETOXAZOL, WARFARIN
Adverse Events (AE) Preferred term	1. Muscle haemorrhage 2. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 01FEB2010 (5) - 08FEB2010 (12) 2. 14FEB2010 (18) - 14FEB2010 (18)
Duration of AE	1. 8 2. 1
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 2. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220033014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220033014/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/88/WHITE/ITALY/YES
Medical history	Benign prostatic hyperplasia, Hiatus hernia, Temporal arteritis, Hypertension, Inguinal hernia repair, Inguinal hernia repair, Peptic ulcer, Polymyalgia rheumatica, Thrombophlebitis superficial
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DELTACORTENE, FOSAVANCE, KCL RETARD, METOPROLOLO, OLPREZIDE, TIKLID, TORVAST, XATRAL
Adverse Events (AE) Preferred term	1. Abdominal pain upper 2. Hypercholesterolaemia 3. Hypokalaemia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/NO/YES
Start/stop date of event with relative date	1. 10JUL2009 (122) - 16JUL2009 (128) 2. 10JUL2009 (122) - 16JUL2009 (128) 3. 10JUL2009 (122) - 16JUL2009 (128)
Duration of AE	1. 7 2. 7 3. 7
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220043004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220043004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/76/WHITE/ITALY/YES
Medical history	Gastric cancer, Gastrectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	LIMPIDEX
Adverse Events (AE) Preferred term	1. Fatigue
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 04MAR2008 (92) - 05MAR2008 (93)
Duration of AE	1. 2
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220053010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220053010/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/84/WHITE/ITALY/YES
Medical history	Anxiety, Humerus fracture, Skin neoplasm excision, Osteoporosis, Supraventricular tachycardia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALMARYTM, AMIODARONE, AUGUMENTIN, CANREONATO LUVION, CARVEDILOLO, CEFTRIAXONE, ENOXAPARIN, KCL RETARD (K), KCL RETARD (K), LASIX, LENTOKALIUM, METOPROLOLO, OMEPRAZOLO, OXYGEN, TACHIDOL, TAVOR [LORAZEPAM], TAZOCIN, VERAPAMIL, WARFARIN
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Supraventricular tachycardia 3. Pneumonia 4. Supraventricular tachycardia 5. Pleural effusion 6. Pleural effusion 7. Supraventricular tachycardia 8. Pleural effusion 9. Cardiac failure 10. Cerebral ischaemia 11. Hypokalaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MODERATE/NO/YES/YES 8. MODERATE/NO/YES/YES 9. MODERATE/NO/YES/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 24JUN2010 (9) - 01JUL2010 (16) 2. 04JUL2010 (19) - 09JUL2010 (24) 3. 04JUL2010 (19) - 09JUL2010 (24) 4. 26AUG2010 (72) - 31AUG2010 (77) 5. 02SEP2010 (79) - 08SEP2010 (85) 6. 19SEP2010 (96) - 26SEP2010 (103) 7. 21SEP2010 (98) - 28SEP2010 (105) 8. 03NOV2010 (141) - 13DEC2010 (181) 9. 03NOV2010 (141) - 13DEC2010 (181) 10. 03NOV2010 (141) - --------- (.) 11. 08NOV2010 (146) - 10NOV2010 (148)
Duration of AE	1. 8 2. 6 3. 6

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220053010

Parameter	Value
	4. 6
	5. 7
	6. 8
	7. 8
	8. 41
	9. 41
	10. .
	11. 3
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	8. NONE
	9. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220053010

Parameter	Value
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. UNCHANGED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220093011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220093011/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/77/WHITE/ITALY/YES
Medical history	Renal failure chronic, Chronic obstructive pulmonary disease, Diabetes mellitus, Enteritis, Postmenopause, Congestive cardiomyopathy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CARDICOR, LANSOX, ZYLORIC
Adverse Events (AE) Preferred term	1. Sudden death
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 12FEB2008 (13) - 12FEB2008 (13)
Duration of AE	1. 1
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. F
Action taken	1. NONE
Outcome of event	1. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-220093011[5)]	SUDDEN DEATH（PT：突然死） 治験担当医は、心不全が死亡に関連している可能性はあるものの、報告事象との関連性があると判断した。ドイツ本社安全性部門は、リバーロキサバン投与開始前から認められている心不全が関与した可能性があり因果関係は低いと評価している。弊社もリバーロキサバンが関与した可能性は低いと考えるが、情報不足であることや治験担当医の評価を考慮した場合、完全には否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

被験者番号：11702-220093011

死亡に至るまでの経過（因果関係が否定できない死亡）

被験者は 77 歳、白人女性。2008 年 1 月 30 日に肺塞栓症と診断され、翌日リバーロキサバン（30mg）の投与を開始した。

2008 年 2 月 12 日、被験者は死亡した〔突然死（原因不明の突然死）〕。本事象は重篤な有害事象とされた。治験責任（分担）医師は、本事象の重症度は高度で、治験薬との因果関係は「あり」と判断した。被験者は拡張型心筋症の病歴を有していた。2008 年 1 月 28 日、本試験への組み入れ前に併用薬の acetylsalicylic acid、furosemide 及び lorsatan potassium の投与を中止した。2008 年 2 月 12 日の早朝、被験者の姉妹がベッドで死亡している被験者を発見した。死体検案書には、「死後硬直。死亡を確認。死亡原因：心停止」と記載されていた。剖検は実施されなかった。

CIAC は本事象は血管事象ではないと結論づけ、死亡原因は「不明であり、肺塞栓症である可能性は否定できない」とした。

Laboratory Parameter	Normal Range	Date	Result	Date	Result
Alkaline Phosphatase	Central: 36-118 U/L	31 Jan 2008	**138 U/L (H)**		
Amylase	Central: 28-100 U/L	31 Jan 2008	**133 U/L (H)**		
Bilirubin, Direct	Central: 0.10-0.32mg/dL	31 Jan 2008	0.11 mg/dL		
Bilirubin, Total	Central: 0.22-1.28mg/dL	31 Jan 2008	0.39 mg/dL		
Creatinine	Local: 0.60-1.10mg/dL	30 Jan 2008	**1.19 mg/dL (H)**		
SGOT/AST	Central: 11-37 U/L	31 Jan 2008	36 U/L		
SGPT/ALT	Central: 8-43 U/L [a] Local: 10-37 U/L	30 Jan 2008	17 U/L [a]	31 Jan 2008	17 U/L
PICT Seconds	Central: 24.80-36.40 S	31 Jan 2008	**65.30 S (H)**		
Prothrombin Time (PT)	Central: 11.80-15.50 S	31 Jan 2008	**18.00 S (H)**		
PT Ratio	Central: 0.70-1.20 %	31 Jan 2008	**0.58 % (L)**		
PT, INR	Central: 0.9-1.2	31 Jan 2008	**1.5 (H)**		

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220093038

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220093038/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/76/WHITE/ITALY/YES
Medical history	Hypersensitivity, Chronic hepatitis, Pyrexia, Obesity, Bronchitis chronic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BRONCOVALEAS, CLENIL A, ENOXAPARIN, HUMAN COMPLEX [PROTHROMBIN COMPLEX CONCENTRATES], LANSOPRAZOLO, LEVOXACIN, MEDROL, OXIVENT, TRIMETON, URBASON, VITAMIN K, WARFARIN
Adverse Events (AE) Preferred term	1. Chest injury 2. Mediastinal haemorrhage 3. Sternal fracture 4. Chest injury
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/YES/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 14OCT2009 (83) - 21OCT2009 (90) 2. 14OCT2009 (83) - 21OCT2009 (90) 3. 14OCT2009 (83) - 21OCT2009 (90) 4. 22OCT2009 (91) - --------- (.)
Duration of AE	1. 8 2. 8 3. 8 4. .
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED PERMANENTLY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220093038

Parameter	Value
	4. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-220093038[4)]	HAEMOMEDIASTINUM（PT：縦隔出血） 治験担当医は、投与中の偶発症である交通事故によるものであり、否定できると判断した。弊社は、交通事故による可能性とも考えられるが、ワルファリンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220133003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220133003/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/72/WHITE/ITALY/YES
Medical history	Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CIPROXIN, NADROPARINE, NORVASC, TRIATEC
Adverse Events (AE) Preferred term	1. Dyspnoea
	2. Hypertension
	3. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 07OCT2007 (17) - 17OCT2007 (27)
	2. 07OCT2007 (17) - --------- (.)
	3. 08OCT2007 (18) - 17OCT2007 (27)
Duration of AE	1. 11
	2. .
	3. 10
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
Dose status on AE onset	1. .
	2. .
	3. I
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220133007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220133007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/67/WHITE/ITALY/YES
Medical history	Crohn's disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, KONAKION, MICONAZOLE, PENTASA, WARFARIN
Adverse Events (AE) Preferred term	1. International normalised ratio increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/YES/YES
Start/stop date of event with relative date	1. 01MAY2008 (169) - 03MAY2008 (171)
Duration of AE	1. 3
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220133013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220133013/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/67/WHITE/ITALY/YES
Medical history	Hypoplastic anaemia, Renal cancer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AVODART, CIPROXIN, TAMSULOSIN
Adverse Events (AE) Preferred term	1. Priapism
	2. Pleural effusion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 08MAR2008 (17) - 08MAR2008 (17)
	2. 09MAR2008 (18) - 11MAR2008 (20)
Duration of AE	1. 1
	2. 3
Dose on AE onset	1. 15 mg
	2. 15 mg
Dose status on AE onset	1. .
	2. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220143017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220143017/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/74/WHITE/ITALY/YES
Medical history	Hypertension, Obesity, Renal failure
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CARDIOASPIRINA, ISOLYTE, LIMPIDEX, LOBIVON, LORAZEPAM, MEPRAL, MODURETIC, PRITOR PLUS, ROCEFIN
Adverse Events (AE) Preferred term	1. Pyrexia 2. Blood amylase increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 12JAN2008 (16) - 16JAN2008 (20) 2. 12JAN2008 (16) - 14JAN2008 (18)
Duration of AE	1. 5 2. 3
Dose on AE onset	1. 15 mg 2. 15 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220143042

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220143042/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/60/WHITE/ITALY/YES
Medical history	Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, IBUPROFENE, WARFARIN
Adverse Events (AE) Preferred term	1. Pyrexia 2. Headache 3. Metastasis 4. Arthralgia 5. Syncope 6. Renal cancer 7. Anaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES 6. SEVERE/NO/YES/NO 7. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 12SEP2009 (3) - 14SEP2009 (5) 2. 12SEP2009 (3) - 14SEP2009 (5) 3. 14SEP2009 (5) - --------- (.) 4. 21SEP2009 (12) - 06OCT2009 (27) 5. 21SEP2009 (12) - 21SEP2009 (12) 6. 05OCT2009 (26) - 03NOV2009 (55) 7. 02NOV2009 (54) - 05NOV2009 (57)
Duration of AE	1. 3 2. 3 3. . 4. 16 5. 1 6. 30 7. 4
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220143042

Parameter	Value
	5.
	6.
	7.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. OTHER
	7. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220143044

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220143044/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/83/WHITE/ITALY/YES
Medical history	Cardiac failure acute, Anaemia, Dyspepsia, Hypertension, Hyperthyroidism, Renal failure chronic, Prostatectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CARDURA, CODEINA, ENOXAPARIN, FERROGRAD, ISOPTIN, KONAKION, LANSOPRAZOLO, LASITONE, LASIX, PARACETAMOLO, RIOPAN, TAPAZOLE, TAVANIC, TAVOR [LORAZEPAM], TRIATEC, WARFARIN
Adverse Events (AE) Preferred term	1. Neck pain 2. Pyrexia 3. Haematochezia 4. Atrial fibrillation 5. Oral candidiasis 6. Pericardial effusion 7. Cough 8. Pyrexia 9. Lung neoplasm malignant 10. Tracheobronchitis 11. Pericardial haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. SEVERE/NO/YES/YES 10. MILD/NO/NO/YES 11. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 27JAN2010 (1) - 05FEB2010 (10) 2. 29JAN2010 (3) - 29JAN2010 (3) 3. 30JAN2010 (4) - 09FEB2010 (14) 4. 30JAN2010 (4) - 02FEB2010 (7) 5. 02FEB2010 (7) - 05FEB2010 (10) 6. 02FEB2010 (7) - 28FEB2010 (33) 7. 05FEB2010 (10) - --------- (.) 8. 15FEB2010 (20) - 16FEB2010 (21) 9. 17FEB2010 (22) - --------- (.) 10. 17FEB2010 (22) - --------- (.) 11. 01MAR2010 (34) - 25MAR2010 (58)
Duration of AE	1. 10 2. 1 3. 11

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220143044

Parameter	Value
	4. 4
	5. 4
	6. 27
	7. .
	8. 2
	9. .
	10. .
	11. 25
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220143044

Parameter	Value
	4. RESOLVED
	5. RESOLVED
	6. WORSENED
	7. UNCHANGED
	8. RESOLVED
	9. UNCHANGED
	10. INSUFFICIENT FOLLOW-UP
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220143050

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220143050/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/60/WHITE/ITALY/YES
Medical history	Abdominal discomfort, Cholecystectomy, Hepatic steatosis, Hypertension, Menopause, Obesity, Umbilical hernia, Gastric disorder, Dyslipidaemia, Venous insufficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CONTROLOC, METOCLOPRAMIDE, NEBILET, NORVASC, PARACETAMOL
Adverse Events (AE) Preferred term	1. Tooth abscess 2. Abdominal hernia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 05AUG2010 (38) - 14AUG2010 (47) 2. 01DEC2010 (156) - --------- (.)
Duration of AE	1. 10 2. .
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE
Outcome of event	1. RESOLVED 2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220143054

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220143054/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/82/WHITE/ITALY/YES
Medical history	Breast cancer, Gastritis, Hypertension, Osteoporosis, Mastectomy, Malignant melanoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CARDIAZOL, CIPROXIN, ENAPREN, ENOXAPARIN, IDEOS, MINIAS, NORVASC, PROTELOS, RIOPAN, TORECAN
Adverse Events (AE) Preferred term	1. Metastases to lymph nodes
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 11OCT2010 (14) - --------- (.)
Duration of AE	1. .
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
Outcome of event	1. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220143055

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220143055/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/ITALY/YES
Medical history	Aortic aneurysm, Hypertension, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATENOLOLO, BECLOMETASONE/SALBUTAMOL, BRONCOVALEAS, ENOXAPARIN, ESIDREX, LASIX, SELECTIN
Adverse Events (AE) Preferred term	1. Cough 2. Gastrointestinal stromal tumour
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 20OCT2010 (8) - 22OCT2010 (10) 2. 09NOV2010 (28) - 15NOV2010 (34)
Duration of AE	1. 3 2. 7
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220143059

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220143059/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/75/WHITE/ITALY/YES
Medical history	Back pain, Hypercholesterolaemia, Hypertension, Gastric disorder, Constipation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, LAEVOLAC, LIMPIDEX, LOSAZID, TACHIDOL, TORVAST, WARFARIN
Adverse Events (AE) Preferred term	1. Autoimmune thyroiditis 2. Blood follicle stimulating hormone increased 3. Anti-thyroid antibody positive 4. Breast cancer
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 15FEB2011 (3) - --------- (.) 2. 15FEB2011 (3) - --------- (.) 3. 16FEB2011 (4) - --------- (.) 4. 04MAY2011 (81) - --------- (.)
Duration of AE	1. . 2. . 3. . 4. .
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. NONE 3. NONE 4. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. UNCHANGED 2. INSUFFICIENT FOLLOW-UP 3. INSUFFICIENT FOLLOW-UP

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220143059

Parameter	Value
	4. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-220143059[1)]	BREAST CANCER（PT：乳癌） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、投与中の偶発症であると判断し、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220153004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220153004/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/61/WHITE/ITALY/YES
Medical history	Idiopathic thrombocytopenic purpura, Pneumonitis, Intervertebral disc protrusion, Spinal column stenosis, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AVALOX, BUPIVACAINE, CONTRAMAL, ENOXAPARIN, KENOCORT, LEXOTAN, ROCEFIN, TACHIDOL, TAVANIC, WARFARIN
Adverse Events (AE) Preferred term	1. Haematuria 2. Urinary tract infection 3. Headache 4. Back pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 08NOV2007 (1) - 08NOV2007 (1) 2. 19NOV2007 (12) - 25NOV2007 (18) 3. 01JAN2008 (55) - 10JAN2008 (64) 4. 01JAN2008 (55) - 12JAN2008 (66)
Duration of AE	1. 1 2. 7 3. 10 4. 12
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220153004

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220153007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220153007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/72/WHITE/ITALY/YES
Medical history	Breast cancer, Thermal burn, Cholelithiasis, Gastritis, Hypertension, Oophorectomy, Osteoarthritis, Mastectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATENOL, COUMADIN, DEURSIL, ENOXAPARIN, LANSOX, MODURETIC, TRIATEC 5 MG, WARFARIN
Adverse Events (AE) Preferred term	1. Cholangitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 30JUL2008 (191) - 07AUG2008 (199)
Duration of AE	1. 9
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220153014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220153014/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/ITALY/YES
Medical history	Inguinal hernia, Peptic ulcer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	COSOPT, LIPOVISC, OMEPRAZOLO
Adverse Events (AE) Preferred term	1. Benign prostatic hyperplasia 2. Angina pectoris 3. Abdominal pain upper 4. Glaucoma
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 10DEC2008 (12) - --------- (.) 2. 13JAN2009 (46) - 15JAN2009 (48) 3. 14JAN2009 (47) - --------- (.) 4. 13APR2009 (136) - --------- (.)
Duration of AE	1. . 2. 3 3. . 4. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. NONE 2. NONE 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. RESOLVED 3. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220153014

Parameter	Value
	4. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 220153015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/220153015/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/82/WHITE/ITALY/YES
Medical history	Dermatitis, Hypertension, Bronchitis chronic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, IGROSELES, RANITIDINA, UNFRACTIONATED HEPARIN, UNFRACTIONED HEPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Colonic polyp 2. Post procedural haemorrhage 3. Diverticulitis intestinal haemorrhagic
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/NO 2. MODERATE/YES/YES/NO 3. MILD/YES/NO/NO
Start/stop date of event with relative date	1. 07SEP2009 (21) - 07SEP2009 (21) 2. 10SEP2009 (24) - 10SEP2009 (24) 3. 18SEP2009 (32) - 19SEP2009 (33)
Duration of AE	1. 1 2. 1 3. 2
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. REMEDIAL DRUG THERAPY,OTHER 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240023015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240023015/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/66/WHITE/SPAIN/YES
Medical history	Prostatitis, Cholecystectomy, Hip arthroplasty, Hypertension, Nephrectomy, Nephrolithiasis, Urinary tract infection, Tuberculosis, Tuberculosis bladder, Renal failure chronic, Cryptorchism, Bladder repair, Intestinal obstruction, Cataract operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, CEFTRIAXONA, ENOXAPARIN, FLUIMUCIL ORAL FORTE, FOSFOMICINA, FRAGMIN, METOCLOPRAMIDA, OMEPRAZOL, PANTOPRAZOL, PARACETAMOL, PHYSIOLOGIC SALT SOLUTION, PIPERACILINA/TAZOBACTAM, SEPTRIN, TELMISARTAN
Adverse Events (AE) Preferred term	1. Haematuria 2. Nausea 3. Transaminases increased 4. Haematuria
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 06NOV2008 (3) - 11NOV2008 (8) 2. 09NOV2008 (6) - 09NOV2008 (6) 3. 10NOV2008 (7) - 04DEC2008 (31) 4. 03APR2009 (151) - 04APR2009 (152)
Duration of AE	1. 6 2. 1 3. 25 4. 2
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. NONE 4. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240023015

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240023016

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240023016/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/55/WHITE/SPAIN/YES
Medical history	Anxiety, Appendicectomy, Iron deficiency anaemia, Menopause, Obesity, Ovarian cancer, Parkinson's disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CEFIXIMA, CEFTRIAXONA, CLEXANE, DEPRAX, DIAZEPAM, ENANTYUM, FERRO-GRADUMET, FUROSEMIDA, LEVOFLOXACINO, MICRALAX, MIRAPEIXIN, MIRAPEXIN, NOLOTIL, OMEPRAZOL, ORFIDAL, PARACETAMOL, SINEMET PLUS 2, SINEMET RETARD
Adverse Events (AE) Preferred term	1. Pneumonia 2. Insomnia 3. Constipation 4. Non-cardiac chest pain 5. Lung infection 6. Lung infection 7. Anxiety 8. Lung infection 9. Pleuritic pain
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. SEVERE/NO/YES/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 05NOV2008 (1) - 22NOV2008 (18) 2. 09NOV2008 (5) - --------- (.) 3. 10NOV2008 (6) - 13NOV2008 (9) 4. 12FEB2009 (100) - 22FEB2009 (110) 5. 27FEB2009 (115) - 27FEB2009 (115) 6. 28FEB2009 (116) - 04MAR2009 (120) 7. 28FEB2009 (116) - --------- (.) 8. 04MAR2009 (120) - 10MAR2009 (126) 9. 17JUL2009 (255) - 18JUL2009 (256)
Duration of AE	1. 18 2. . 3. 4 4. 11 5. 1 6. 5 7. . 8. 7 9. 2
Dose on AE onset	1. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240023016

Parameter	Value
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. I
	7. I
	8. .
	9. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. OTHER
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. WORSENED
	6. IMPROVED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240023017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240023017/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/78/WHITE/SPAIN/YES
Medical history	Pyelonephritis acute, Anaemia, Constipation, Chronic obstructive pulmonary disease, Finger amputation, Glaucoma, Hypertension, Inguinal hernia repair, Insomnia, Pulmonary tuberculosis, Respiratory tract infection, Urinary tract infection, Renal failure chronic, Urinary tract infection bacterial, Cystoprostatectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPINO, CITORSAL, COLISTIMETATO OF SODIUM, FUROSEMIDA, IPRATROPIO, LACTITOL, LEVOFLOXACINO, LORAZEPAM, METILPREDNISOLONA, MOTILIUM, NISTATINA, OMEPRAZOL, PANTOPRAZOL, PARACETAMOL, PREDNISONA, SALBUTAMOL, SALMETEROL
Adverse Events (AE) Preferred term	1. Haematuria 2. Chronic obstructive pulmonary disease 3. Chronic obstructive pulmonary disease 4. Urinary tract infection 5. Insomnia 6. Haematuria 7. Anaemia 8. Constipation 9. Candidiasis 10. Haematuria 11. Haematuria 12. Gastroenteritis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/YES/NO/YES 7. MODERATE/YES/NO/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES 10. MILD/YES/NO/YES 11. MILD/YES/NO/YES 12. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 29NOV2008 (2) - 01DEC2008 (4) 2. 09DEC2008 (12) - 11DEC2008 (14) 3. 12DEC2008 (15) - 22DEC2008 (25) 4. 12DEC2008 (15) - 21DEC2008 (24) 5. 13DEC2008 (16) - --------- (.) 6. 14DEC2008 (17) - 14DEC2008 (17) 7. 14DEC2008 (17) - --------- (.) 8. 15DEC2008 (18) - 18DEC2008 (21) 9. 15DEC2008 (18) - 22DEC2008 (25) 10. 18DEC2008 (21) - 19DEC2008 (22) 11. 25DEC2008 (28) - 23JAN2009 (57)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240023017

Parameter	Value
	12. 25MAR2009 (118) - 30MAR2009 (123)
Duration of AE	1. 3
	2. 3
	3. 11
	4. 10
	5. .
	6. 1
	7. .
	8. 4
	9. 8
	10. 2
	11. 30
	12. 6
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 20 mg
	12. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240023017

Parameter	Value
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. NONE
	12. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. WORSENED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240043018

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240043018/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/SPAIN/YES
Medical history	Cataract, Cardiac failure chronic, Dementia, Hyperlipidaemia, Hypertension, Insomnia, Osteoporosis, Temporal arteritis, Transient ischaemic attack, Postmenopause, Venous angioma of brain, Dyslipidaemia, Atrial fibrillation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AAS, CALCIUM SANDOZ FORTE D, CARVEDILOL, DACORTIN, ENALAPRIL, ENALAPRIL/HIDROCLOROTIAZIDA, ENALAPRIL/HIDROCLORTIAZIDA, FOSAMAX, FUROSEMIDA, FUROSEMIDE, GALVUS, GLUCOSE, HIDROCLORTIAZIDE, HYDROCHLOROTHIAZIDE, INSULIN LEVEMIR FLEXPEN, INSULINA NOVORAPID FLEXPEN PLUMA, LORMETAZEPAM, OMEPRAZOL, PARACETAMOL, REPAGLINDIN, REPAGLINIDA, REPAGLINIDINA, SITAGLIPTINA, STILNOX
Adverse Events (AE) Preferred term	1. Musculoskeletal chest pain 2. Oedema peripheral 3. Cardiac failure congestive 4. Type 2 diabetes mellitus 5. Type 2 diabetes mellitus
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 17DEC2009 (35) - 26JAN2010 (75) 2. 13JAN2010 (62) - 26JAN2010 (75) 3. 13JAN2010 (62) - --------- (.) 4. 26JAN2010 (75) - 18FEB2010 (98) 5. 19FEB2010 (99) - --------- (.)
Duration of AE	1. 41 2. 14 3. . 4. 24 5. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. NONE 2. NONE 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240043018

Parameter	Value
Outcome of event	5. REMEDIAL DRUG THERAPY 1. RESOLVED 2. RESOLVED 3. UNCHANGED 4. IMPROVED 5. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240043021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240043021/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/75/WHITE/SPAIN/YES
Medical history	Bone graft, Depression, Hypertension, Hysterectomy, Knee arthroplasty, Obesity, Osteoarthritis, Thrombophlebitis, Uterine prolapse, Venous insufficiency, Diarrhoea
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETILCISTEINE, CEFAZOLINA, CODEISAN, DAFLON [DIOSMINA+FLAVONOIDES], DALTAPERINA, DALTEPARINE, ESBERIVEN, HEMORRANE, LORAZEPAM, LOSARTAN, METAMIZOL, OMEPRAZOL, PARACETAMOL, PAROXETINA, PETIDINA, VINCOSEDAN, ZALDIAR
Adverse Events (AE) Preferred term	1. Osteochondritis 2. Respiratory tract infection 3. Femur fracture 4. Radius fracture 5. Rectal haemorrhage 6. Haemorrhoids
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 07JAN2011 (4) - 15JAN2011 (12) 2. 09JAN2011 (6) - 24JAN2011 (21) 3. 28FEB2011 (56) - 07MAR2011 (63) 4. 28FEB2011 (56) - 10MAY2011 (127) 5. 26APR2011 (113) - 26APR2011 (113) 6. 26APR2011 (113) - --------- (.)
Duration of AE	1. 9 2. 16 3. 8 4. 72 5. 1 6. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240043021

Parameter	Value
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240073010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240073010/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/83/WHITE/SPAIN/YES
Medical history	Angina pectoris, Asthma, Foot deformity, Myocardial infarction, Hypertension, Renal failure chronic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADIRO, AMOXICILLIN, BUDESONIDE, CLAVULANATE, CLEXANE, ENALAPRIL, FORMOTEROL, HIDROCLOROTIAZIDE, MASDIL RETARD, PANTECTA, PERTIL RETARD, SIMVASTATINA, ZOCOR
Adverse Events (AE) Preferred term	1. Haematoma 2. Pain in extremity 3. Localised infection 4. Cough 5. Productive cough 6. Anaemia 7. Insomnia 8. Gastric polyps 9. Colonic polyp 10. Gastritis atrophic 11. Diverticulum intestinal 12. Gastrooesophageal sphincter insufficiency 13. Hyperuricaemia 14. Iron deficiency 15. Respiratory tract infection 16. Rhinitis allergic 17. Localised infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. SEVERE/YES/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/NO 9. MILD/NO/NO/NO 10. MILD/NO/NO/NO 11. MILD/NO/NO/NO 12. MILD/NO/NO/NO 13. MILD/NO/NO/NO 14. MILD/NO/NO/NO 15. MILD/NO/NO/NO 16. MILD/NO/NO/NO 17. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 06OCT2009 (23) - 09OCT2009 (26) 2. 10NOV2009 (58) - 16FEB2010 (156) 3. 04DEC2009 (82) - 11DEC2009 (89) 4. 11JAN2010 (120) - 12FEB2010 (152)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240073010

Parameter	Value
	5. 11JAN2010 (120) - 12FEB2010 (152)
	6. 02FEB2010 (142) - 10MAR2010 (178)
	7. 14FEB2010 (154) - 21FEB2010 (161)
	8. 17FEB2010 (157) - 17FEB2010 (157)
	9. 17FEB2010 (157) - 20FEB2010 (160)
	10. 17FEB2010 (157) - --------- (.)
	11. 17FEB2010 (157) - --------- (.)
	12. 17FEB2010 (157) - --------- (.)
	13. 18FEB2010 (158) - --------- (.)
	14. 18FEB2010 (158) - 21FEB2010 (161)
	15. 22FEB2010 (162) - 02MAR2010 (170)
	16. 23MAR2010 (191) - --------- (.)
	17. 24MAR2010 (192) - --------- (.)
Duration of AE	1. 4
	2. 99
	3. 8
	4. 33
	5. 33
	6. 37
	7. 8
	8. 1
	9. 4
	10. .
	11. .
	12. .
	13. .
	14. 4
	15. 9
	16. .
	17. .
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240073010

Parameter	Value
	15. 20 mg
	16. 20 mg
	17. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. F
	8. F
	9. F
	10. F
	11. F
	12. F
	13. F
	14. F
	15. F
	16. F
	17. F
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. OTHER
	9. OTHER
	10. NONE
	11. NONE
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240073010

Parameter	Value
	8. RESOLVED
	9. RESOLVED
	10. INSUFFICIENT FOLLOW-UP
	11. INSUFFICIENT FOLLOW-UP
	12. INSUFFICIENT FOLLOW-UP
	13. UNCHANGED
	14. RESOLVED
	15. RESOLVED
	16. UNCHANGED
	17. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240073026

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240073026/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/77/WHITE/SPAIN/YES
Medical history	Benign prostatic hyperplasia, Spinal osteoarthritis, Chronic obstructive pulmonary disease, Constipation, Renal cyst, Depression, Diverticulum intestinal, Hepatic steatosis, Inguinal hernia, Obesity, Obstructive uropathy, Calculus urinary, Urosepsis, Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ANAGASTRA, BLASTOESTIMULINA, CASENBIOTIC, CEFTRIAXONA, CLAFORAN, CLEXANE, DILUTOL, DUPHALAC [LACTULOSE], ENANTYUM, ENEMA CASEN, ENOXAPARIN, FLAGYL, FORTASEC, ISODIUR, KURGAN, LEXATIN, LOITIN, LORAZEPAM, MERONEM, MYCOSTATIN, NOCTAMID, PANTECTA, PERFALGAN, PLANTABEN, REXER FLASH, RIFAXIMINA, SEGURIL, SERETIDE, SINTROM, SPIRIVA, TERMALGIN
Adverse Events (AE) Preferred term	1. Oral fungal infection 2. Constipation 3. Diarrhoea 4. Diarrhoea 5. Constipation 6. Diarrhoea 7. Constipation 8. Haemorrhoids 9. Constipation 10. Bacteraemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 27AUG2010 (2) - 05SEP2010 (11) 2. 28AUG2010 (3) - 30AUG2010 (5) 3. 31AUG2010 (6) - 03SEP2010 (9) 4. 05SEP2010 (11) - 12SEP2010 (18) 5. 14SEP2010 (20) - 15SEP2010 (21) 6. 15SEP2010 (21) - 18SEP2010 (24) 7. 18SEP2010 (24) - 27SEP2010 (33) 8. 23SEP2010 (29) - 28SEP2010 (34) 9. 28SEP2010 (34) - 30SEP2010 (36) 10. 26NOV2010 (93) - 29NOV2010 (96)
Duration of AE	1. 10 2. 3 3. 4

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240073026

Parameter	Value
	4. 8
	5. 2
	6. 4
	7. 10
	8. 6
	9. 3
	10. 4
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240073026

Parameter	Value
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240073028

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240073028/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/72/WHITE/SPAIN/YES
Medical history	Goitre, Hypertension, Hypothyroidism, Insomnia, Procedural nausea, Obesity, Hyperparathyroidism primary, Postmenopause, Thyroidectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AMOXICILINE/CLAVULANATE, ANAGASTRA, ATARAX, DAFLON [DIOSMIN + HESPERIDIN], ENOXAPARIN, EUTIROX, LEVOTHROID, NOCTAMID, NOLOTIL, PERFALGAN, TERMALGIN, URBASON, YATROX
Adverse Events (AE) Preferred term	1. Incision site haemorrhage 2. Urticaria 3. Respiratory tract infection 4. Poor peripheral circulation
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 27SEP2010 (3) - 28SEP2010 (4) 2. 29SEP2010 (5) - 12OCT2010 (18) 3. 29SEP2010 (5) - 29SEP2010 (5) 4. 20APR2011 (208) - --------- (.)
Duration of AE	1. 2 2. 14 3. 1 4. .
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240073028

Parameter	Value
	4. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-240073028[4)]	TIROIDECTOMY WOUND BLEEDING（PT：切開部位出血） 治験担当医は、合併症（甲状腺除去）によるものであり、否定できると判断した。弊社は、エノキサパリン及びアセノクマロールの抗凝固作用により出血リスクが高まったこと及び投報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240073029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240073029/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/65/WHITE/SPAIN/YES
Medical history	Asthenia, Diaphragmatic hernia, Gingival bleeding, Hypercholesterolaemia, Hypertension, Hypothyroidism, Obesity, Pneumonia, Intervertebral disc protrusion, Post-traumatic pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, CO-DIOVAN, DINISOR RETARD, EUTIROX, LEVOTHROID, MEPIVACAINA, PERFALGAN, TRIGON
Adverse Events (AE) Preferred term	1. Asthenia 2. Asthenia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 11FEB2011 (134) - 23FEB2011 (146) 2. 24FEB2011 (147) - 31MAR2011 (182)
Duration of AE	1. 13 2. 36
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. F
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER 2. NONE
Outcome of event	1. IMPROVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240073038

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240073038/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/65/WHITE/SPAIN/YES
Medical history	Breast cancer in situ, Exostosis, Menopause, Cystocele, Depression, Diverticulum, Insomnia, Laparotomy, Tendonitis, Varicose vein, Vertigo, Abdominal abscess, Intervertebral disc disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANAGASTRA, CIPRALEX, ENANTIUM, ESCITALOPRAM, MOTILIUM, MUCOFLUID [MESNA], NOCTAMID, NOLOTIL, OMEPRAZOL, OXALIPLATINO, PANTECTA, PERFALGAN, SULFATO DE CALCIO, SULFATO DE MAGNESIO, TERMALGIN, TRANKIMAZIN, XELODA, YATROX
Adverse Events (AE) Preferred term	1. Abdominal pain 2. Abdominal pain upper 3. Productive cough 4. Colorectal cancer 5. Nausea 6. Confusional state 7. Infusion site extravasation 8. Nipple exudate bloody
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 27DEC2010 (5) - 06JAN2011 (15) 2. 01JAN2011 (10) - 11FEB2011 (51) 3. 27JAN2011 (36) - 04FEB2011 (44) 4. 28JAN2011 (37) - --------- (.) 5. 28JAN2011 (37) - 30JAN2011 (39) 6. 19FEB2011 (59) - 19FEB2011 (59) 7. 08APR2011 (107) - --APR2011 (.) 8. 14AUG2011 (235) - 15AUG2011 (236)
Duration of AE	1. 11 2. 42 3. 9 4. . 5. 3 6. 1 7. . 8. 2
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240073038

Parameter	Value
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. I
	5. I
	6. .
	7. .
	8. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240073041

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240073041/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/SPAIN/YES
Medical history	Dementia Alzheimer's type, Anaemia, Contusion, Cardiac failure, Cystocele, Depression, Glaucoma, Hysterectomy, Varicose vein, Osteoarthritis, Spondylitis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DEPAKINE, DINISOR, DUPHALAC [GALACTOSE + LACTULOSE + LACTOSE], LORAZEPAM, MICRALAX, MORFINE, PERFALGAN, REXER FLASH, SEGURIL, SODIUM HEPARINE, TRANGOREX, URBASON, UROTROL NEO, VANDRAL RETARD
Adverse Events (AE) Preferred term	1. Constipation 2. Insomnia 3. Supraventricular tachycardia 4. Pulmonary embolism
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 25JAN2011 (2) - 28JAN2011 (5) 2. 25JAN2011 (2) - 25JAN2011 (2) 3. 28JAN2011 (5) - 29JAN2011 (6) 4. 28JAN2011 (5) - 29JAN2011 (6)
Duration of AE	1. 4 2. 1 3. 2 4. 2
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240073041

Parameter	Value
	4. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240103001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240103001/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/31/WHITE/SPAIN/YES
Medical history	Depression, Tobacco user
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENANTYUM, FLUMIL [ACETYLCYSTEINE], NOLOTIL, OMEPRAZOL, PARACETAMOL, PAROXETINA, TAVANIC
Adverse Events (AE) Preferred term	1. Pneumonia 2. Cough 3. Headache
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 16APR2010 (74) - 05MAY2010 (93) 2. 06MAY2010 (94) - 24JUN2010 (143) 3. 05AUG2010 (185) - --------- (.)
Duration of AE	1. 20 2. 50 3. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. F
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240103003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240103003/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/62/WHITE/SPAIN/YES
Medical history	Depression, Hypercholesterolaemia, Idiopathic thrombocytopenic purpura, Menopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPRAZOLAM, DACORTIN, OMEPRAZOL, PAROXETINA, SINTROM
Adverse Events (AE) Preferred term	1. Epistaxis 2. Gingival bleeding 3. Antiphospholipid syndrome
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 01MAR2010 (6) - --MAR2010 (.) 2. 01MAR2010 (6) - --APR2010 (.) 3. 16JUL2010 (143) - --------- (.)
Duration of AE	1. . 2. . 3. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. NONE 2. NONE 3. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240113002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240113002/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/61/WHITE/SPAIN/YES
Medical history	Dermal cyst, Rash, Venous thrombosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AERORED, AMPICILINA, ATACAND [CANDERSARTAN CILEXETIL], CAPTOPRIL, CLEXANE, CLOXACILINA, FOLIC ACID, GENTAMICINA, IBUPROFENO, IMIPENEM, LORATADINA, MENODERM, OMEPRAZOL, OPTOVITE B12, ORFIDAL, PANTOPRAZOL, PANTROPAZOL, PENICILINA G SÓDICA, PRUINA, ROMILAR [DEXTROMETHORPHAN HYDROBROMIDE], SEGURIL
Adverse Events (AE) Preferred term	1. Arthralgia 2. Throat irritation 3. Conjunctival hyperaemia 4. Anaemia folate deficiency 5. Melaena 6. Mitral valve incompetence 7. Hiatus hernia 8. Endocarditis bacterial 9. Flatulence 10. Cough 11. Pneumonia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. SEVERE/NO/YES/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES
Start/stop date of event with relative date	1. -----2010 (.) - 13APR2011 (307) 2. 16JUL2010 (36) - -----2010 (.) 3. 15OCT2010 (127) - 19OCT2010 (131) 4. 06FEB2011 (241) - 28JUN2011 (383) 5. 11FEB2011 (246) - 11FEB2011 (246) 6. 15FEB2011 (250) - --------- (.) 7. 15FEB2011 (250) - --------- (.) 8. 30MAR2011 (293) - 25MAY2011 (349) 9. 18APR2011 (312) - 25MAY2011 (349) 10. 09MAY2011 (333) - 25MAY2011 (349) 11. 12MAY2011 (336) - 20MAY2011 (344)
Duration of AE	1. . 2. . 3. 5

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240113002

Parameter	Value
	4. 143
	5. 1
	6. .
	7. .
	8. 57
	9. 38
	10. 17
	11. 9
Dose on AE onset	1.
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. I
	6. I
	7. I
	8. .
	9. .
	10. I
	11. I
Action taken	1. NONE
	2. NONE
	3. NONE
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. NONE
	6. NONE
	7. NONE
	8. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240113002

Parameter	Value
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-240113002[1)]	ANAEMIA MACROCYTIC FOLIC ACID（PT：葉酸欠乏性貧血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、リバーロキサバン投与前の発現のため、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240113003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/240113003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/74/WHITE/SPAIN/YES
Medical history	Cataract, Hypertension, Pulmonary embolism, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ACFOL, ADIRO, APROVEL, AUGMENTINE, CLEXANE, CLINDAMICINA, DUPHALAC [LACTULOSE], ENOXAPARIN, GENTAMICINA, IBUPROFENO, NOLOTIL, NORVAS, OMEPRAZOL, ORFIDAL, PARACETAMOL, TOBRADEX
Adverse Events (AE) Preferred term	1. Insomnia 2. Skin infection 3. Subcutaneous haematoma 4. Anaemia folate deficiency
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 25JUN2010 (4) - 30JUN2010 (9) 2. 16JAN2011 (209) - 23FEB2011 (247) 3. 21JAN2011 (214) - 23FEB2011 (247) 4. 21JAN2011 (214) - --------- (.)
Duration of AE	1. 6 2. 39 3. 34 4. .
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 3. OTHER 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 240113003

Parameter	Value
	4. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-240113003[4)]	HAEMATOMA CUTANEOUS LEFT HAND（PT：皮下血腫） 治験担当医は、因果関係を否定できると判断した。弊社は、投与中に起こった偶発的な犬咬傷による感染とも考えられるが、アセノクマロールの抗凝固作用を考慮し、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260053012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/260053012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/56/WHITE/CANADA/YES
Medical history	Alcohol abuse, Arthritis, Cardiomyopathy, Cardiac failure chronic, Chronic obstructive pulmonary disease, Coronary artery disease, Hypertension, Hysterectomy, Insomnia, Mitral valve incompetence, Myocardial infarction, Pneumothorax, Nicotine dependence, Gastrooesophageal reflux disease, Coronary artery bypass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMITRIPTYLINE, ASA, ATIVAN, CANDESARTAN, CODEINE, COREG, DIOVOL [ALUMINUM AND MAGNESIUM HYDROXIDE], DOCUSATE SODIUM, ENOXAPARIN, EZETROL, FRAGMIN, K-DUR, LASIX, MORPHINE, NITROGLYCERIN, NORMAL SALINE, PARIET, PREVACID, RATIO-CODEINE, RATIO-OXYCOCET, SPIRIVA, TORADOL, TRANS DERM NITRO, TYLENOL #3, TYLENOL#3, VENTOLIN, VITAMIN B1, VITAMIN K, WARFARIN, ZOPICLONE
Adverse Events (AE) Preferred term	1. Ischaemic stroke 2. Hypoalbuminaemia 3. Upper respiratory tract infection 4. Non-cardiac chest pain 5. Hypokalaemia 6. Contusion 7. Humerus fracture 8. Wrist fracture 9. Fall 10. Facial bones fracture 11. Urinary tract infection 12. Hyponatraemia 13. Agitation 14. Drug withdrawal syndrome 15. Acute respiratory failure 16. Hypotension 17. Cardiac failure congestive 18. Alcohol withdrawal syndrome 19. Hypomagnesaemia 20. Hypokalaemia 21. Pneumonia 22. Dysphagia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. SEVERE/NO/YES/YES 8. MILD/NO/NO/YES 9. SEVERE/NO/YES/YES 10. MODERATE/NO/NO/YES 11. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260053012

Parameter	Value
	12. SEVERE/NO/YES/YES
	13. MODERATE/NO/NO/YES
	14. MODERATE/NO/NO/YES
	15. SEVERE/NO/YES/NO
	16. SEVERE/NO/NO/NO
	17. MODERATE/NO/YES/NO
	18. MODERATE/NO/NO/NO
	19. SEVERE/NO/NO/NO
	20. SEVERE/NO/NO/NO
	21. MODERATE/NO/NO/NO
	22. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. -----2008 (.) - --------- (.)
	2. 28JAN2008 (18) - --------- (.)
	3. 31JAN2008 (21) - 28FEB2008 (49)
	4. 08FEB2008 (29) - 10FEB2008 (31)
	5. 08FEB2008 (29) - 08FEB2008 (29)
	6. 01MAR2008 (51) - --------- (.)
	7. 01MAR2008 (51) - --------- (.)
	8. 01MAR2008 (51) - --------- (.)
	9. 01MAR2008 (51) - 01MAR2008 (51)
	10. 01MAR2008 (51) - 04MAR2008 (54)
	11. 11MAR2008 (61) - --------- (.)
	12. 09APR2008 (90) - 08MAY2008 (119)
	13. 09APR2008 (90) - 10APR2008 (91)
	14. 09APR2008 (90) - 10APR2008 (91)
	15. 19APR2008 (100) - 03MAY2008 (114)
	16. 19APR2008 (100) - 19APR2008 (100)
	17. 19APR2008 (100) - 18MAY2008 (129)
	18. 20APR2008 (101) - 10MAY2008 (121)
	19. 20APR2008 (101) - --------- (.)
	20. 24APR2008 (105) - 12MAY2008 (123)
	21. 02MAY2008 (113) - --------- (.)
	22. 02MAY2008 (113) - --------- (.)
Duration of AE	1. .
	2. .
	3. 29
	4. 3
	5. 1
	6. .
	7. .
	8. .
	9. 1
	10. 4
	11. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260053012

Parameter	Value
	12. 30
	13. 2
	14. 2
	15. 15
	16. 1
	17. 30
	18. 21
	19. .
	20. 19
	21. .
	22. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260053012

Parameter	Value
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
	16. NONE
	17. REMEDIAL DRUG THERAPY
	18. REMEDIAL DRUG THERAPY
	19. REMEDIAL DRUG THERAPY
	20. REMEDIAL DRUG THERAPY
	21. NONE
	22. OTHER
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. IMPROVED
	7. UNCHANGED
	8. UNCHANGED
	9. RESOLVED
	10. RESOLVED
	11. INSUFFICIENT FOLLOW-UP

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260053012

Parameter	Value
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. UNCHANGED
	20. RESOLVED
	21. UNCHANGED
	22. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260053020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/260053020/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/68/WHITE/CANADA/YES
Medical history	Ataxia, Cerebrovascular accident, Dyspepsia, Epididymal cyst removal, Hypertension, Cataract operation, Cataract operation, Arnold-Chiari malformation, Hydrocele operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANCEF, ASA, CALCIUM, DIMENHYDRINATE, DIOVAN [HYDROCHLOROTHIAZIDE + VALSARTAN], ENOXAPARIN, FRAGMIN, IBUPROFEN, LIPITOR, MONOCOR, POTASSIUM CHLORIDE, TYLENOL #3, VITAMIN D, WARFARIN
Adverse Events (AE) Preferred term	1. Cholelithiasis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 22APR2008 (69) - 05JUN2008 (113)
Duration of AE	1. 45
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260053092

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/260053092/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/43/WHITE/CANADA/YES
Medical history	Fibula fracture, Hypertension, Hyperthyroidism, Thyroidectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DEXTROSE 5% WATER, ENOXAPARIN, FRAGMIN, HEPARIN, HEPARIN DRIP, PERCOCET, TYLENOL #3, WARFARIN
Adverse Events (AE) Preferred term	1. Dizziness 2. Haematoma 3. Chest pain 4. Cough 5. Headache 6. Haemoptysis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 03SEP2009 (1) - --------- (.) 2. 05SEP2009 (3) - 08SEP2009 (6) 3. 29SEP2009 (27) - 30SEP2009 (28) 4. 19OCT2009 (47) - 03NOV2009 (62) 5. 26OCT2009 (54) - --------- (.) 6. 30OCT2009 (58) - 02NOV2009 (61)
Duration of AE	1. . 2. 4 3. 2 4. 16 5. . 6. 4
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260053092

Parameter	Value
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. IMPROVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260053098

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/260053098/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/CANADA/YES
Medical history	Ex-tobacco user, Hypertension, Insomnia, Cataract operation, Migraine, Cataract operation, Salivary gland resection, Tonsillectomy, Transient ischaemic attack, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASA, ATIVAN, ATORVASTATIN, CALCIUM, CELEBREX, COLACE, ENOXAPARIN, GLUCOSAMINE, HYDROCHLOROTHIAZIDE, METOPROLOL, NITROGLYCERIN, NORVASC, OMEGA 3-6-9, OMEPRAZOLE, PHILLIPS MAGNESIUM HYDROXIDE, PLAVIX, SENOKOT, TYLENOL #2, TYLENOL [PARACETAMOL], VENTOLIN PUFFER, VITALUX, VITAMIN B, VITAMIN D, VITAMIN E
Adverse Events (AE) Preferred term	1. Musculoskeletal chest pain 2. Tachycardia 3. Hyperlipidaemia 4. Haemorrhoidal haemorrhage 5. Vaginal haemorrhage 6. Epistaxis 7. Age-related macular degeneration
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 03JAN2010 (53) - 20FEB2010 (101) 2. 05JAN2010 (55) - 06JAN2010 (56) 3. 05JAN2010 (55) - --------- (.) 4. 14FEB2010 (95) - 15FEB2010 (96) 5. 01APR2010 (141) - 01APR2010 (141) 6. 06APR2010 (146) - 06APR2010 (146) 7. 19JUL2010 (250) - --------- (.)
Duration of AE	1. 49 2. 2 3. . 4. 2 5. 1 6. 1 7. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260053098

Parameter	Value
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. . 7. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. NONE 5. NONE 6. NONE 7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. UNCHANGED 4. RESOLVED 5. RESOLVED 6. RESOLVED 7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260053119

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/260053119/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/57/WHITE/CANADA/YES
Medical history	Mammoplasty, Diabetes mellitus, Hyperlipidaemia, Insomnia, Irritable bowel syndrome, Obesity, Osteoarthritis, Umbilical hernia repair, Fibromyalgia, Postmenopause, Cough
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASA, ATROVENT, AZITHROMYCIN, CODEINE, CRESTOR, GRAVOL, IMODIUM, IMOVANE, LANSOPRAZOLE, LEVOFLOXACIN, METFORMIN, NOVORAPID INSULIN, TORADOL, TYLENOL [PARACETAMOL], VENTOLIN
Adverse Events (AE) Preferred term	1. Pneumonia 2. Thyroid neoplasm 3. Dyspnoea 4. Cyanosis 5. Diabetes mellitus 6. Hyponatraemia 7. Cough 8. Tendonitis 9. Reflux laryngitis 10. Viral upper respiratory tract infection 11. Pain in extremity
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/NO 11. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 22AUG2010 (6) - 30SEP2010 (45) 2. 22AUG2010 (6) - --------- (.) 3. 22AUG2010 (6) - 30SEP2010 (45) 4. 22AUG2010 (6) - 30SEP2010 (45) 5. 22AUG2010 (6) - 26AUG2010 (10) 6. 24AUG2010 (8) - 26AUG2010 (10) 7. 10NOV2010 (86) - --------- (.) 8. 08JAN2011 (145) - --------- (.) 9. 10FEB2011 (178) - --------- (.) 10. 09MAR2011 (205) - --------- (.) 11. 14MAR2011 (210) - --------- (.)
Duration of AE	1. 40 2. . 3. 40

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260053119

Parameter	Value
	4. 40
	5. 5
	6. 3
	7. .
	8. .
	9. .
	10. .
	11. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. F
	11. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260053119

Parameter	Value
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. UNCHANGED
	9. UNCHANGED
	10. IMPROVED
	11. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260053127

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/260053127/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/CANADA/YES
Medical history	Appendicectomy, Coronary artery disease, Haemorrhoid operation, Haemorrhoids, Hypercholesterolaemia, Hypertension, Myocardial infarction, Osteoporosis, Coronary artery bypass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALENDRONATE, ASPIRIN, CRESTOR, ENOXAPARIN, METOPROLOL, RAMIPRIL, WARFARIN
Adverse Events (AE) Preferred term	1. Death
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 10JAN2011 (21) - 10JAN2011 (21)
Duration of AE	1. 1
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. NONE
Outcome of event	1. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-260053127[2)]	DEATH（PT：死亡） 治験担当医はエノキサパリン及びワルファリンと報告事象との関連性があると判断した。弊社は、合併症（高血圧、冠動脈疾患、高コレステロール血症）及び既往の心筋梗塞を有していることから、エノキサパリン及びワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

被験者番号：11702-260053127

死亡に至るまでの経過

被験者は 80 歳、白人女性。2010 年 12 月 20 日に肺塞栓症と診断され、翌日エノキサパリン（120mg）／用量調節ワルファリンの投与を開始した。

2010 年 12 月 24 日、被験者は肺塞栓症を再発した。CIAC において評価項目の肺塞栓症であると判定された。

2011 年 1 月 10 日、被験者は死亡した〔死亡（特定不能の死亡）〕。本事象は重篤とされた。治験責任（分担）医師は、本事象の重症度は高度で、治験薬との因果関係は「あり」と判断した。被験者は、高血圧、高コレステロール血症、冠動脈疾患、心筋梗塞、3 度のバイパス形成手術及び骨粗鬆症の病歴を有していた。死亡の前週、被験者は肺塞栓症の疑いにより検査を受けた。確定診断には至らなかったが、症状はわずかに改善した。週末にかけて息切れが悪化したため、被験者は救急搬送された。搬送中及び救急処置室で蘇生を試みたがバイタルサインは確認されず、到着時には死亡していた。この死亡が心筋梗塞もしくは致死的肺塞栓症に起因するものであれば、ワルファリンによる治療の失敗が示唆された。治験責任（分担）医師は心筋梗塞／冠動脈疾患が併発していた可能性についても言及した。本事象により治験薬は変更されなかった。本事象に対する治療は行われなかった。2011 年 1 月 10 日、本事象により被験者は死亡に至った。剖検は実施されなかった。

CIAC は、死亡原因は不明であり肺塞栓症の可能性は否定できないとした。

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
Alkaline Phosphatase	Central: 36-118 U/L	21 Dec 2010	**302 U/L (H)**	07 Jan 2011	**312 U/L (H)**		
Amylase	Central: 28-100 U/L	21 Dec 2010	46 U/L				
Bilirubin, Direct	Central: 0.10-0.32 mg/dL	21 Dec 2010	**<0.10 mg/dL (L)**	07 Jan 2011	**<0.10 mg/dL (L)**		
Bilirubin, Total	Central: 0.22-1.28 mg/dL	21 Dec 2010	0.41 mg/dL	07 Jan 2011	0.26 mg/dL		
SGOT/AST	Central: 11-37 U/L	21 Dec 2010	**62 U/L (H)**	07 Jan 2011	**71 U/L (H)**		
SGPT/ALT	Central: 8-43 U/L [a] Local: 10-40 U/L	20 Dec 2010	**55 U/L (H)** [a]	21 Dec 2010	**55 U/L (H)**	07 Jan 2011	**64 U/L (H)**

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260123067

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/260123067/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/53/WHITE/CANADA/YES
Medical history	Depression, Blood cholesterol increased, Hypertension, Obesity, Sleep apnoea syndrome, Hip arthroplasty, Type 2 diabetes mellitus, Knee operation, Androgen deficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALTACE, ANDROGEL, AVANDAMET, CYMBALTA, DALTEPARIN, DIAMICRON, LIPITOR, MORPHINE, SEROQUEL
Adverse Events (AE) Preferred term	1. Muscle haemorrhage 2. Nephrolithiasis
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 03AUG2009 (19) - 08AUG2009 (24) 2. 22SEP2009 (69) - 23SEP2009 (70)
Duration of AE	1. 6 2. 2
Dose on AE onset	1. 15 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260123075

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/260123075/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/57/WHITE/CANADA/YES
Medical history	Asthma, Depression, Dry eye, Gastrooesophageal reflux disease, Lymphadenopathy, Menopause, Obesity, Osteoarthritis, Restless legs syndrome, Sleep apnoea syndrome, Female sterilisation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETAMINOPHEN, CEFTRIAXONE, DALTEPARIN, DIMENHYDRINATE, EFFEXOR, ENOXAPARIN, FLOVENT, MORPHINE, ONDANSETRON, PANTALOC, PEPCID COMPLETE, SALBUTAMOL, SYSTANE EYE GTTS, WARFARIN, WELLBUTRIN
Adverse Events (AE) Preferred term	1. Gastrooesophageal reflux disease 2. Cholelithiasis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. --NOV2009 (.) - --------- (.) 2. 23JAN2010 (86) - 27JAN2010 (90)
Duration of AE	1. . 2. 5
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260123080

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/260123080/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/62/WHITE/CANADA/YES
Medical history	Gastrooesophageal reflux disease, Rheumatoid arthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTONEL, CEFTRIAXONE, CEFUROXIME AXETIL, CELEBREX, ENOXAPARIN, FOLIC ACID, HYDROXYQUIN, LAMISIL, LEFLUNOMIDE, METHOTREXATE, MORPHINE, PANTALOC, PREDNISONE, WARFARIN
Adverse Events (AE) Preferred term	1. Tinea versicolour 2. Dizziness 3. Palpitations 4. Pneumonia 5. Chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 20APR2010 (27) - 20OCT2010 (210) 2. 04AUG2010 (133) - 04AUG2010 (133) 3. 04AUG2010 (133) - 04AUG2010 (133) 4. 18SEP2010 (178) - 21SEP2010 (181) 5. 20NOV2010 (241) - 21NOV2010 (242)
Duration of AE	1. 184 2. 1 3. 1 4. 4 5. 2
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. NONE 4. REMEDIAL DRUG THERAPY 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 260123080

Parameter	Value
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013003/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/BELGIUM/YES
Medical history	Appendicectomy, Hypercholesterolaemia, Hypertension, Hysterectomy, Obesity, Phlebitis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CAPTOPRIL, CLEXANE, CO BISOPROLOL, PANADOL, ZOCOR, ZYRTEC [CETIRIZINE HYDROCHLORIDE ALONE]
Adverse Events (AE) Preferred term	1. Arthralgia 2. Abdominal discomfort 3. Rash 4. Fatigue 5. Arthralgia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. --APR2008 (.) - 09SEP2008 (288) 2. 28NOV2007 (2) - 29NOV2007 (3) 3. 02DEC2007 (6) - 08DEC2007 (12) 4. 01APR2008 (127) - --------- (.) 5. 10SEP2008 (289) - 19SEP2008 (298)
Duration of AE	1. . 2. 2 3. 7 4. . 5. 10
Dose on AE onset	1. 2. 15 mg 3. 15 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. . 5. I
Action taken	1. NONE 2. NONE 3. REMEDIAL DRUG THERAPY 4. NONE 5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. WORSENED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013003

Parameter	Value
	4. UNCHANGED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013004/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/BELGIUM/YES
Medical history	Ankle fracture, Cerebrovascular accident, Influenza, Hypertension, Knee arthroplasty, Knee arthroplasty, Polyneuropathy, Type 2 diabetes mellitus, Hip arthroplasty
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOR, ASAFLOW, CLAMOXYL [AMOXICILLIN], CONTRAMAL, DAFALGAN, ENOXAPARIN, IMODIUM [LOPERAMIDE], INSULIN ACTRAPID, MOTILIUM, MOVICOL, UNI DIAMICRON, WARFARIN, ZESTRIL
Adverse Events (AE) Preferred term	1. Constipation 2. Abdominal pain 3. Muscle haemorrhage 4. Gastroenteritis viral 5. Rash 6. Influenza
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/YES/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 30NOV2007 (3) - 10DEC2007 (13) 2. 03DEC2007 (6) - 09DEC2007 (12) 3. 04DEC2007 (7) - 12DEC2007 (15) 4. 19JAN2008 (53) - 23JAN2008 (57) 5. 17FEB2008 (82) - 02MAR2008 (96) 6. 16APR2008 (141) - 06MAY2008 (161)
Duration of AE	1. 11 2. 7 3. 9 4. 5 5. 15 6. 21
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013004

Parameter	Value
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY,OTHER
	3. STUDY DRUG DISCONTINUED AND RESTARTED
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/BELGIUM/YES
Medical history	Appendicectomy, Cataract, Haemoptysis, Hypertension, Insomnia, Obesity, Oedema peripheral, Phlebitis, Gastric ulcer, Tendon operation, Tricuspid valve incompetence, Type 2 diabetes mellitus, Varicose vein, Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, AMLOR, CEFAZOLINE, CHIROCAINE, CLAMOXYL [AMOXICILLIN ALONE], CLEXANE, CONTRAMAL, CORUNO, DAFALGAN, DEPO MEDROL, DEPOMEDROL, DIPIDOLOR, ENOXAPARIN, FERROGRADUMET, HYALURON ACID, LINISOL, PERFUSALGAN, STILNOCT, TRADONAL, TRAMADOL RETARD, TRAMIUM, WARFARIN, ZALDIAR, ZANTAC
Adverse Events (AE) Preferred term	1. Sciatica 2. Spinal osteoarthritis 3. Periorbital haematoma 4. Bronchitis 5. Breast necrosis 6. Toothache 7. Osteoarthritis 8. Arthralgia 9. Abdominal pain upper
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/YES/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 06MAR2008 (71) - --------- (.) 2. 06MAR2008 (71) - --------- (.) 3. 11MAR2008 (76) - --JUN2008 (.) 4. 30MAY2008 (156) - 06JUN2008 (163) 5. 04JUN2008 (161) - --------- (.) 6. 06AUG2008 (224) - 14AUG2008 (232) 7. 30OCT2008 (309) - 10NOV2008 (320) 8. 31OCT2008 (310) - --------- (.) 9. 31OCT2008 (310) - 10NOV2008 (320)
Duration of AE	1. . 2. . 3. . 4. 8 5. . 6. 9 7. 12

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013007

Parameter	Value
	8. .
	9. 11
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	7. OTHER
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. IMPROVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013007

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013009/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/66/WHITE/BELGIUM/YES
Medical history	Blood glucose increased, Dizziness, Headache, Hepatic steatosis, Post thrombotic syndrome, Spinal osteoarthritis, Systemic lupus erythematosus, Meniere's disease, Obesity, Osteoporosis postmenopausal, Palpitations, Sjogren's syndrome, Phlebitis, Mental disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTONEL, ASAFLOW, BETAHISTINE, CACIT D3 1000/880, CIPROXINE, DAFALGAN, DIPROSONE, IMODIUM [LOPERAMIDE HYDROCHLORIDE], INDERAL RETARD, MARCOUMAR, MEDROL, MELOXICAM, MOTILIUM, RANITIDINE, SOLUCORTEF, SOTALEX, STAPHYCID
Adverse Events (AE) Preferred term	1. Dyspepsia 2. Wound 3. Hypoaesthesia 4. Diarrhoea 5. Headache 6. Back pain 7. Sinus bradycardia 8. Dizziness 9. Nausea 10. Deafness 11. Dizziness 12. Rash 13. Blood iron increased 14. Ovarian cyst
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/YES/YES 6. MODERATE/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/YES/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/YES/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --MAR2008 (.) - --------- (.) 2. --JUL2008 (.) - 15OCT2008 (266) 3. --DEC2008 (.) - --------- (.) 4. 29JAN2008 (6) - 29JAN2008 (6) 5. 01FEB2008 (9) - 02FEB2008 (10) 6. 01FEB2008 (9) - 10MAR2008 (47) 7. 01FEB2008 (9) - 07FEB2008 (15)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013009

Parameter	Value
	8. 03FEB2008 (11) - 09FEB2008 (17)
	9. 03FEB2008 (11) - 10MAR2008 (47)
	10. 03FEB2008 (11) - 03FEB2008 (11)
	11. 10FEB2008 (18) - 19MAY2008 (117)
	12. 01APR2008 (69) - 20MAY2008 (118)
	13. 08APR2008 (76) - --------- (.)
	14. 22MAY2008 (120) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. 1
	5. 2
	6. 39
	7. 7
	8. 7
	9. 37
	10. 1
	11. 100
	12. 50
	13. .
	14. .
Dose on AE onset	1.
	2.
	3.
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 15 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013009

Parameter	Value
	10. .
	11. .
	12. .
	13. .
	14. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. NONE
	14. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. UNCHANGED
	14. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013022

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013022/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/57/WHITE/BELGIUM/YES
Medical history	Anxiety, Aortic valve incompetence, Asthma, Neck pain, Depression, Diabetes mellitus, Hepatic steatosis, Hypercholesterolaemia, Hypertension, Hysterectomy, Back pain, Melaena, Mitral valve incompetence, Obesity, Oesophagitis, Tricuspid valve incompetence, Urinary tract infection, Varicose vein, Pancreas lipomatosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMISULPRIDE, ASAFLOW, ATENOLOL, AUGMENTIN, CYMBALTA, DAFALGAN, DUOVENT, ENOXAPARIN, ENOXAPARINE, GLUCOPHAGE, IMMODIUM, ISOPTINE, LAMBIPOL, LASIX, LYSOMUCIL, OMEPRAZOLE, Q-VAR, SERETIDE 50/500, SIMVASTATINE, TRITACE, TUSSIPECT, WARFARIN, WARFARINE, XANAX
Adverse Events (AE) Preferred term	1. Diarrhoea 2. International normalised ratio increased 3. Dyspnoea 4. Diarrhoea 5. Renal failure acute 6. Hyperhidrosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 07FEB2009 (2) - 07FEB2009 (2) 2. 09FEB2009 (4) - 13FEB2009 (8) 3. 16FEB2009 (11) - 20FEB2009 (15) 4. 16FEB2009 (11) - 16FEB2009 (11) 5. 16FEB2009 (11) - 16FEB2009 (11) 6. 10JAN2010 (339) - --------- (.)
Duration of AE	1. 1 2. 5 3. 5 4. 1 5. 1 6. .
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013022

Parameter	Value
	5.
	6.
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED
	3. NONE
	4. OTHER
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013023/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/76/WHITE/BELGIUM/YES
Medical history	Asthma, Supraventricular tachycardia, Cataract, Confusional state, Fall, Mitral valve incompetence, Osteoporosis, Palpitations, Pulmonary hypertension, Tricuspid valve incompetence, Aortic valve incompetence, Pulmonary valve incompetence, Abdominal discomfort
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTONEL, ADRENALINE, ALDACTONE [SPIRONOLACTONE], ATROVENT, ENOXAPARIN, FRAXODI, LASIX, LIDOCAINE, LODIXAL, LOMUDAL, MEDROL, SERETIDE 50/500, SPIRIVA, TOPCAL D3, WARFARIN, XANTHIUM, ZANTAC
Adverse Events (AE) Preferred term	1. Squamous cell carcinoma of skin 2. Actinic keratosis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 21APR2009 (72) - 15MAY2009 (96) 2. 21APR2009 (72) - --------- (.)
Duration of AE	1. 25 2. .
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 2. NONE
Outcome of event	1. RESOLVED 2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013026

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013026/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/69/WHITE/BELGIUM/YES
Medical history	Abdominal pain, Angina pectoris, Atrial fibrillation, Bronchitis, Bronchitis, Gout, Hepatic function abnormal, Hepatic steatosis, Insomnia, Myocardial ischaemia, Mitral valve incompetence, Myocardial infarction, Oesophagitis, Transurethral prostatectomy, Pulmonary infarction, Tricuspid valve incompetence, Cholelithiasis, Renal failure chronic, Polyp, Coronary artery bypass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASAFLOW, ASPEGIC, AUGMENTIN, BURINEX, CEDOCARD, CLEXANE, COLCHICINE, CORDARONE, CORUNO, CORVATON, COVERSYL, DAFALGAN, DIAZEPAM, EMCONCOR, ENOXAPARIN, ENOXAPARINE, FLEET, FORLAX, LITICAN, LYSOMUCIL, MIDAZOLAM, MORFINE, MOTILIUM, NEPRESOL, NOBITEN, OMEPRAZOLE, PANTOMED, PERFUSALGAN, PETHIDINE, PLAVIX, ROCEPHINE, SPIRONOLACTONE, WARFARIN, XANAX, ZANTAC, ZOCOR, ZYLORIC
Adverse Events (AE) Preferred term	1. Bronchitis 2. Nasopharyngitis 3. Oedema peripheral 4. Pain in extremity 5. Presyncope 6. Decreased appetite 7. Dyspnoea 8. Rectal haemorrhage 9. Rectal haemorrhage 10. Haemorrhoids 11. Troponin increased 12. Rectal haemorrhage 13. Rectal haemorrhage 14. Abdominal pain 15. Abdominal pain 16. Angina pectoris 17. Ventricular tachycardia 18. Nephrolithiasis 19. Diarrhoea 20. Acute myocardial infarction 21. Angina pectoris 22. Vomiting 23. Constipation 24. Gastrooesophageal reflux disease 25. Gastrooesophageal reflux disease 26. Angina pectoris 27. Gastrooesophageal reflux disease
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013026

Parameter	Value
	6. MILD/NO/NO/YES
	7. MILD/NO/NO/YES
	8. MILD/YES/NO/YES
	9. MILD/YES/YES/YES
	10. MILD/NO/NO/YES
	11. MILD/NO/NO/YES
	12. MILD/YES/YES/YES
	13. MILD/YES/NO/YES
	14. MODERATE/NO/NO/YES
	15. MODERATE/NO/YES/YES
	16. MODERATE/NO/YES/YES
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MILD/NO/NO/YES
	20. MODERATE/NO/YES/YES
	21. MODERATE/NO/YES/YES
	22. MILD/NO/NO/YES
	23. MILD/NO/NO/YES
	24. MILD/NO/NO/YES
	25. MODERATE/NO/YES/YES
	26. MODERATE/NO/NO/YES
	27. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --APR2009 (.) - 19APR2009 (45)
	2. --MAR2009 (.) - --------- (.)
	3. --MAR2009 (.) - --------- (.)
	4. --SEP2009 (.) - 28SEP2009 (207)
	5. --MAY2009 (.) - --------- (.)
	6. 16MAR2009 (11) - --------- (.)
	7. 23MAR2009 (18) - 09APR2009 (35)
	8. 29MAR2009 (24) - 29MAR2009 (24)
	9. 30MAR2009 (25) - 02APR2009 (28)
	10. 30MAR2009 (25) - 17APR2009 (43)
	11. 30MAR2009 (25) - --------- (.)
	12. 09APR2009 (35) - 24APR2009 (50)
	13. 25APR2009 (51) - 20MAY2009 (76)
	14. 26AUG2009 (174) - 27AUG2009 (175)
	15. 28AUG2009 (176) - 04SEP2009 (183)
	16. 28AUG2009 (176) - 04SEP2009 (183)
	17. 28AUG2009 (176) - --------- (.)
	18. 30AUG2009 (178) - --------- (.)
	19. 31AUG2009 (179) - 31AUG2009 (179)
	20. 02SEP2009 (181) - 02SEP2009 (181)
	21. 08SEP2009 (187) - 18SEP2009 (197)
	22. 08SEP2009 (187) - 08SEP2009 (187)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013026

Parameter	Value
	23. 12SEP2009 (191) - 13SEP2009 (192)
	24. 14DEC2009 (284) - 29JAN2010 (330)
	25. 30JAN2010 (331) - 04FEB2010 (336)
	26. 30JAN2010 (331) - --------- (.)
	27. 05FEB2010 (337) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. 18
	8. 1
	9. 4
	10. 19
	11. .
	12. 16
	13. 26
	14. 2
	15. 8
	16. 8
	17. .
	18. .
	19. 1
	20. 1
	21. 11
	22. 1
	23. 2
	24. 47
	25. 6
	26. .
	27. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013026

Parameter	Value
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
	27.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
	27.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013026

Parameter	Value
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. STUDY DRUG DISCONTINUED AND RESTARTED
	10. OTHER
	11. OTHER
	12. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	13. NONE
	14. NONE
	15. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	16. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	17. REMEDIAL DRUG THERAPY
	18. NONE
	19. NONE
	20. OTHER
	21. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	22. REMEDIAL DRUG THERAPY
	23. REMEDIAL DRUG THERAPY
	24. REMEDIAL DRUG THERAPY
	25. REMEDIAL DRUG THERAPY
	26. REMEDIAL DRUG THERAPY
	27. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. UNCHANGED
	7. RESOLVED
	8. WORSENED
	9. RESOLVED
	10. RESOLVED
	11. UNCHANGED
	12. IMPROVED
	13. RESOLVED
	14. WORSENED
	15. RESOLVED
	16. RESOLVED
	17. UNCHANGED
	18. UNCHANGED
	19. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013026

Parameter	Value
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED
	23. RESOLVED
	24. WORSENED
	25. IMPROVED
	26. UNCHANGED
	27. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-280013026[1),1)]	RECTAL BLOOD LOSS（PT：直腸出血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリン投与終了 3～4 週間後の発現であり、時間的関連性がないことから、エノキサパリンとの因果関係は否定できると考える。 RECTAL BLOOD LOSS INTERMITTENT（PT：直腸出血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリン投与終了 3～4 週間後の発現であり、時間的関連性がないことから、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013027

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013027/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/77/WHITE/BELGIUM/YES
Medical history	Aortic valve sclerosis, Atrial fibrillation, Atrial fibrillation, Cataract, Drug hypersensitivity, Hepatic steatosis, Hiatus hernia, Hypertension, Hysterectomy, Insomnia, Iron deficiency anaemia, Mitral valve incompetence, Osteoarthritis, Tricuspid valve incompetence, Venous insufficiency, Osteoarthritis, Osteoarthritis, Osteopenia, Cholelithiasis, Aortic valve incompetence, Pulmonary valve incompetence, Abdominal discomfort, Seronegative arthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTONEL, AMLODIPINE, AVELOX, CACIT D3, CARDIOASPIRIN, CO-BISOPROLOL, DAFALGAN, DAFALGAN FORTE, DAFLON [DIOSMIN + BIOFLAVONOIDS], DEICOL, ENOXAPARIN, ENOXAPARINE, FOLIC ACID, INDOCOLLYRE, LEDERTREXATE, LOCAL ANESTHETICUM NOS, MABTHERA, MEDROL, OMEPRAZOLE, SIMVASTATINE, SOLUMEDROL, WARFARIN, ZOLPIDEM, ZYRTEC
Adverse Events (AE) Preferred term	1. Respiratory tract infection 2. Hypercholesterolaemia 3. Spinal compression fracture 4. Cataract 5. Bronchitis 6. Bronchitis 7. Urinary tract infection 8. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --OCT2009 (.) - -----2009 (.) 2. 13JUL2009 (126) - --------- (.) 3. 28DEC2009 (294) - --------- (.) 4. 12JAN2010 (309) - 12JAN2010 (309) 5. 03FEB2010 (331) - 06FEB2010 (334) 6. 07FEB2010 (335) - 09FEB2010 (337) 7. 07FEB2010 (335) - 13FEB2010 (341) 8. 10FEB2010 (338) - 01APR2010 (388)
Duration of AE	1. . 2. . 3. . 4. 1 5. 4 6. 3 7. 7

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013027

Parameter	Value
	8. 51
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. UNCHANGED
	4. RESOLVED
	5. WORSENED
	6. IMPROVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013038

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013038/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/29/WHITE/BELGIUM/YES
Medical history	Bipolar I disorder, Psychotic disorder, Testis cancer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	LAMBIPOL, LORMETAZEPAM, SEROQUEL, SOLIAN
Adverse Events (AE) Preferred term	1. Traumatic haematoma
	2. Bipolar I disorder
	3. Insomnia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES
	2. MODERATE/NO/YES/YES
	3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 22NOV2009 (13) - --------- (.)
	2. 04JAN2010 (56) - 07MAR2010 (118)
	3. 04JAN2010 (56) - --------- (.)
Duration of AE	1. .
	2. 63
	3. .
Dose on AE onset	1. 15 mg
	2. 20 mg
	3. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
Outcome of event	1. INSUFFICIENT FOLLOW-UP
	2. RESOLVED
	3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013039

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013039/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/74/WHITE/BELGIUM/YES
Medical history	Angina pectoris, Angina pectoris, Angina pectoris, Angina pectoris, Carotid artery stenosis, Cataract, Cataract, Chronic obstructive pulmonary disease, Hepatic steatosis, Hiatus hernia, Hypercholesterolaemia, Hypertension, Hyperventilation, Insomnia, Multiple allergies, Nystagmus, Transient ischaemic attack, Transient ischaemic attack, Transient ischaemic attack, Spinal osteoarthritis, Gastric neoplasm
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTONE [SPIRONOLACTONE], AMLOR, AUGMENTIN, BURINEX, BUSCOPAN, CETOMACROGOLCREME, COVERSYL, DAFALGAN, DAKTOSIN, DUOVENT, ENTEROL [SACCHAROMYCES BOULARDII], IBUPROFEN, IMMODIUM, LASIX, LOSEC, LYSOMUCIL, MAGNETOP, MEDROL, MOTILIUM, OMEPRAZOLE, PERFUSALGAN, POTASSIUM CHLORIDE, SERETIDE, SOLUCORTEF, SOLUMEDROL, SPIRIVA, TUSSIPECT, XANAX, XYLOCAINE, ZOCOR, ZYRTEC
Adverse Events (AE) Preferred term	1. Intertrigo 2. Erythema 3. Rash 4. Chronic obstructive pulmonary disease 5. Oedema peripheral 6. Oedema peripheral 7. Pain in extremity 8. Right ventricular failure 9. Pulmonary hypertension 10. Post gastric surgery syndrome 11. Hyperglycaemia 12. Dyspnoea 13. Cough 14. Chronic obstructive pulmonary disease 15. Pain in extremity 16. Muscle spasms 17. Muscle spasms 18. Muscle spasms 19. Gastroenteritis 20. Dizziness postural 21. Gastroenteritis 22. Renal failure acute 23. Hypotension 24. Normochromic normocytic anaemia 25. Diverticulum intestinal 26. General physical health deterioration 27. General physical health deterioration 28. Renal failure acute 29. Arthralgia 30. Intertrigo 31. Skin papilloma

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013039

Parameter	Value
	32. Fibroma
	33. Fibroma
	34. Oedema peripheral
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/YES/NO/YES
	4. MODERATE/NO/YES/YES
	5. MILD/NO/NO/YES
	6. MILD/NO/NO/YES
	7. MILD/NO/NO/YES
	8. MILD/NO/NO/YES
	9. MILD/NO/NO/YES
	10. MILD/NO/NO/YES
	11. MILD/NO/NO/YES
	12. MILD/NO/NO/YES
	13. MILD/NO/NO/YES
	14. MODERATE/NO/YES/YES
	15. MILD/NO/NO/YES
	16. MILD/NO/NO/YES
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MILD/NO/NO/YES
	20. MILD/NO/NO/YES
	21. MODERATE/NO/YES/YES
	22. MILD/NO/NO/YES
	23. MILD/NO/NO/YES
	24. MILD/YES/NO/YES
	25. MILD/NO/NO/YES
	26. MILD/NO/NO/YES
	27. MILD/NO/YES/YES
	28. MILD/NO/NO/YES
	29. MILD/NO/NO/YES
	30. MILD/NO/NO/YES
	31. MILD/NO/NO/YES
	32. MILD/NO/NO/YES
	33. MILD/NO/NO/YES
	34. MILD/NO/NO/YES
Start/stop date of event with relative date	1. -----2010 (.) - 28SEP2010 (321)
	2. -----2010 (.) - 28SEP2010 (321)
	3. 30NOV2009 (19) - 05DEC2009 (24)
	4. 06DEC2009 (25) - 18DEC2009 (37)
	5. 06DEC2009 (25) - --FEB2010 (.)
	6. 06DEC2009 (25) - --FEB2010 (.)
	7. 06DEC2009 (25) - 18DEC2009 (37)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013039

Parameter	Value
	8. 10DEC2009 (29) - 27JUL2010 (258)
	9. 10DEC2009 (29) - --------- (.)
	10. 01JAN2010 (51) - 02NOV2010 (356)
	11. 01JAN2010 (51) - 02NOV2010 (356)
	12. 17MAR2010 (126) - 19MAR2010 (128)
	13. 17MAR2010 (126) - 19MAR2010 (128)
	14. 20MAR2010 (129) - 30MAR2010 (139)
	15. 27MAR2010 (136) - 26APR2010 (166)
	16. 27MAR2010 (136) - 20AUG2010 (282)
	17. 27MAR2010 (136) - 20AUG2010 (282)
	18. 27MAR2010 (136) - 20AUG2010 (282)
	19. 05APR2010 (145) - 04MAY2010 (174)
	20. 27APR2010 (167) - --------- (.)
	21. 05MAY2010 (175) - 11MAY2010 (181)
	22. 05MAY2010 (175) - 11MAY2010 (181)
	23. 05MAY2010 (175) - 06MAY2010 (176)
	24. 06MAY2010 (176) - --------- (.)
	25. 07MAY2010 (177) - --------- (.)
	26. 11MAY2010 (181) - 10JUL2010 (241)
	27. 11JUL2010 (242) - 15JUL2010 (246)
	28. 11JUL2010 (242) - 15JUL2010 (246)
	29. 13JUL2010 (244) - 14JUL2010 (245)
	30. 13JUL2010 (244) - --------- (.)
	31. 13JUL2010 (244) - 28SEP2010 (321)
	32. 13JUL2010 (244) - 28SEP2010 (321)
	33. 13JUL2010 (244) - 28SEP2010 (321)
	34. 27JUL2010 (258) - --------- (.)
Duration of AE	1. .
	2. .
	3. 6
	4. 13
	5. .
	6. .
	7. 13
	8. 230
	9. .
	10. 306
	11. 306
	12. 3
	13. 3
	14. 11
	15. 31
	16. 147
	17. 147

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013039

Parameter	Value
	18. 147
	19. 30
	20. .
	21. 7
	22. 7
	23. 2
	24. .
	25. .
	26. 61
	27. 5
	28. 5
	29. 2
	30. .
	31. 78
	32. 78
	33. 78
	34. .
Dose on AE onset	1.
	2.
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
	22. 20 mg
	23. 20 mg
	24. 20 mg
	25. 20 mg
	26. 20 mg
	27. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013039

Parameter	Value
	28. 20 mg
	29. 20 mg
	30. 20 mg
	31. 20 mg
	32. 20 mg
	33. 20 mg
	34. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
	18. .
	19. .
	20. .
	21. .
	22. .
	23. .
	24. .
	25. .
	26. .
	27. .
	28. .
	29. .
	30. .
	31. .
	32. .
	33. .
	34. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013039

Parameter	Value
	4. REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. NONE
	12. NONE
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. NONE
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. REMEDIAL DRUG THERAPY
	19. REMEDIAL DRUG THERAPY
	20. OTHER
	21. REMEDIAL DRUG THERAPY
	22. OTHER
	23. OTHER
	24. OTHER
	25. NONE
	26. REMEDIAL DRUG THERAPY
	27. REMEDIAL DRUG THERAPY
	28. OTHER
	29. REMEDIAL DRUG THERAPY
	30. NONE
	31. OTHER
	32. OTHER
	33. OTHER
	34. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. WORSENED
	13. WORSENED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013039

Parameter	Value
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. WORSENED
	20. UNCHANGED
	21. RESOLVED
	22. RESOLVED
	23. RESOLVED
	24. UNCHANGED
	25. UNCHANGED
	26. WORSENED
	27. RESOLVED
	28. RESOLVED
	29. RESOLVED
	30. UNCHANGED
	31. RESOLVED
	32. RESOLVED
	33. RESOLVED
	34. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013044

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013044/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/49/WHITE/BELGIUM/YES
Medical history	Depression, Dermatitis contact, Drug hypersensitivity, Seasonal allergy, Hiatus hernia, Drug hypersensitivity, Gastrooesophageal reflux disease, Temporomandibular joint syndrome
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CITALOPRAM, ENOXAPARIN, NUVARING, PANTOMED, WARFARIN
Adverse Events (AE) Preferred term	1. Temporomandibular joint syndrome
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/NO
Start/stop date of event with relative date	1. 04JUN2010 (144) - 07JUN2010 (147)
Duration of AE	1. 4
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013045

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013045/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/88/WHITE/BELGIUM/YES
Medical history	Aortic valve incompetence, Cataract, Cholecystitis, Constipation, Depression, Diverticulum, Gastritis, Haemorrhoids, Humerus fracture, Hypertension, Ilium fracture, Leukoencephalopathy, Orthostatic hypotension, Osteoporosis, Radius fracture, Rectal prolapse, Syncope, Ulna fracture, Osteoarthritis, Rib fracture, Avulsion fracture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACLASTA, ACTONEL, AMLODIPINE, BEFACT FORTE, CACIT VIT D3, DEPAKINE, DIPRIVAN, EBRANTYL, ENOXAPARIN, KONAKION, LAXOBERON, LITICAN, MOVICOL, PPSB, SIPRALEXA, TRIANAL [LIDOCA?NE + TRIAMCINOLON], VALIUM, WARFARIN, ZYRTEC
Adverse Events (AE) Preferred term	1. Haemorrhoidal haemorrhage 2. Xanthoma 3. Pruritus generalised 4. Epilepsy 5. Epilepsy 6. Epilepsy 7. General physical health deterioration
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES 7. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 17JAN2010 (3) - --------- (.) 2. 16FEB2010 (33) - --------- (.) 3. 25FEB2010 (42) - 05MAR2010 (50) 4. 07MAR2010 (52) - 08MAR2010 (53) 5. 09MAR2010 (54) - 27MAY2010 (133) 6. 28MAY2010 (134) - --------- (.) 7. 28MAY2010 (134) - 07JUN2010 (144)
Duration of AE	1. . 2. . 3. 9 4. 2 5. 80 6. . 7. 11
Dose on AE onset	1. 2. 3. 4. 5. 6.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013045

Parameter	Value
	7.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. IMPROVED
	5. WORSENED
	6. UNCHANGED
	7. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013051

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013051/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/77/WHITE/BELGIUM/YES
Medical history	Drug hypersensitivity, Drug hypersensitivity, Constipation, Depression, Drug hypersensitivity, Dysphagia, Abdominal pain upper, Gastric ulcer, Hypercholesterolaemia, Insomnia, Lumbar spinal stenosis, Osteoporosis, Palpitations, Drug hypersensitivity, Pulmonary hypertension, Blood thyroid stimulating hormone decreased, Tricuspid valve incompetence, Urinary tract infection, Vitamin B12 deficiency, Dilatation ventricular, Decreased appetite
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTONEL, ASPEGIC, CACIT D3 1000/880, CLEXANE, CONTRAMAL, DAFALGAN, ENOXAPARIN, IMODIUM, INNOHEP, KONAKION, LIPANTHYLNANO, LORAZEPAM, MOTILIUM, MOVICOL, PANTOMED, RAMIPRIL, SERLAIN, SOTALEX, TRADONAL RETARD, TRITACE, WARFARIN, XANAX
Adverse Events (AE) Preferred term	1. Diarrhoea 2. International normalised ratio increased 3. Liver function test abnormal 4. Dyspnoea 5. Cardiac valve disease 6. Dyspnoea 7. Hepatomegaly 8. Pancreas lipomatosis 9. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/NO/YES 3. MILD/YES/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 03APR2010 (4) - 06APR2010 (7) 2. 03APR2010 (4) - 03APR2010 (4) 3. 15APR2010 (16) - 04MAY2010 (35) 4. 29SEP2010 (183) - 28NOV2010 (243) 5. 29OCT2010 (213) - --------- (.) 6. 29NOV2010 (244) - 03DEC2010 (248) 7. 29NOV2010 (244) - --------- (.) 8. 29NOV2010 (244) - --------- (.) 9. 04DEC2010 (249) - --------- (.)
Duration of AE	1. 4 2. 1 3. 20 4. 61 5. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013051

Parameter	Value
	6. 5
	7. .
	8. .
	9. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. NONE
	4. OTHER
	5. NONE
	6. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	7. NONE
	8. NONE
	9. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. WORSENED
	5. UNCHANGED
	6. IMPROVED
	7. UNCHANGED
	8. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013051

Parameter	Value
	9. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013059

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013059/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/76/WHITE/BELGIUM/YES
Medical history	Rhinitis allergic, Constipation, Epilepsy, Hepatic steatosis, Hypercholesterolaemia, Hypertension, Ischaemic cardiomyopathy, Acute myocardial infarction, Coronary artery disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASAFLOW, ASPEGIC, CEDOCARD, CLEXANE, CORUNO RETARD, DIPHANTOINE, EMCONCOR, ENOXAPARIN, FENTANYL, LIPITOR, MOVICOL, SIMVASTATINE, TAVANIC, TERAZOSAB, TERAZOSABB, TRITACE, VETHOINE, WARFARIN, ZYRTEC
Adverse Events (AE) Preferred term	1. Pruritus 2. Chest pain 3. Urinary tract infection 4. Chest pain 5. Chest pain 6. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 09AUG2010 (4) - 09AUG2010 (4) 2. 20SEP2010 (46) - 22SEP2010 (48) 3. 05MAR2011 (212) - 03APR2011 (241) 4. 19JUL2011 (348) - 20JUL2011 (349) 5. 01AUG2011 (361) - --------- (.) 6. 01AUG2011 (361) - --------- (.)
Duration of AE	1. 1 2. 3 3. 30 4. 2 5. . 6. .
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013059

Parameter	Value
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. OTHER
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013061

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013061/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/61/WHITE/BELGIUM/YES
Medical history	Multiple allergies, Hypercholesterolaemia, Oesophagitis, Pulmonary hypertension, Right ventricular hypertrophy, Sleep apnoea syndrome
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, ALDACTONE [SPIRONOLACTONE], ASAFLOW, CLEXANE, CONTRAMAL, CONTRAMAL RETARD, DAFALGAN, DUPHALAC [ONLY LACTULOSE], ENOXAPARIN, FLAMINAL FORTE, HEPARINE, HIBITANE [CHLORHEXIDINE GLUCONATE], LASIX, LIPANTHYLNANO, LIPITOR, LITICAN, METROPOLOL, MOVICOL, PANTOMED, PERFUSALGAN, PHENERGAN, SOLUCORTEF, TARADYL, WARFARIN, XANAX, ZANTAC
Adverse Events (AE) Preferred term	1. Decubitus ulcer 2. Vascular pseudoaneurysm 3. Epistaxis 4. Pulmonary hypertension 5. Sleep apnoea syndrome 6. Epistaxis 7. Anaemia postoperative 8. Procedural pain 9. Constipation 10. Insomnia 11. Chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/YES/YES 6. MILD/YES/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JAN2011 (.) - 28FEB2011 (165) 2. 18SEP2010 (2) - 27SEP2010 (11) 3. 01OCT2010 (15) - 01NOV2010 (46) 4. 26NOV2010 (71) - 05FEB2011 (142) 5. 13DEC2010 (88) - 14DEC2010 (89) 6. 01JAN2011 (107) - 10FEB2011 (147) 7. 25JAN2011 (131) - 16MAY2011 (242) 8. 25JAN2011 (131) - 04MAR2011 (169) 9. 27JAN2011 (133) - 01FEB2011 (138) 10. 31JAN2011 (137) - 31JAN2011 (137) 11. 01JUL2011 (288) - 02JUL2011 (289)
Duration of AE	1. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013061

Parameter	Value
	2. 10
	3. 32
	4. 72
	5. 2
	6. 41
	7. 112
	8. 39
	9. 6
	10. 1
	11. 2
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	3. NONE
	4. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	5. OTHER
	6. NONE
	7. OTHER
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013061

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013070

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013070/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/57/WHITE/BELGIUM/YES
Medical history	Hepatic steatosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPEGIC, AUGMENTIN, AUGMENTINE, CATAFLAM, CONTRAMAL, DAFALGAN FORTE, ENOXAPARIN, LOSEC, WARFARIN
Adverse Events (AE) Preferred term	1. Chest pain 2. Dyspnoea 3. Tachypnoea 4. Rash 5. Rash 6. Gamma-glutamyltransferase increased 7. Back pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/YES/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 18NOV2010 (3) - 22NOV2010 (7) 2. 18NOV2010 (3) - 22NOV2010 (7) 3. 18NOV2010 (3) - 22NOV2010 (7) 4. 18NOV2010 (3) - 01MAR2011 (106) 5. 18NOV2010 (3) - 01MAR2011 (106) 6. 22NOV2010 (7) - 09AUG2011 (267) 7. 12JUL2011 (239) - 01SEP2011 (290)
Duration of AE	1. 5 2. 5 3. 5 4. 104 5. 104 6. 261 7. 52
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013070

Parameter	Value
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013071

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013071/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/48/WHITE/BELGIUM/YES
Medical history	Pancreatitis acute, Conjunctivitis allergic, Abdominal pain upper, House dust allergy, Hypertension, Insomnia, Menorrhagia, Osteoarthritis, Palpitations, Seasonal allergy, Ventilation/perfusion scan abnormal, Anti factor VIII antibody positive, Dermatitis contact, Right ventricular dysfunction
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BISOPROLOL EG, CARDIOASPIRINE, CLEXANE, CONTRAMAL, DAFALGAN, DAFALGAN FORTE, EMCONCOR, FERRO GRAD 500, LITICAN, LUTENYL, MAREVAN, PERFUSALGAN, TRAZOLAN, ULTRA K, ZYRTEC
Adverse Events (AE) Preferred term	1. Menorrhagia 2. Syncope 3. Menorrhagia 4. Anaemia 5. Hypokalaemia 6. Menorrhagia 7. Menorrhagia 8. Chest pain 9. Abdominal pain 10. Headache 11. Menorrhagia 12. Menorrhagia 13. Tooth injury 14. Concussion 15. Ovarian cyst 16. Ecchymosis 17. Contusion 18. Ecchymosis 19. Menorrhagia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/YES/YES/YES 4. MODERATE/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/YES/YES/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/YES/NO/YES 12. MILD/YES/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/YES/YES 15. MILD/NO/NO/YES 16. MILD/YES/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013071

Parameter	Value
	17. MILD/NO/NO/YES
	18. MILD/YES/NO/YES
	19. MODERATE/YES/NO/YES
Start/stop date of event with relative date	1. 18NOV2010 (3) - 20NOV2010 (5)
	2. 20NOV2010 (5) - 21NOV2010 (6)
	3. 21NOV2010 (6) - 24NOV2010 (9)
	4. 21NOV2010 (6) - 11JAN2011 (57)
	5. 23NOV2010 (8) - 23NOV2010 (8)
	6. 25NOV2010 (10) - 09DEC2010 (24)
	7. 10DEC2010 (25) - 18DEC2010 (33)
	8. 10DEC2010 (25) - 18DEC2010 (33)
	9. 12DEC2010 (27) - 12DEC2010 (27)
	10. 16DEC2010 (31) - --------- (.)
	11. 19DEC2010 (34) - 24JAN2011 (70)
	12. 25JAN2011 (71) - 13AUG2011 (271)
	13. 15JUN2011 (212) - --------- (.)
	14. 15JUN2011 (212) - 16JUN2011 (213)
	15. 15JUN2011 (212) - --------- (.)
	16. 15JUN2011 (212) - 09AUG2011 (267)
	17. 15JUN2011 (212) - --JUL2011 (.)
	18. 15JUN2011 (212) - 09AUG2011 (267)
	19. 14AUG2011 (272) - --------- (.)
Duration of AE	1. 3
	2. 2
	3. 4
	4. 52
	5. 1
	6. 15
	7. 9
	8. 9
	9. 1
	10. .
	11. 37
	12. 201
	13. .
	14. 2
	15. .
	16. 56
	17. .
	18. 56
	19. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013071

Parameter	Value
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. I
	10. I
	11. I
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
	18. .
	19. .
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY,OTHER
	4. OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	8. NONE
	9. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013071

Parameter	Value
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. OTHER
	14. NONE
	15. NONE
	16. NONE
	17. NONE
	18. NONE
	19. REMEDIAL DRUG THERAPY
Outcome of event	1. WORSENED
	2. RESOLVED
	3. IMPROVED
	4. RESOLVED
	5. RESOLVED
	6. WORSENED
	7. IMPROVED
	8. RESOLVED
	9. RESOLVED
	10. UNCHANGED
	11. RESOLVED
	12. WORSENED
	13. UNCHANGED
	14. RESOLVED
	15. UNCHANGED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013076

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013076/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/37/WHITE/BELGIUM/YES
Medical history	Constipation, Hypercholesterolaemia, Hypertension, Ovarian cyst, Pulmonary infarction, Pulmonary haemorrhage
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACEDICON, ACEDICONE, AMLOR, AUGMENTIN, CLEXANE, CONTRAMAL, CONTRAMAL RETARD, COTRAMAL, DAFALGAN FORTE, HIBITANE LIDOCAINE, LASIX, LITICAN, MOTILIUM, MOVICOL, OLMETEC, PERFUSALGAN, TAZOCIN, TUSSIPECT, TUSSPECT, ULTRA K, ZYLORIC
Adverse Events (AE) Preferred term	1. Weight increased 2. Dyspnoea 3. Diarrhoea 4. Acute prerenal failure 5. Inflammation 6. Blood potassium decreased 7. Anaemia 8. Haematuria 9. Haemoptysis 10. Pneumonia necrotising 11. Vena cava thrombosis 12. Hypercholesterolaemia 13. Hydronephrosis 14. Haemangioma of liver 15. Ovarian cyst 16. Oedema peripheral
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. SEVERE/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MODERATE/NO/YES/YES 11. MODERATE/NO/YES/YES 12. MODERATE/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MILD/NO/NO/YES 15. MILD/NO/NO/YES 16. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --JAN2011 (.) - --------- (.) 2. --JUN2011 (.) - --------- (.) 3. --JAN2011 (.) - --FEB2011 (.) 4. 11JAN2011 (2) - 15JAN2011 (6)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013076

Parameter	Value
	5. 11JAN2011 (2) - 30JAN2011 (21)
	6. 12JAN2011 (3) - 05FEB2011 (27)
	7. 13JAN2011 (4) - 02MAR2011 (52)
	8. 13JAN2011 (4) - --------- (.)
	9. 30JAN2011 (21) - 02MAR2011 (52)
	10. 31JAN2011 (22) - 09FEB2011 (31)
	11. 10MAY2011 (121) - 05JUL2011 (177)
	12. 07JUN2011 (149) - --------- (.)
	13. 07JUN2011 (149) - 05JUL2011 (177)
	14. 07JUN2011 (149) - 05JUL2011 (177)
	15. 07JUN2011 (149) - --------- (.)
	16. 05JUL2011 (177) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. 5
	5. 20
	6. 25
	7. 49
	8. .
	9. 32
	10. 10
	11. 57
	12. .
	13. 29
	14. 29
	15. .
	16. .
Dose on AE onset	1.
	2.
	3.
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013076

Parameter	Value
Dose status on AE onset	1.
	2.
	3.
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. NONE
	10. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	11. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	12. NONE
	13. NONE
	14. NONE
	15. OTHER
	16. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. INSUFFICIENT FOLLOW-UP
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013076

Parameter	Value
	13. RESOLVED
	14. RESOLVED
	15. UNCHANGED
	16. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013077

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013077/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/BELGIUM/YES
Medical history	Osteoarthritis, Goitre, Gout, Hypercholesterolaemia, Hypertension, Menopause, Renal cyst, Stress urinary incontinence, Supraventricular tachycardia, Ventricular hypokinesia, Haematuria
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASAFLOW, DAFALGAN FORTE, IBEXONE, LIPITOR, SELOZOK, TEVETEN, ZYLORIC
Adverse Events (AE) Preferred term	1. Chest pain 2. Back pain 3. Drug eruption 4. Muscle spasms 5. Rectal haemorrhage 6. Oedema peripheral 7. Cardiac failure 8. Anaemia 9. Anaemia 10. Liver function test abnormal 11. Gastritis 12. Colon neoplasm 13. Constipation 14. Subcutaneous haematoma 15. Anxiety 16. Anaemia 17. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/YES/NO/YES 9. MODERATE/YES/YES/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/YES/NO 13. MILD/NO/NO/NO 14. MILD/NO/NO/NO 15. MILD/NO/NO/NO 16. MODERATE/YES/NO/NO 17. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --JUL2011 (.) - --------- (.) 2. --MAY2011 (.) - --MAY2011 (.) 3. --JUN2011 (.) - 28JUN2011 (156) 4. -----2011 (.) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013077

Parameter	Value
	5. 09FEB2011 (17) - --------- (.)
	6. 02MAY2011 (99) - --------- (.)
	7. 09MAY2011 (106) - 09JUN2011 (137)
	8. 30MAY2011 (127) - 30MAY2011 (127)
	9. 31MAY2011 (128) - 09JUN2011 (137)
	10. 31MAY2011 (128) - --------- (.)
	11. 01JUN2011 (129) - --------- (.)
	12. 06JUN2011 (134) - --------- (.)
	13. 06JUN2011 (134) - 09JUN2011 (137)
	14. 07JUN2011 (135) - --------- (.)
	15. 08JUN2011 (136) - --------- (.)
	16. 10JUN2011 (138) - --------- (.)
	17. 10JUN2011 (138) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. 32
	8. 1
	9. 10
	10. .
	11. .
	12. .
	13. 4
	14. .
	15. .
	16. .
	17. .
Dose on AE onset	1.
	2.
	3.
	4.
	5. 15 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013077

Parameter	Value
	15. 20 mg
	16. 20 mg
	17. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4.
	5. I
	6. .
	7. .
	8. .
	9. F
	10. F
	11. F
	12. F
	13. F
	14. F
	15. F
	16. F
	17. F
Action taken	1. NONE
	2. NONE
	3. OTHER
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED
	6. NONE
	7. NONE
	8. OTHER
	9. REMEDIAL DRUG THERAPY,OTHER
	10. NONE
	11. NONE
	12. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. NONE
	17. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED
	7. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013077

Parameter	Value
	8. WORSENED
	9. IMPROVED
	10. UNCHANGED
	11. INSUFFICIENT FOLLOW-UP
	12. UNCHANGED
	13. RESOLVED
	14. UNCHANGED
	15. UNCHANGED
	16. UNCHANGED
	17. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013078

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280013078/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/56/WHITE/BELGIUM/YES
Medical history	Emphysema, Lipoma, Lipoma, Oesophagitis, Pneumothorax, Splenomegaly, Cholelithiasis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPEGIC, AUGMENTIN, BEFACTE FORTE, CLEXANE, DAFALGAN, DUOVENT, ENOXAPARIN, KONAKION, MIDAZOLAM, MOVICOL, ONBREZ, PERFUSALGAN, PETHIDINE, SEREVENT, SPIRIVA, SYMBICORT, TRIBVIT, WARFARIN, XYLOCAINE
Adverse Events (AE) Preferred term	1. Nasopharyngitis 2. International normalised ratio increased 3. Diarrhoea 4. Hepatomegaly 5. Chronic obstructive pulmonary disease 6. Chronic obstructive pulmonary disease 7. Vitamin B12 deficiency 8. Chest pain 9. Chronic obstructive pulmonary disease 10. Melaena 11. Lower gastrointestinal haemorrhage 12. Haemorrhoids
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/YES/NO/YES 11. MILD/YES/NO/YES 12. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --MAY2011 (.) - --JUN2011 (.) 2. 10FEB2011 (4) - 11FEB2011 (5) 3. 11FEB2011 (5) - 11FEB2011 (5) 4. 12FEB2011 (6) - --------- (.) 5. 13FEB2011 (7) - 13FEB2011 (7) 6. 14FEB2011 (8) - 17FEB2011 (11) 7. 14FEB2011 (8) - --------- (.) 8. 18FEB2011 (12) - --------- (.) 9. 18FEB2011 (12) - --------- (.) 10. 04MAR2011 (26) - --------- (.) 11. 04MAR2011 (26) - --------- (.) 12. 27MAY2011 (110) - --------- (.)
Duration of AE	1. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013078

Parameter	Value
	2. 2
	3. 1
	4. .
	5. 1
	6. 4
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280013078

Parameter	Value
	10. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	11. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	12. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. WORSENED
	6. IMPROVED
	7. UNCHANGED
	8. UNCHANGED
	9. UNCHANGED
	10. UNCHANGED
	11. UNCHANGED
	12. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280033002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280033002/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/82/WHITE/BELGIUM/YES
Medical history	Prostate cancer, Decreased appetite, Gastritis, Hypertension, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLCYSTEINE EG, CONTRAMAL, DECAPEPTYL [DECAPEPTYL CONTAINS TRIPTORELIN ACETATE.], DUOVENT, ESTRACYT, FRAXIPARINE, GLURENORM, INFLUVAC, LITICAN, LUCRIN DEPOT, MEDROL, MOTILIUM, PANTOZOL, PERFUSALGAN, PREDNISON, PREDNISONE, PRETERAX, PROVERA, TAXOTERE, ZANTAC
Adverse Events (AE) Preferred term	1. Neoplasm prostate 2. Fatigue 3. Productive cough 4. Neoplasm prostate 5. Decreased appetite 6. Pneumonia 7. Haemoptysis 8. Platelet count decreased
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. SEVERE/NO/YES/YES 6. SEVERE/NO/YES/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 04OCT2007 (72) - 23NOV2007 (122) 2. 13NOV2007 (112) - --------- (.) 3. 14NOV2007 (113) - --------- (.) 4. 24NOV2007 (123) - 11DEC2007 (140) 5. 24NOV2007 (123) - --------- (.) 6. 24NOV2007 (123) - --------- (.) 7. 29NOV2007 (128) - 29NOV2007 (128) 8. 03DEC2007 (132) - -----2007 (.)
Duration of AE	1. 51 2. . 3. . 4. 18 5. . 6. . 7. 1 8. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280033002

Parameter	Value
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. F
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
Outcome of event	1. WORSENED
	2. UNCHANGED
	3. UNCHANGED
	4. DEATH
	5. UNCHANGED
	6. UNCHANGED
	7. RESOLVED
	8. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280073008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280073008/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/77/WHITE/BELGIUM/YES
Medical history	Hypertension, Nephrectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTAZINE, ALDACTONE [ALDACTONE =SPIRONOLACTONE], AMLOR, ASAFLOW, CIPROXINE, CORUNO, DAFALGAN, ENOXAPARIN, LOSFERON, WARFARIN
Adverse Events (AE) Preferred term	1. Intra-abdominal haemorrhage 2. Intra-abdominal haematoma 3. Weight decreased 4. Anaemia 5. Renal failure acute 6. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 04JUL2008 (3) - 22JUL2008 (21) 2. 04JUL2008 (3) - --------- (.) 3. 04JUL2008 (3) - --DEC2008 (.) 4. 05JUL2008 (4) - 19AUG2008 (49) 5. 07JUL2008 (6) - 10JUL2008 (9) 6. 12JUL2008 (11) - 17JUL2008 (16)
Duration of AE	1. 19 2. . 3. . 4. 46 5. 4 6. 6
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 2. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280073008

Parameter	Value
	3. NONE
	4. REMEDIAL DRUG THERAPY,OTHER
	5. OTHER
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. IMPROVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-280073008[4)]	INTRA ABDOMINAL HEMORRHAGE（PT：腹腔内出血） 治験担当医は、投与時の不正確な注射手技によるものであり、否定できると判断した。弊社は、エノキサパリンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280073010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280073010/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/70/WHITE/BELGIUM/YES
Medical history	Chronic obstructive pulmonary disease, Hypercholesterolaemia, Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, COLCHICINE, DAFALGAN, DAKTARIN, DOCMELOXI, DUOVENT, ENOXAPARIN, PLAQUENIL, SEREVENT, SPIRIVA, SYMBICORT TURBOHALER, TRADONAL RETARD, VAXIGRIP
Adverse Events (AE) Preferred term	1. Oral candidiasis 2. Chest pain 3. Bronchitis 4. Bronchitis 5. Bronchitis 6. Oral candidiasis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. SEVERE/NO/YES/NO 6. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 07AUG2008 (13) - 16AUG2008 (22) 2. 06SEP2008 (43) - 12SEP2008 (49) 3. 09SEP2008 (46) - 12SEP2008 (49) 4. 13SEP2008 (50) - 07OCT2008 (74) 5. 01FEB2009 (191) - 11FEB2009 (201) 6. 06FEB2009 (196) - 11FEB2009 (201)
Duration of AE	1. 10 2. 7 3. 4 4. 25 5. 11 6. 6
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280073010

Parameter	Value
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. IMPROVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280073021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280073021/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/54/WHITE/BELGIUM/YES
Medical history	Colon cancer, Ex-tobacco user, Inguinal hernia repair, Colectomy, Chemotherapy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BUSCOPAN, DAFALGAN, HARTMANN VIAFLO, TAMSULOSINE, TARADYL, VOLTAREN
Adverse Events (AE) Preferred term	1. Nephritis 2. Haematoma 3. Colonic polyp
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 14JUN2009 (117) - 24JUN2009 (127) 2. 09JUL2009 (142) - 09MAR2010 (385) 3. 06NOV2009 (262) - 06NOV2009 (262)
Duration of AE	1. 11 2. 244 3. 1
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. I
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. NONE 3. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280073034

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280073034/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/60/WHITE/BELGIUM/YES
Medical history	Appendicectomy, Asthenia, Hiatus hernia, Insomnia, Malformation venous, Mitral valve incompetence, Portal hypertension, Splenomegaly, Tonsillectomy, Tuberculosis, Uterine leiomyoma, Postmenopause, Iodine allergy, Rectal haemorrhage, Diarrhoea, Gastrointestinal surgery
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AUGMENTIN, DAFALGAN, DUROSEGIC, ENOXAPARIN, FRAXODI, IBUPROFENE, INDERAL, LYSOMUSIL, MEDROL, MOVICOL, MS CONTIN, SIPRALEXA, STILNOCT, VAGIFEM, VALTRAN, VOLTAREN, XYZALL
Adverse Events (AE) Preferred term	1. Epistaxis 2. Bronchopneumonia 3. Haemoptysis 4. Rectal haemorrhage 5. Anaemia 6. Metrorrhagia 7. Depression
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/YES/NO/YES 4. SEVERE/YES/YES/YES 5. MILD/NO/NO/YES 6. MILD/YES/NO/YES 7. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 01DEC2009 (78) - 18MAR2010 (185) 2. 19APR2010 (217) - 30APR2010 (228) 3. 20APR2010 (218) - --APR2010 (.) 4. 22APR2010 (220) - 27APR2010 (225) 5. 22APR2010 (220) - 09AUG2010 (329) 6. 01JUN2010 (260) - 02JUN2010 (261) 7. 09AUG2010 (329) - --------- (.)
Duration of AE	1. 108 2. 12 3. . 4. 6 5. 110 6. 2 7. .
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280073034

Parameter	Value
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. STUDY DRUG DISCONTINUED AND RESTARTED
	5. NONE
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280073042

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280073042/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/81/WHITE/BELGIUM/YES
Medical history	Anaemia, Arthropathy, Cough, Serum ferritin decreased, Folate deficiency, Hyperglycaemia, Hypertension, Mitral valve incompetence, Muscle spasms, Oedema peripheral, Osteitis, Polyneuropathy, Inguinal hernia, Vitamin B12 deficiency, Ventricular hypokinesia, Crystal arthropathy, Prostatic operation, Pulmonary arterial hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTAPULGITE, AMLODIPINE, BEFACT FORTE, CATAPRESSAN, CEFURIM, DAFALGAN, DULCOLAX [BISACODYL], FERO-GRADUMET, FLAGYL, FRAXIPARINE, GLUCOSE 5%+NACL 0.3%+KCL0.3, GLUCOSE 5%+NACL 0.3%+KCL0.3%, HARTMANN VIAFLO, IMODIUM, LITICAN, LOSEC, MIRTAZAPINE, MORPHINE, MOVIPREP, NEXIAM, PERFUSALGAN, PRIMPERAN, TEMESTA, TRADONAL, TRIBVIT, ULTRA MG BAGS, VOLULYTE 6%, XANAX, ZANTAC
Adverse Events (AE) Preferred term	1. Diarrhoea 2. Sciatica 3. Fatigue 4. Colon cancer 5. Colonic polyp 6. Thyroid neoplasm 7. Vomiting 8. Pyrexia 9. Postoperative ileus
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --MAY2010 (.) - --------- (.) 2. 09JAN2010 (5) - 01FEB2010 (28) 3. 08APR2010 (94) - 25JAN2011 (386) 4. 27AUG2010 (235) - --------- (.) 5. 27AUG2010 (235) - --------- (.) 6. 30AUG2010 (238) - --------- (.) 7. 29SEP2010 (268) - --OCT2010 (.) 8. 01OCT2010 (270) - 02OCT2010 (271) 9. 11OCT2010 (280) - 18OCT2010 (287)
Duration of AE	1. . 2. 24 3. 293 4. . 5. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280073042

Parameter	Value
	6. .
	7. .
	8. 2
	9. 8
Dose on AE onset	1.
	2. 15 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. I
	8. I
	9. I
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. OTHER
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. UNCHANGED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280073042

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280083006/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/BELGIUM/YES
Medical history	Angina pectoris, Anxiety, Coronary artery bypass, Hypercholesterolaemia, Hypertension, Atrial fibrillation, Pneumonia, Postmenopause, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, BISOPROLOL, CARDIOASPIRINE, CEDOCARD, CORUNO, ENALAPRIL EG, ENOXAPARIN, FURACINE, KEFZOL, KONAKION, LASIX, LORMETAZEPAM, MEDROL, REGULTON, SIMVASTATINE, STAPHYCID
Adverse Events (AE) Preferred term	1. Muscle haemorrhage 2. Anaemia 3. Muscle haemorrhage 4. Chest pain 5. Nausea 6. Erysipelas
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MODERATE/NO/NO/YES 3. MODERATE/YES/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 25MAR2008 (79) - 29MAR2008 (83) 2. 28MAR2008 (82) - 10JUL2008 (186) 3. 30MAR2008 (84) - --JUN2008 (.) 4. 31MAR2008 (85) - 03APR2008 (88) 5. 31MAR2008 (85) - 31MAR2008 (85) 6. 11APR2008 (96) - 30MAY2008 (145)
Duration of AE	1. 5 2. 105 3. . 4. 4 5. 1 6. 50
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083006

Parameter	Value
Action taken	1. DOSE OF STUDY DRUG REDUCED,REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-280083006[1)]	INTRAMUSCULAR ABDOMINAL HEMATOMA（PT：筋肉内出血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、投与終了約 2 ヵ月半後の発現であり、時間的関連性がないことから、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280083010/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/86/WHITE/BELGIUM/YES
Medical history	Atrial fibrillation, Cataract, Cerebrovascular accident, Depression, Hypercholesterolaemia, Hypertension, Hyperthyroidism, Insomnia, Osteoporosis, Syncope, Myocardial ischaemia, Cognitive disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLINE, ARICEPT, ASAFLOW, BRONCHOSEDAL, CLAMOXYL, CORUNO, COVERSYL, DAFALGAN, ENTEROL [SACCHARROMYCES BOULARDII], IMODIUM, LIPITOR, REMERGON, RISPERDAL, SIPRALEXA, TEMESTA
Adverse Events (AE) Preferred term	1. Haematuria 2. Urinary tract infection 3. Urinary tract infection 4. Nasopharyngitis 5. Gastroenteritis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 06JUL2008 (3) - 10JUL2008 (7) 2. 08JUL2008 (5) - 17JUL2008 (14) 3. 28AUG2008 (56) - -----2008 (.) 4. 26SEP2008 (85) - 01OCT2008 (90) 5. 18NOV2008 (138) - 24NOV2008 (144)
Duration of AE	1. 5 2. 10 3. . 4. 6 5. 7
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. NONE 4. REMEDIAL DRUG THERAPY 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083010

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083018

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280083018/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/83/WHITE/BELGIUM/YES
Medical history	Rheumatoid arthritis, Depression, Haemangioma congenital, Hiatus hernia, Hypercholesterolaemia, Hypertension, Muscular weakness, Neuropathy peripheral, Osteoporosis, Pleural effusion, Renal cyst
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, CALCIUM, DUOVENT, ENOXAPARIN, INNOHEP, MEDROL, MESTINON, OMEPRAZOLE, REMERGON, REPARIL, SOLUMEDROL, TILDIEM, XANAX, ZALDIAR(PARACETAMOL 325MG+TRAMADOL37.5MG, ZESTORETIC
Adverse Events (AE) Preferred term	1. Sudden death
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 12JUL2009 (3) - 12JUL2009 (3)
Duration of AE	1. 1
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. NONE
Outcome of event	1. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280083023/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/60/WHITE/BELGIUM/YES
Medical history	Appendicectomy, Ankle fracture, Haemorrhoids, Myocardial infarction, Obesity, Oesophagitis, Pericardial cyst, Postmenopause, Anaemia postoperative, Ear neoplasm, Myocardial ischaemia, Ex-tobacco user, Gastroplasty
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ACTRAPID, ASAFLOW, CAPTOPRIL, CARDIOASPIRINE, COVERSYL, DAFALGAN, ENOXAPARIN, FRAXODI, HEPARIN, ISOTEN, LASIX, LITICAN, LORAMET, MORPHINE, NEXIAM, NITRATE INFUSION [ORGANIC NITRATES], OMEPRAZOLE, PERFUSALGAN, SIMVASTATINE, SOLUMEDROL, TRADONAL, VACCIN H1N1, VOLTAREN, XANAX, ZANTAC, ZINACEF
Adverse Events (AE) Preferred term	1. Pain in extremity 2. Angina unstable 3. Hypercholesterolaemia 4. Hypertension 5. Coronary artery disease 6. Coronary artery disease 7. Carotid arteriosclerosis 8. Anaemia postoperative 9. Hyperglycaemia 10. Procedural pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. SEVERE/NO/YES/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/YES/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --OCT2009 (.) - --DEC2009 (.) 2. 07SEP2009 (5) - 23OCT2009 (51) 3. 07SEP2009 (5) - --------- (.) 4. 07SEP2009 (5) - --------- (.) 5. 07OCT2009 (35) - 02NOV2009 (61) 6. 22OCT2009 (50) - --------- (.) 7. 22OCT2009 (50) - --------- (.) 8. 23OCT2009 (51) - --------- (.) 9. 23OCT2009 (51) - 24OCT2009 (52) 10. 23OCT2009 (51) - 02NOV2009 (61)
Duration of AE	1. . 2. 47 3. . 4. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083023

Parameter	Value
	5. 27
	6. .
	7. .
	8. .
	9. 2
	10. 11
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	6. NONE
	7. NONE
	8. OTHER
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. UNCHANGED
	5. RESOLVED
	6. UNCHANGED
	7. UNCHANGED
	8. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083023

Parameter	Value
	9. RESOLVED
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083024

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280083024/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/BELGIUM/YES
Medical history	Appendicectomy, Barrett's oesophagus, Mammoplasty, Cholecystectomy, Cholecystitis, Renal cyst, Diverticulum intestinal, Dyspnoea, Fall, Hypercholesterolaemia, Hysterectomy, Microcytic anaemia, Nasal septum deviation, Osteoporosis, Pelvic mass, Pulmonary hypertension, Syncope, Syringomyelia, Haemorrhoids, Breast cyst excision, Hepatitis A antibody positive, Cataract operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CEFACIDAL, CEFITRIAXONE, CIFAZOLINE, CIPROXINE, CLEXANE, COLOPEG, DAFALGAN, DEANXIT [FLUPENTIXOL 0,5 MG + MÉLITRACÈNE 10 MG, DIPIDOLOR, DITROPAN, FERO GRADUMET, FLAGYL, IMMODIUM, INFLUVAC, KALEORID, LASIX, LITICAN, LORAZEPAM, LOSFERRON, MORPHINE, MOVICOL, NAPROSINE, NAPROZINE, NEOMYCINE, NEXIAM, NITROLUINGAL, PANTOMED, PERFUSALGAN, PNEUMO 23, PRUNASINE, TRADONAL, VOLTAREN, XANAX
Adverse Events (AE) Preferred term	1. Pyrexia 2. Constipation 3. Anxiety 4. Pulmonary hypertension 5. Microcytic anaemia 6. Urinary tract infection 7. Hypokalaemia 8. Oedema peripheral 9. Pyrexia 10. Sepsis 11. Diarrhoea 12. Rectal haemorrhage 13. Microcytic anaemia 14. Ovarian epithelial cancer 15. Diverticulum intestinal 16. Procedural pain 17. Asthenia 18. Anxiety 19. Colonic stenosis 20. Ureteric perforation 21. Procedural pain 22. Device related infection 23. Procedural pain 24. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MODERATE/YES/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083024

Parameter	Value
	8. MILD/NO/NO/YES
	9. MILD/NO/NO/YES
	10. SEVERE/NO/YES/YES
	11. MILD/NO/NO/YES
	12. MILD/YES/NO/YES
	13. MODERATE/YES/NO/YES
	14. SEVERE/NO/YES/YES
	15. SEVERE/NO/YES/YES
	16. MODERATE/NO/NO/YES
	17. MODERATE/NO/NO/YES
	18. MODERATE/NO/NO/YES
	19. SEVERE/NO/YES/YES
	20. MODERATE/NO/NO/YES
	21. MODERATE/NO/NO/YES
	22. MODERATE/NO/NO/YES
	23. MODERATE/NO/NO/YES
	24. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 19SEP2009 (2) - 20SEP2009 (3)
	2. 20SEP2009 (3) - 20SEP2009 (3)
	3. 20SEP2009 (3) - 21SEP2009 (4)
	4. 22SEP2009 (5) - 02OCT2009 (15)
	5. 24SEP2009 (7) - 27SEP2009 (10)
	6. 24SEP2009 (7) - 08OCT2009 (21)
	7. 24SEP2009 (7) - 03OCT2009 (16)
	8. 02OCT2009 (15) - --OCT2009 (.)
	9. 03OCT2009 (16) - 03OCT2009 (16)
	10. 04OCT2009 (17) - 14OCT2009 (27)
	11. 11OCT2009 (24) - 11OCT2009 (24)
	12. 14OCT2009 (27) - 14OCT2009 (27)
	13. 14OCT2009 (27) - 29OCT2009 (42)
	14. 15OCT2009 (28) - 15OCT2009 (28)
	15. 15OCT2009 (28) - 15OCT2009 (28)
	16. 15OCT2009 (28) - --OCT2009 (.)
	17. 20OCT2009 (33) - --------- (.)
	18. 20OCT2009 (33) - --------- (.)
	19. 24JAN2010 (129) - 25JAN2010 (130)
	20. 25JAN2010 (130) - 30JAN2010 (135)
	21. 25JAN2010 (130) - --FEB2010 (.)
	22. 28JAN2010 (133) - 06FEB2010 (142)
	23. 11MAR2010 (175) - 23MAR2010 (187)
	24. 13MAR2010 (177) - --------- (.)
Duration of AE	1. 2
	2. 1
	3. 2

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083024

Parameter	Value
	4. 11
	5. 4
	6. 15
	7. 10
	8. .
	9. 1
	10. 11
	11. 1
	12. 1
	13. 16
	14. 1
	15. 1
	16. .
	17. .
	18. .
	19. 2
	20. 6
	21. .
	22. 10
	23. 13
	24. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
	22. 20 mg
	23. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083024

Parameter	Value
	24. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. I
	13. I
	14. I
	15. I
	16. I
	17. .
	18. .
	19. I
	20. I
	21. I
	22. .
	23. I
	24. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. OTHER
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. OTHER
	13. OTHER
	14. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	15. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	16. REMEDIAL DRUG THERAPY
	17. NONE
	18. NONE
	19. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083024

Parameter	Value
	20. OTHER
	21. REMEDIAL DRUG THERAPY
	22. REMEDIAL DRUG THERAPY
	23. REMEDIAL DRUG THERAPY
	24. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. IMPROVED
	18. IMPROVED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED
	23. RESOLVED
	24. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083025

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280083025/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/69/WHITE/BELGIUM/YES
Medical history	Alcoholism, Arteriosclerosis, Rhinitis, Conjunctivitis, Haemoptysis, Hypertension, Erectile dysfunction, Insomnia, Back pain, Intervertebral disc degeneration, Macrocytosis, Osteoarthritis, Prostatitis, Osteopenia, Biliary cyst, Parkinson's disease, Constipation, Dementia with Lewy bodies
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AZILECT, BETARSEC, COZAAR, DAFALGAN, DUPHALAC(LACTULOSE), EXELON, INDERAL, MIDAZOLAM, MORPHINE, MOTILIUM, MYOLASTAN, OMEPRAZOLE, PANTOMED, PROLOPA, STAVELO, STEOVIT, STILNOCT, TEMGESIC, TOBREX, TRADONAL, TRANSTEC, VITAMIN B (BEFACT F), ZOPICLONE
Adverse Events (AE) Preferred term	1. Mitral valve incompetence 2. Haemoptysis 3. Back pain 4. Oesophagitis 5. Gastric mucosa erythema
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 14DEC2009 (5) - --------- (.) 2. 03MAR2010 (84) - --------- (.) 3. 03MAR2010 (84) - 04MAR2010 (85) 4. 15MAR2010 (96) - --------- (.) 5. 01APR2010 (113) - --------- (.)
Duration of AE	1. . 2. . 3. 2 4. . 5. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. NONE 2. OTHER 3. REMEDIAL DRUG THERAPY 4. OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083025

Parameter	Value
Outcome of event	5. REMEDIAL DRUG THERAPY 1. UNCHANGED 2. UNCHANGED 3. RESOLVED 4. UNCHANGED 5. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083028

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280083028/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/40/WHITE/BELGIUM/YES
Medical history	Abscess, Asthma, Depression, Drug hypersensitivity, Fall, Pyrexia, Insomnia, Obesity, Suicide attempt, Wound infection, Tobacco user, Ligament operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AVELOX, BEFACT, BENERVA, DAFALGAN, DEANXIT, DOLZAM, DOMINAL, DULCOLAX [BISACODYL], DUOVENT (FÉNOTÉROL 50 µG + IPRATROPIUM 20 µG /), FLAGYL, FLIXOTIDE, GAVISCON, IBUPROFEN, INFLUVAC, INVEGA, LACTULOSE, LAXOBERON, LORAZEPAM, LOSEC, MAGNESPASMYL, MAXIPIM, MEDROL, MORPHINE, MOVICOL, PERFUSALGAN, PRUNASINE, RANITIDINE, SEROQUEL, SINUTAB, SIPRALEXA, SULFAREM, TEMESTA, TRADONAL, TRANSXENE, TRANXENE, TRAZOLAN, VOLTAREN, XANAX
Adverse Events (AE) Preferred term	1. Asthma 2. Bursitis 3. Haemoptysis 4. Pleural effusion 5. Constipation 6. Depression 7. Pyrexia 8. Pneumonia 9. Dry mouth 10. Bursitis 11. Nasopharyngitis 12. Gastritis 13. Hypomagnesaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/YES/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. SEVERE/NO/YES/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/YES/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MODERATE/NO/NO/YES 13. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --MAY2010 (.) - --------- (.) 2. --JAN2011 (.) - --JAN2011 (.) 3. 22FEB2010 (4) - 02MAR2010 (12) 4. 22FEB2010 (4) - 22MAR2010 (32) 5. 23FEB2010 (5) - --------- (.) 6. 02MAR2010 (12) - 20APR2010 (61) 7. 12MAR2010 (22) - 13MAR2010 (23)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083028

Parameter	Value
	8. 16MAY2010 (87) - 28MAY2010 (99)
	9. 15JUN2010 (117) - --------- (.)
	10. 08SEP2010 (202) - --SEP2010 (.)
	11. 13SEP2010 (207) - 17SEP2010 (211)
	12. 26OCT2010 (250) - 16NOV2010 (271)
	13. 30DEC2010 (315) - 29JAN2011 (345)
Duration of AE	1. .
	2. .
	3. 9
	4. 29
	5. .
	6. 50
	7. 2
	8. 13
	9. .
	10. .
	11. 5
	12. 22
	13. 31
Dose on AE onset	1.
	2.
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083028

Parameter	Value
	13. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. OTHER
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. OTHER
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280083029/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/BELGIUM/YES
Medical history	Dementia Alzheimer's type, Anxiety, Aortic aneurysm, Appendicectomy, Osteoarthritis, Asthenia, Asthma, Atrioventricular block first degree, Carpal tunnel decompression, Cerebral atrophy, Cholecystectomy, Renal cyst, Deafness, Depression, Dilatation ventricular, Dizziness, Glaucoma, Goitre, Foot deformity, Haemorrhoids, Hiatus hernia, Hip fracture, Hypercholesterolaemia, Hypersomnia, Hypertension, Hypokalaemia, Insomnia, Cough, Oesophagitis, Osteoporosis, Pneumonia, Pulmonary hypertension, Urinary tract infection, Renal failure, Tremor, Urinary incontinence, Tobacco user, Osteopenia, Tricuspid valve incompetence, Lung neoplasm, Postmenopause, Procedural pain, Dyspnoea exertional, Cranial nerve disorder, Constipation, Cataract operation, Diarrhoea
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLCISTEINE, ARICEPT, ASAFLOW, CALCIUM, COVERSYL, DAFALGAN, DUOVENT, FERO-GRADUMET, FOSAMAX, INDERAL, LASIX, LORMETAZEPAM, MOVICOL, MYOLASTAN, NEO GENYL, OMEPRAZOLE, PANTOMED, PERDOLAN, SERETIDE, SIMVASTATINE, SIPRALEXA, VESICARE, VITAMIN D, XYLOCAINE 2 %
Adverse Events (AE) Preferred term	1. Headache 2. Fall 3. Serum ferritin decreased 4. Hypoproteinaemia 5. Cough 6. General physical health deterioration 7. General physical health deterioration 8. Mitral valve incompetence 9. Aortic dilatation
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MODERATE/NO/YES/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --SEP2010 (.) - --------- (.) 2. 25APR2010 (48) - 14MAY2010 (67) 3. 27APR2010 (50) - --FEB2011 (.) 4. 27APR2010 (50) - 14JUN2010 (98) 5. 25MAY2010 (78) - --JUN2010 (.) 6. 14JUN2010 (98) - 18JUN2010 (102) 7. 05SEP2010 (181) - 10SEP2010 (186) 8. 10SEP2010 (186) - --------- (.) 9. 10SEP2010 (186) - --------- (.)
Duration of AE	1. . 2. 20

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083029

Parameter	Value
	3. .
	4. 49
	5. .
	6. 5
	7. 6
	8. .
	9. .
Dose on AE onset	1.
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1.
	2. .
	3. I
	4. I
	5. I
	6. .
	7. .
	8. .
	9. .
Action taken	1. OTHER
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. OTHER
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
	9. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083029

Parameter	Value
	9. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083031

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280083031/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/59/WHITE/BELGIUM/YES
Medical history	Oedema peripheral, Anxiety, Arrhythmia, Lymphadenopathy, Breast cancer, Pain in extremity, Constipation, Dyspnoea, Cholelithiasis, Hypothyroidism, Hypovitaminosis, Lymphadenopathy, Mastectomy, Pleural effusion, Pneumonia, Tachycardia, Hypoacusis, Postmenopause, Bundle branch block right
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AUGMENTIN, CA CO3, D CURE, DAFALGAN, ENOXAPARIN, ENOXAPARINE, LITICAN, MOVICOL
Adverse Events (AE) Preferred term	1. Pericardial effusion 2. Breast cancer recurrent 3. Metastases to bone 4. Metastases to lung 5. Epistaxis 6. Decubitus ulcer 7. Anaemia 8. Throat tightness 9. Leukopenia 10. Thrombocytopenia 11. Neutropenia 12. Liver function test abnormal 13. Lung infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES 3. SEVERE/NO/NO/YES 4. SEVERE/NO/NO/YES 5. MODERATE/YES/NO/NO 6. MODERATE/NO/NO/NO 7. MODERATE/NO/NO/NO 8. MILD/NO/NO/NO 9. MODERATE/NO/NO/NO 10. MODERATE/NO/NO/NO 11. MILD/NO/NO/NO 12. SEVERE/NO/NO/NO 13. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 31MAR2010 (2) - --------- (.) 2. 02APR2010 (4) - --------- (.) 3. 07APR2010 (9) - --------- (.) 4. 07APR2010 (9) - --------- (.) 5. 10APR2010 (12) - 10APR2010 (12) 6. 14APR2010 (16) - --------- (.) 7. 15APR2010 (17) - 04MAY2010 (36) 8. 19APR2010 (21) - --------- (.) 9. 22APR2010 (24) - 26APR2010 (28) 10. 22APR2010 (24) - 26APR2010 (28)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083031

Parameter	Value
	11. 22APR2010 (24) - 26APR2010 (28)
	12. 23APR2010 (25) - --------- (.)
	13. 08MAY2010 (40) - 18MAY2010 (50)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. 1
	6. .
	7. 20
	8. .
	9. 5
	10. 5
	11. 5
	12. .
	13. 11
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083031

Parameter	Value
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. OTHER
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. IMPROVED
	3. IMPROVED
	4. IMPROVED
	5. RESOLVED
	6. INSUFFICIENT FOLLOW-UP
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED
	13. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083032

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280083032/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/73/WHITE/BELGIUM/YES
Medical history	Alcoholism, Anaemia, Anxiety, Urinary tract infection, Confusional state, Fall, Hypercholesterolaemia, Hypertension, Hyperuricaemia, Ligament sprain, Obesity, Type 2 diabetes mellitus, Subdural haematoma, Postmenopause, Subdural haematoma evacuation, Diarrhoea
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOR, BEFACT, DEPAKINE, GLUCOPHAGE, IMMODIUM, LIPITOR, LOSEC, PERFUSALGAN, UNI DIAMICRON
Adverse Events (AE) Preferred term	1. Subdural haematoma 2. Confusional state
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 03JUN2010 (3) - 02AUG2010 (63) 2. 03JUN2010 (3) - --------- (.)
Duration of AE	1. 61 2. .
Dose on AE onset	1. 15 mg 2. 15 mg
Dose status on AE onset	1. . 2. .
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER 2. NONE
Outcome of event	1. DEATH 2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-280083032[6),6)]	PERSISTENT COMA（PT：昏睡） 治験担当医は報告事象との因果関係評価を行っていない。ドイツ本社安全性部門は、投与中止後 6 週間以上経過してからの発現であるため、リバーロキサバンとの因果関係は否定できると評価している。しかしながら、報告者の評価、臨床経過等の詳細な情報が得られていないため、弊社では因果関係の評価は困難と考える。したがって、リバーロキサバンとの因果関係については否定できないと考える。 RECURRENT MULTIFOCAL EPILEPSY（PT：てんかん） 治験担当医は報告事象との因果関係評価を行っていない。ドイツ本社安全性部門は、投与中止後 6 週間以上経過してからの発現であるため、リバーロキサバンとの因果関係は否定できると評価している。しかしながら、報告者の評価、臨床経過等の詳細な情報が得られていないため、弊社では因果関係の評価は困難と考える。したがって、リバーロキサバンとの因果関係については否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

被験者番号：11702-280083032

死亡に至るまでの経過

被験者は 73 歳、白人女性。2010 年 6 月 1 日に肺塞栓症と診断され、同日リバーロキサバン（30mg）の投与を開始した。

2010 年 6 月 3 日、被験者は硬膜下血腫（出血：硬膜下血腫の悪化）を発現した。本事象は重大な医学的事象と考えられ、かつ被験者は入院し死亡に至ったため、重篤とされた。本事象により被験者の治験は中止された。治験責任（分担）医師は、本事象の重症度は高度で、治験薬との因果関係は「あり」と判断した。被験者は、慢性硬膜下血腫（右）、慢性硬膜下血腫手術及び錯乱の病歴を有していた。被験者は本事象の発現前に慢性硬膜下血腫を発現し、2010 年 5 月 24 日に外科的ドレナージを受けていた。2010 年 6 月 3 日、被験者は錯乱状態（錯乱）を発現し、この事象は非重篤な有害事象として報告された。2010 年 6 月 1 日、被験者は肺塞栓症を発現し、リバーロキサバンの投与を開始した。2010 年 6 月 3 日、錯乱状態の原因を調べるために頭部 CT スキャンを実施したところ、血腫が 12mm から 16mm に増大していた。2010 年 6 月 7 日には 16mm から 18mm に増大した。2010 年 6 月 3 日のヘモグロビン値は 11.7g/dL、血小板数は 353giga/L であった。2010 年 6 月 7 日、本事象により治験薬の投与は中止された。2010 年 7 月 20 日、被験者の容体が悪化したため、外科的ドレナージを行った。2010 年 7 月 23 日、被験者を集中治療室に収容し再手術を実施した。収容時に傾眠及びバビンスキー徴候両側陽性の左半身まひがみられた。神経学的退化、全身のけいれん発作及び長時間の深昏睡の進行が顕著であった。2010 年 7 月、頭部 CT スキャンにより、右硬膜下に血腫の集まり、及び中程度の腫瘤が依然認められた。valproate sodium、Keppra、Diphantoine、Topamax による 4 薬併用療法を行ったが、けいれんの発作が起こり危険な状態が続いた。2010 年 7 月 27 日、バルビタール昏睡療法を実施した。デブロッキング法を実施したところ、抗てんかん薬の適正用量による治療を行ったにもかかわらず多発性てんかんが再発した。家人と相談の上、治療の中止が決定された。本事象に対する治療は行われなかった。2010 年 8 月 2 日、ヘモグロビン値 8.0g/dL。同日、本事象により被験者は死亡に至った。剖検は実施されなかった。

CIAC は、硬膜下血腫（出血：硬膜下血腫悪化）を「重大な出血事象」とみなし、死亡原因を出血と判定した。

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
Hemoglobin	Local: 11.8-15.5 g/dL	31 May 2010	**10.8 g/dL (L)**	03 Jun 2010	**11.7 g/dL (L)**	02 Aug 2010	**8.0 g/dL (L)**
Platelets	Local: 174-402 giga/L	31 May 2010	292 giga/L	03 Jun 2010	353 giga/L		
PICT Seconds	Central: 24.80-36.40 S	01 Jun 2010	**36.70 S (H)**				

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083033

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280083033/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/89/WHITE/BELGIUM/YES
Medical history	Cardiac failure, Urinary tract infection, Fall, Hypertension, Insomnia, Bundle branch block left, Loss of consciousness, Oedema peripheral, Overweight, Periorbital haematoma, Uterine leiomyoma, Renal failure chronic, Postmenopause, Vessel puncture site haematoma, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTONE [SPIRONOLACTONE], AMOXICLAV, ASAFLOW, AUGMENTIN, BURINEX, CAPOTEN, CARDIOASPIRINE, CETRIZINE, CIPROXINE, CLEXANE, CONTRAMAL, DAFALGAN, DUROGESIC, FLAGYL, HEPARIN, ISOTEN, KALEORID, LASIX, LEXOTAN, LOSEC, MAGNETOP, MEDROL, MODURETIC, MOTILIUM, OXYNORM, RANITIDINE, SCHERIPROCT [HYDROCHLORIDE,PREDNISOLONE CAPROATE], XANAX
Adverse Events (AE) Preferred term	1. Biliary tract infection bacterial 2. Depression 3. Haemorrhoids 4. Epistaxis 5. Metrorrhagia 6. Hypokalaemia 7. Dizziness 8. Haematuria 9. Hepatic enzyme increased 10. Pruritus 11. Mitral valve incompetence 12. Aortic valve incompetence 13. Hypomagnesaemia 14. Cellulitis 15. Nausea 16. Vomiting 17. Abdominal pain 18. Hyperuricaemia 19. Gallbladder cancer 20. Cholelithiasis 21. Subcutaneous haematoma 22. Pain in extremity 23. Diarrhoea 24. Rectal haemorrhage 25. Fall
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. SEVERE/YES/YES/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/YES/YES 8. MODERATE/YES/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083033

Parameter	Value
	9. SEVERE/NO/NO/YES
	10. MODERATE/NO/NO/YES
	11. MILD/NO/NO/YES
	12. MODERATE/NO/NO/YES
	13. MODERATE/NO/NO/YES
	14. MODERATE/NO/NO/YES
	15. MODERATE/NO/NO/YES
	16. MILD/NO/NO/YES
	17. SEVERE/NO/NO/YES
	18. MILD/NO/NO/YES
	19. SEVERE/NO/YES/YES
	20. SEVERE/NO/YES/YES
	21. MODERATE/YES/NO/YES
	22. MILD/NO/NO/YES
	23. MILD/NO/NO/YES
	24. MODERATE/YES/NO/YES
	25. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --AUG2010 (.) - --------- (.)
	2. --SEP2010 (.) - --------- (.)
	3. --SEP2010 (.) - --------- (.)
	4. 18JUN2010 (3) - 18JUN2010 (3)
	5. 21JUN2010 (6) - 23JUN2010 (8)
	6. 24JUN2010 (9) - --------- (.)
	7. 25JUN2010 (10) - 05JUL2010 (20)
	8. 25JUN2010 (10) - --AUG2010 (.)
	9. 25JUN2010 (10) - --------- (.)
	10. 02JUL2010 (17) - --------- (.)
	11. 02JUL2010 (17) - --------- (.)
	12. 02JUL2010 (17) - --------- (.)
	13. 02JUL2010 (17) - 03JUL2010 (18)
	14. 07JUL2010 (22) - --------- (.)
	15. 14JUL2010 (29) - --------- (.)
	16. 04AUG2010 (50) - 04AUG2010 (50)
	17. 05AUG2010 (51) - --------- (.)
	18. 10AUG2010 (56) - --------- (.)
	19. 11AUG2010 (57) - 17OCT2010 (124)
	20. 11AUG2010 (57) - 17AUG2010 (63)
	21. 18AUG2010 (64) - --------- (.)
	22. 18AUG2010 (64) - --AUG2010 (.)
	23. 26AUG2010 (72) - 26AUG2010 (72)
	24. 27SEP2010 (104) - --------- (.)
	25. 27SEP2010 (104) - 27SEP2010 (104)
Duration of AE	1. .
	2. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083033

Parameter	Value
	3. .
	4. 1
	5. 3
	6. .
	7. 11
	8. .
	9. .
	10. .
	11. .
	12. .
	13. 2
	14. .
	15. .
	16. 1
	17. .
	18. .
	19. 68
	20. 7
	21. .
	22. .
	23. 1
	24. .
	25. 1
Dose on AE onset	1.
	2.
	3.
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 15 mg
	12. 15 mg
	13. 15 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083033

Parameter	Value
	22. 20 mg
	23. 20 mg
	24. 20 mg
	25. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
	18. .
	19. I
	20. I
	21. .
	22. .
	23. .
	24. .
	25. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. OTHER
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083033

Parameter	Value
	16. NONE
	17. REMEDIAL DRUG THERAPY
	18. NONE
	19. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	20. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	21. NONE
	22. NONE
	23. NONE
	24. NONE
	25. NONE
Outcome of event	1. INSUFFICIENT FOLLOW-UP
	2. UNCHANGED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. INSUFFICIENT FOLLOW-UP
	7. RESOLVED
	8. RESOLVED
	9. IMPROVED
	10. INSUFFICIENT FOLLOW-UP
	11. UNCHANGED
	12. UNCHANGED
	13. RESOLVED
	14. UNCHANGED
	15. UNCHANGED
	16. RESOLVED
	17. UNCHANGED
	18. INSUFFICIENT FOLLOW-UP
	19. DEATH
	20. RESOLVED
	21. INSUFFICIENT FOLLOW-UP
	22. RESOLVED
	23. RESOLVED
	24. INSUFFICIENT FOLLOW-UP
	25. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083041

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280083041/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/43/WHITE/BELGIUM/YES
Medical history	Complex regional pain syndrome, Anxiety, Diverticulum intestinal, Crohn's disease, Depression, Endometriosis, Gastritis, Hepatic steatosis, Hiatus hernia, Hypercholesterolaemia, Myocardial infarction, Obesity, Female sterilisation, Tobacco user
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, BROMAZEPAM, BUSCOPAN, CARDIOASPIRINE, CLEXANE, DAFALGAN, DIPRIVAN, FENTANYL, FLEET ENEMA, LITICAN, MICROLAX, PANTOMED, PERFUSALGAN, PRIMOLUT [NORETHISTERONE], PRIMPERAN, SIMVASTATINE, SPAMOMEN, TILDIEM RETARD, TRADONAL, XANAX
Adverse Events (AE) Preferred term	1. Visual acuity reduced 2. Constipation 3. Pruritus 4. Cholelithiasis 5. Cholelithiasis 6. Benign bone neoplasm
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --DEC2010 (.) - --------- (.) 2. 28SEP2010 (2) - 29SEP2010 (3) 3. 30SEP2010 (4) - 11OCT2010 (15) 4. 10NOV2010 (45) - 26NOV2010 (61) 5. 27NOV2010 (62) - 07DEC2010 (72) 6. 24JAN2011 (120) - --------- (.)
Duration of AE	1. . 2. 2 3. 12 4. 17 5. 11 6. .
Dose on AE onset	1. 2. 15 mg 3. 15 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083041

Parameter	Value
	5. I
	6. F
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	6. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083042

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280083042/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/73/WHITE/BELGIUM/YES
Medical history	Abdominal pain, Alopecia, Asthenia, Breast cancer, Breast reconstruction, Constipation, Cough, Haemorrhoid operation, Hepatic cyst, Hypercholesterolaemia, Hysterectomy, Mastectomy, Oedema peripheral, Oesophagitis, Osteoporosis, Pleural effusion, Respiratory failure, Sclerotherapy, Venous insufficiency, Pneumonia, Arthritis, Haemorrhagic hepatic cyst
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, ALDACTONE [SPIRONOLACTONE], ASAFLOW, AVELOX, BECOZYME, CALCIUM, CARDIOASPIRINE, D CURE, DAFALGAN, DOLZAM, EZETIBINE, LASIX, LITICAN, METOCLOPRAMIDE, MOVICOL, OMEPRAZOLE, PARAFINE, SIMVASTATINE, SIPRALEXA, TRADONAL, WYLAXINE, XANAX
Adverse Events (AE) Preferred term	1. Salivary gland enlargement 2. Respiratory failure 3. Anxiety 4. Hyperglycaemia 5. Anaemia of chronic disease 6. Thrombocytosis 7. Hiatus hernia 8. Gastric polyps 9. Gastritis 10. Depression 11. Pain in extremity 12. Inferior vena caval occlusion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/YES/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --JUN2011 (.) - --------- (.) 2. 08DEC2010 (3) - 10DEC2010 (5) 3. 08DEC2010 (3) - 20DEC2010 (15) 4. 08DEC2010 (3) - 08DEC2010 (3) 5. 10DEC2010 (5) - 01FEB2011 (58) 6. 16DEC2010 (11) - 01FEB2011 (58) 7. 17DEC2010 (12) - --------- (.) 8. 17DEC2010 (12) - --------- (.) 9. 17DEC2010 (12) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083042

Parameter	Value
	10. 16FEB2011 (73) - --MAR2011 (.)
	11. 01APR2011 (117) - --------- (.)
	12. 15JUN2011 (192) - --------- (.)
Duration of AE	1. .
	2. 3
	3. 13
	4. 1
	5. 54
	6. 48
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. OTHER
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083042

Parameter	Value
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. UNCHANGED
	9. UNCHANGED
	10. RESOLVED
	11. UNCHANGED
	12. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083043

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280083043/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/33/WHITE/BELGIUM/YES
Medical history	Back pain, Depression, Foot fracture, Hypercholesterolaemia, Meigs' syndrome, Palpitations, Pleural effusion, Schizophrenia, Vitamin D deficiency, Dyspnoea exertional
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, CALCIT D3 CALCIUM CARBONATE 2,5 G + COLÉCALCIFÉROL 880 UI], CERAZETTE, DAFALGAN, DIANE, DIPIPERON, EDRONAX, ENOXAPARIN, KONAKION, RIVOTRIL, SEROQUEL, SIPRALEXA, TRADONAL, ZYRTEC
Adverse Events (AE) Preferred term	1. Food intolerance 2. Depression 3. Suicide attempt 4. Overdose 5. Rhabdomyolysis 6. Pain in extremity
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 31JAN2011 (19) - 01FEB2011 (20) 2. 15FEB2011 (34) - --------- (.) 3. 04APR2011 (82) - 04APR2011 (82) 4. 04APR2011 (82) - 05APR2011 (83) 5. 06APR2011 (84) - --------- (.) 6. 05MAY2011 (113) - 06MAY2011 (114)
Duration of AE	1. 2 2. . 3. 1 4. 2 5. . 6. 2
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280083043

Parameter	Value
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED PERMANENTLY
	4. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280123002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280123002/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/25/WHITE/BELGIUM/YES
Medical history	Arthralgia, Crohn's disease, Erythema nodosum, Tachycardia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALIZAPRIDE, AMOXICILLIN W/CLAVULANIC ACID, CACIT VITAMINE D3 1000/880, CIPROFLOXACINE, ENOXAPARIN, MESALAZINE, METHOTREXAAT, METHYLPREDNISILON, METHYLPREDNISOLON, MOXIFLOXACIN, NADROPARIN, PARACETAMOL, PHYTOMENADION, PIPERACILLIN W/TAXOBACTAM, PIPERACILLIN W/TAZOBACTAM, RANITIDINE, TRAMADOL HYDROCHLORIDE, VENOFER, WARFARIN
Adverse Events (AE) Preferred term	1. Pyrexia 2. Pain in extremity 3. Pyrexia 4. Pyrexia 5. Epistaxis 6. Viral infection 7. Intestinal haemorrhage 8. Pyrexia 9. Intestinal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. SEVERE/YES/YES/YES 8. MODERATE/NO/NO/NO 9. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 17SEP2007 (5) - 24SEP2007 (12) 2. 07OCT2007 (25) - 07OCT2007 (25) 3. 11OCT2007 (29) - 21OCT2007 (39) 4. 22OCT2007 (40) - 17NOV2007 (66) 5. 24DEC2007 (103) - 07JAN2008 (117) 6. 01JAN2008 (111) - --JAN2008 (.) 7. 04JAN2008 (114) - 07JAN2008 (117) 8. 22JAN2008 (132) - 07FEB2008 (148) 9. 23JAN2008 (133) - 12FEB2008 (153)
Duration of AE	1. 8 2. 1 3. 11 4. 27 5. 15 6. . 7. 4 8. 17

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280123002

Parameter	Value
	9. 21
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED
	6. REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280123002

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280133003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280133003/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/55/WHITE/BELGIUM/YES
Medical history	Rosacea, Constipation, Emphysema, Pyrexia, Hypercholesterolaemia, Cough, Nervousness, Lobar pneumonia, Pulmonary infarction, Tobacco user, Exposure to chemical pollution
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CETIRIZINE, DAFALGAN, DIPIDOLOR, DUOVENT (AEROSOL), EPSIPAM, IMPORTAL, INFLUVAC (VACCINE), LYSOMUCIL, PERFUSALGAN, PNEUMOCOCCUS VACCINE, SOLUMEDROL, SPIRIVA, TEDIVAX (VACCINE), TETRALYSAL, XANAX, ZANTAC, ZOCOR
Adverse Events (AE) Preferred term	1. Rosacea 2. Liver function test abnormal 3. Pneumothorax 4. Constipation 5. Lobar pneumonia 6. Constipation 7. Acute sinusitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/NO 6. MILD/NO/NO/NO 7. SEVERE/NO/NO/NO
Start/stop date of event with relative date	1. --JUL2007 (.) - --AUG2007 (.) 2. 27JUN2007 (1) - 12JUL2007 (16) 3. 28JUL2007 (32) - 28JUL2007 (32) 4. 30JUL2007 (34) - 03AUG2007 (38) 5. 10JAN2008 (198) - 18JAN2008 (206) 6. 11JAN2008 (199) - 18JAN2008 (206) 7. 12JAN2008 (200) - --------- (.)
Duration of AE	1. . 2. 16 3. 1 4. 5 5. 9 6. 8 7. .
Dose on AE onset	1. 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg
Dose status on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280133003

Parameter	Value
	2. .
	3. .
	4. .
	5. F
	6. F
	7. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. IMPROVED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280173001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280173001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/71/WHITE/BELGIUM/YES
Medical history	Anaemia, Appendicectomy, Breast cancer, Breast cancer, Mammoplasty, Carpal tunnel syndrome, Cervical cord compression, Chronic obstructive pulmonary disease, Depression, Diabetes mellitus, Drug hypersensitivity, Goitre, Hypercholesterolaemia, Hypertension, Meniere's disease, Metastases to lung, Spinal laminectomy, Endometrial sarcoma, Pelvic neoplasm, Asthma, Ureteral stent insertion, Intervertebral disc protrusion, Spinal fusion surgery, Spinal osteoarthritis, Thyroidectomy, Metastases to pelvis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AROMASIN, BETASERC, BIFITERAL, BUSCOPAN, CLEXANE, DAFALGAN, DITROPAN, DUROGESIC, ELTHYRONE, ENOXAPARIN, FORLAX, LITICAN, METATOP, MORFINE, MOTILIUM, OXYGEN, PERFUSALGAN, PIRACETAM, SERETIDE, SEROXAT, TRAZOLAN, WARFARIN
Adverse Events (AE) Preferred term	1. Vomiting 2. Urinary tract infection 3. Respiratory failure
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 19APR2010 (6) - 19APR2010 (6) 2. 23APR2010 (10) - --------- (.) 3. 25APR2010 (12) - 25APR2010 (12)
Duration of AE	1. 1 2. . 3. 1
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. NONE
Outcome of event	1. RESOLVED 2. UNCHANGED 3. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280173002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280173002/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/79/WHITE/BELGIUM/YES
Medical history	Osteoarthritis, Bronchitis, Chronic sinusitis, Depression, Hypertension, Interstitial lung disease, Back pain, Pulmonary fibrosis, Polymyalgia rheumatica, Thrombophlebitis, Gastroenteritis viral, Knee operation, Cervical root pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACEDICONE, AUGMENTIN, AVELOX, D-VITAL, FOLIUMACID, FORLAX, HYGROTON, IMURAN, LEDERTREXATE, LYSOMUCIL, MEDROL, OXYGEN, PARACETAMOL, SERETIDE, SOLU-MEDROL
Adverse Events (AE) Preferred term	1. Interstitial lung disease 2. Constipation 3. Tachycardia 4. General physical health deterioration 5. Catheter site haemorrhage 6. Proteus test positive 7. Moraxella test positive 8. Atrial fibrillation 9. Aspergillus test positive 10. Pneumothorax
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/NO 6. MILD/NO/NO/NO 7. MILD/NO/NO/NO 8. MILD/NO/NO/NO 9. MODERATE/NO/NO/NO 10. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 14APR2010 (1) - 13MAY2010 (30) 2. 23APR2010 (10) - --------- (.) 3. 24APR2010 (11) - --------- (.) 4. 24APR2010 (11) - --------- (.) 5. 27APR2010 (14) - 27APR2010 (14) 6. 27APR2010 (14) - --------- (.) 7. 27APR2010 (14) - --------- (.) 8. 29APR2010 (16) - 29APR2010 (16) 9. 03MAY2010 (20) - --------- (.) 10. 06MAY2010 (23) - --------- (.)
Duration of AE	1. 30 2. . 3. . 4. . 5. 1 6. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280173002

Parameter	Value
	7. .
	8. 1
	9. .
	10. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
Dose status on AE onset	1. .
	2. .
	3. F
	4. F
	5. F
	6. F
	7. F
	8. F
	9. F
	10. F
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. OTHER
Outcome of event	1. DEATH
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. RESOLVED
	6. UNCHANGED
	7. UNCHANGED
	8. RESOLVED
	9. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280173002

Parameter	Value
	10. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280173006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280173006/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/39/WHITE/BELGIUM/YES
Medical history	
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DAFALGAN, ENOXAPARIN, PERFUSALGAN, VENTOLIN, WARFARIN
Adverse Events (AE) Preferred term	1. Phlebitis superficial 2. Lung neoplasm 3. Headache 4. Groin pain 5. Aspartate aminotransferase increased 6. Alanine aminotransferase increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 12JUL2010 (57) - 17AUG2010 (93) 2. 30AUG2010 (106) - 03SEP2010 (110) 3. 30AUG2010 (106) - 31AUG2010 (107) 4. 30AUG2010 (106) - 31AUG2010 (107) 5. 17SEP2010 (124) - 08JAN2011 (237) 6. 17SEP2010 (124) - 08JAN2011 (237)
Duration of AE	1. 37 2. 5 3. 2 4. 2 5. 114 6. 114
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. NONE 3. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280173006

Parameter	Value
	4. NONE
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-280173006[2)]	RIGHT LOWER LUNG NODULAR INFILTRATIONS（PT：肺新生物） 治験担当医はワルファリンと報告事象との関連性があると判断した。弊社は、ワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280173022

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280173022/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/67/WHITE/BELGIUM/YES
Medical history	Chronic obstructive pulmonary disease, Diabetes mellitus, Emphysema, Gout, Haemorrhoids, Hypercholesterolaemia, Hypertension, Hypokalaemia, Hyponatraemia, Hypogammaglobulinaemia, Infective exacerbation of chronic obstructive airways disease, Cataract operation, Cataract operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, AERIUS, ALLOPURINOL, ANALGETIC INFILTRATION NOS, AUGMENTIN, AVELOX, AZITHROMYCINE, BELSAR PLUS, BRUFEN, COMBIVENT, DAFALGAN, FENISTIL, FORLAX, IMOVANE, LASIX, MEDROL, METFORMAX, MIXTARD, MULTIGAM, NOVO MIX, NOVOMIX, OLMETEC, OXYGEN, PANADOL, SOLU-MEDROL, SPIRIVA, SYMBICORT, TILDIEM, VENTOLIN, XYZALL, ZOCOR
Adverse Events (AE) Preferred term	1. Alopecia 2. Insomnia 3. Pruritus 4. Back pain 5. Oedema peripheral 6. Bronchitis 7. Pruritus 8. Pneumonia 9. Headache 10. Constipation
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/NO 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/YES/NO/YES 8. MODERATE/NO/YES/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JUN2011 (.) - 13SEP2011 (216) 2. 09FEB2011 (0) - --------- (.) 3. 12FEB2011 (3) - 27FEB2011 (18) 4. 20FEB2011 (11) - 11MAY2011 (91) 5. 10MAR2011 (29) - --------- (.) 6. 12MAR2011 (31) - 26MAR2011 (45) 7. 12JUN2011 (123) - 01AUG2011 (173) 8. 22JUN2011 (133) - 14JUL2011 (155) 9. 01JUL2011 (142) - 01JUL2011 (142) 10. 01JUL2011 (142) - 05JUL2011 (146)
Duration of AE	1. . 2. . 3. 16

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280173022

Parameter	Value
	4. 81
	5. .
	6. 15
	7. 51
	8. 23
	9. 1
	10. 5
Dose on AE onset	1.
	2.
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. IMPROVED
	6. RESOLVED
	7. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280173022

Parameter	Value
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280193001/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/31/WHITE/BELGIUM/YES
Medical history	Bilirubin conjugated increased, Cardiac failure chronic, Constipation, Duchenne muscular dystrophy, Oedema peripheral, Obstructive airways disorder, Osteopenia, Congestive cardiomyopathy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTIFED, AMUKIN, AUGMENTIN, AVELOX, BIOGLUCOSAMINE, BURINEX, BUSCOPAN, CLARITHROMYCINE, COVERSYL, DAFALGAN, DOBUTREX, DOLZAM, FLEET, GLUCOSE, KREDEX, LASIX, LEVOCETIRIZINE, LEVOTUSS, LYSOMUCIL, MERONEM, MOTILIUM, MOVICOL, PERFUSALGAN, PROFLOX, SPIRONOLACTONE, STILNOCT, TETRALYSAL
Adverse Events (AE) Preferred term	1. Dermatitis 2. Decubitus ulcer 3. Nausea 4. Lung infection 5. Abdominal pain 6. Vomiting 7. Cardiac failure 8. Blood bilirubin increased 9. Flatulence 10. Oedema peripheral 11. Cardiac failure 12. Blood bilirubin increased 13. Abdominal pain 14. Abdominal distension 15. Blood bilirubin increased 16. Blood bilirubin increased 17. Abdominal pain 18. Musculoskeletal pain 19. Blood bilirubin increased 20. Bronchopneumonia 21. Haemoptysis 22. Haematuria 23. Vomiting 24. Insomnia 25. Abdominal pain upper 26. Lung infection 27. Arrhythmia 28. Anxiety 29. Chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/YES/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193001

Parameter	Value
	7. SEVERE/NO/YES/YES
	8. MILD/YES/NO/YES
	9. MODERATE/NO/NO/YES
	10. SEVERE/NO/NO/YES
	11. SEVERE/NO/YES/YES
	12. MODERATE/YES/NO/YES
	13. MODERATE/NO/NO/YES
	14. MODERATE/NO/NO/YES
	15. MILD/YES/NO/YES
	16. MILD/YES/NO/YES
	17. MODERATE/NO/NO/YES
	18. MODERATE/NO/NO/YES
	19. MILD/YES/NO/YES
	20. MODERATE/NO/YES/YES
	21. MILD/YES/NO/YES
	22. MILD/YES/NO/YES
	23. MILD/NO/NO/YES
	24. MODERATE/NO/NO/YES
	25. MILD/NO/NO/YES
	26. MODERATE/NO/NO/YES
	27. SEVERE/NO/YES/NO
	28. SEVERE/NO/NO/NO
	29. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --FEB2011 (.) - --------- (.)
	2. 21MAY2010 (2) - 27MAY2010 (8)
	3. 31MAY2010 (12) - 22JUN2010 (34)
	4. 11JUN2010 (23) - 19JUN2010 (31)
	5. 13JUL2010 (55) - 18JUL2010 (60)
	6. 13JUL2010 (55) - 13JUL2010 (55)
	7. 13JUL2010 (55) - 19JUL2010 (61)
	8. 13JUL2010 (55) - 25AUG2010 (98)
	9. 21AUG2010 (94) - 28AUG2010 (101)
	10. 23AUG2010 (96) - 31AUG2010 (104)
	11. 25AUG2010 (98) - 31AUG2010 (104)
	12. 25AUG2010 (98) - 23SEP2010 (127)
	13. 26AUG2010 (99) - 26AUG2010 (99)
	14. 27AUG2010 (100) - 24SEP2010 (128)
	15. 23SEP2010 (127) - 19OCT2010 (153)
	16. 18NOV2010 (183) - 13JAN2011 (239)
	17. 10DEC2010 (205) - 14DEC2010 (209)
	18. 12DEC2010 (207) - 15DEC2010 (210)
	19. 10MAR2011 (295) - --------- (.)
	20. 14APR2011 (330) - 28APR2011 (344)
	21. 16APR2011 (332) - 20APR2011 (336)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193001

Parameter	Value
	22. 17APR2011 (333) - 17APR2011 (333)
	23. 17APR2011 (333) - 17APR2011 (333)
	24. 20APR2011 (336) - --------- (.)
	25. 27APR2011 (343) - 27APR2011 (343)
	26. 04MAY2011 (350) - 13MAY2011 (359)
	27. 18MAY2011 (364) - 18MAY2011 (364)
	28. 18MAY2011 (364) - --------- (.)
	29. 18MAY2011 (364) - --------- (.)
Duration of AE	1. .
	2. 7
	3. 23
	4. 9
	5. 6
	6. 1
	7. 7
	8. 44
	9. 8
	10. 9
	11. 7
	12. 30
	13. 1
	14. 29
	15. 27
	16. 57
	17. 5
	18. 4
	19. .
	20. 15
	21. 5
	22. 1
	23. 1
	24. .
	25. 1
	26. 10
	27. 1
	28. .
	29. .
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193001

Parameter	Value
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
	22. 20 mg
	23. 20 mg
	24. 20 mg
	25. 20 mg
	26. 20 mg
	27. 20 mg
	28. 20 mg
	29. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
	18. .
	19. .
	20. .
	21. .
	22. I

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193001

Parameter	Value
	23. I
	24. .
	25. .
	26. .
	27. F
	28. F
	29. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	8. NONE
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. NONE
	16. NONE
	17. REMEDIAL DRUG THERAPY
	18. REMEDIAL DRUG THERAPY
	19. NONE
	20. REMEDIAL DRUG THERAPY,OTHER
	21. STUDY DRUG DISCONTINUED AND RESTARTED
	22. NONE
	23. NONE
	24. REMEDIAL DRUG THERAPY
	25. REMEDIAL DRUG THERAPY
	26. REMEDIAL DRUG THERAPY
	27. REMEDIAL DRUG THERAPY
	28. REMEDIAL DRUG THERAPY
	29. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. WORSENED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193001

Parameter	Value
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. IMPROVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. UNCHANGED
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED
	23. RESOLVED
	24. UNCHANGED
	25. RESOLVED
	26. RESOLVED
	27. DEATH
	28. UNCHANGED
	29. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280193002/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/83/WHITE/BELGIUM/YES
Medical history	Anaemia, Aortic aneurysm, Osteoarthritis, Asthma, Chronic obstructive pulmonary disease, Cough, Hypercholesterolaemia, Hypertension, Insomnia, Lung infiltration, Myocardial infarction, Phimosis, Benign prostatic hyperplasia, Cataract, Calculus urinary, Calculus urinary, Testicular cyst, Tobacco user, Periarthritis, Bundle branch block right, Coronary arterial stent insertion, Myocardial ischaemia, Sinusitis, Infective exacerbation of chronic obstructive airways disease, Inguinal hernia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ALPRAZOLAM, ATARAX, BEFACTE FORTE, BUSCOPAN, CARDIOASPIRINE, CIPROFLOXACINE, CIPROXINE, CLEXANE, COMBIVENT, COZAAR, D-CURE, DAFALGAN, DIFLUCAN, DOLZAM, DORMICUM, ENOXAPARIN, ENTEROL [SACCHAROMYCES BOULARDII], FASTUM, FOLAVIT, FUROSEMIDE, LITICAN, LORAMET, LYSOMUCIL, MAALOX, MEDROL, MISTABRON, MOTILIUM, MOVICOL, NOBITEN, OMEPRAZOLE, PERFUSALGAN, PRIMPERAN, PULMICORT, SOLU-MEDROL, SPIRIVA, SYMBICORT, TAVANIC, TEVETEN, VOLULYTE 6%, ZANTAC, ZOCOR
Adverse Events (AE) Preferred term	1. Anaemia 2. Abdominal pain 3. Hypotension 4. Fungal oesophagitis 5. Subcutaneous haematoma 6. Cough 7. Respiratory tract congestion 8. Decreased appetite 9. Weight decreased 10. Constipation 11. Vitamin B12 deficiency 12. Folate deficiency 13. Vitamin D deficiency 14. Urinary retention 15. Cystitis haemorrhagic 16. Chronic obstructive pulmonary disease 17. Chronic obstructive pulmonary disease 18. Oedema peripheral 19. Overdose 20. Abdominal pain upper 21. Nausea 22. Vomiting 23. Hypotension 24. Anaemia 25. Pain in extremity 26. Dyspnoea 27. Abdominal pain upper 28. Diarrhoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193002

Parameter	Value
	2. SEVERE/NO/NO/YES
	3. MODERATE/NO/NO/YES
	4. MODERATE/NO/NO/YES
	5. MODERATE/NO/NO/YES
	6. MODERATE/NO/NO/YES
	7. MODERATE/NO/NO/YES
	8. MODERATE/NO/NO/YES
	9. MODERATE/NO/NO/YES
	10. MODERATE/NO/NO/YES
	11. MODERATE/NO/NO/YES
	12. MODERATE/NO/NO/YES
	13. MODERATE/NO/NO/YES
	14. MODERATE/NO/NO/YES
	15. MODERATE/YES/NO/YES
	16. MILD/NO/NO/YES
	17. MODERATE/NO/YES/YES
	18. MILD/NO/NO/YES
	19. MILD/YES/NO/YES
	20. MODERATE/NO/NO/YES
	21. MODERATE/NO/NO/YES
	22. MILD/NO/NO/YES
	23. MODERATE/NO/NO/YES
	24. MODERATE/NO/NO/YES
	25. MODERATE/NO/NO/YES
	26. MODERATE/NO/NO/YES
	27. MODERATE/NO/NO/YES
	28. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 15SEP2010 (6) - 25DEC2010 (107)
	2. 15SEP2010 (6) - 15SEP2010 (6)
	3. 15SEP2010 (6) - 16SEP2010 (7)
	4. 16SEP2010 (7) - 15NOV2010 (67)
	5. 17SEP2010 (8) - 24SEP2010 (15)
	6. 25OCT2010 (46) - 30NOV2010 (82)
	7. 25OCT2010 (46) - 30NOV2010 (82)
	8. 25OCT2010 (46) - 01MAR2011 (173)
	9. 25OCT2010 (46) - --------- (.)
	10. 24NOV2010 (76) - 29NOV2010 (81)
	11. 25NOV2010 (77) - --------- (.)
	12. 25NOV2010 (77) - --------- (.)
	13. 25NOV2010 (77) - --------- (.)
	14. 25NOV2010 (77) - 27FEB2011 (171)
	15. 24DEC2010 (106) - --DEC2010 (.)
	16. 05JAN2011 (118) - 11JAN2011 (124)
	17. 11JAN2011 (124) - 25JAN2011 (138)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193002

Parameter	Value
	18. 11JAN2011 (124) - 25JAN2011 (138)
	19. 13JAN2011 (126) - 16JAN2011 (129)
	20. 14JAN2011 (127) - 14JAN2011 (127)
	21. 14JAN2011 (127) - 14JAN2011 (127)
	22. 21FEB2011 (165) - 21FEB2011 (165)
	23. 21FEB2011 (165) - 25FEB2011 (169)
	24. 22FEB2011 (166) - --------- (.)
	25. 22FEB2011 (166) - 22FEB2011 (166)
	26. 22FEB2011 (166) - 24FEB2011 (168)
	27. 25FEB2011 (169) - 26FEB2011 (170)
	28. 25FEB2011 (169) - 26FEB2011 (170)
Duration of AE	1. 102
	2. 1
	3. 2
	4. 61
	5. 8
	6. 37
	7. 37
	8. 128
	9. .
	10. 6
	11. .
	12. .
	13. .
	14. 95
	15. .
	16. 7
	17. 15
	18. 15
	19. 4
	20. 1
	21. 1
	22. 1
	23. 5
	24. .
	25. 1
	26. 3
	27. 2
	28. 2
Dose on AE onset	1.
	2.
	3.
	4.
	5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193002

Parameter	Value
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
	27.
	28.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193002

Parameter	Value
	22.
	23.
	24.
	25.
	26.
	27.
	28.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. OTHER
	8. NONE
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. OTHER
	15. REMEDIAL DRUG THERAPY
	16. NONE
	17. REMEDIAL DRUG THERAPY
	18. NONE
	19. STUDY DRUG DISCONTINUED AND RESTARTED
	20. REMEDIAL DRUG THERAPY
	21. REMEDIAL DRUG THERAPY
	22. REMEDIAL DRUG THERAPY
	23. REMEDIAL DRUG THERAPY
	24. NONE
	25. REMEDIAL DRUG THERAPY
	26. REMEDIAL DRUG THERAPY
	27. REMEDIAL DRUG THERAPY
	28. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193002

Parameter	Value
	10. RESOLVED
	11. UNCHANGED
	12. UNCHANGED
	13. IMPROVED
	14. RESOLVED
	15. RESOLVED
	16. WORSENED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED
	23. RESOLVED
	24. IMPROVED
	25. RESOLVED
	26. RESOLVED
	27. RESOLVED
	28. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280193004/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/77/WHITE/BELGIUM/YES
Medical history	Anxiety, Arthralgia, Asthenia, Chronic obstructive pulmonary disease, Hypotension, Dyspnoea, Lung adenocarcinoma, Lung adenocarcinoma, Lung carcinoma cell type unspecified recurrent, Lung carcinoma cell type unspecified recurrent, Metastases to spine, Benign prostatic hyperplasia, Skin cyst excision, Thrombophlebitis, Tremor, Varicose vein operation, Hypoacusis, Gastric ulcer helicobacter, Paraesthesia, Hamartoma, Tendon pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ASAFLOW, AUGMENTIN, EFFORTIL, ENOXAPARIN, EUCALYTUX, FOLAVIT, TEMESTA, TERAZOSABB, TRUSOPT, ZOMETA
Adverse Events (AE) Preferred term	1. Glaucoma 2. Cough 3. Cough 4. Hypotension 5. Respiratory tract infection 6. Lung carcinoma cell type unspecified recurrent
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --JAN2011 (.) - --------- (.) 2. 21FEB2011 (127) - 27MAR2011 (161) 3. 28MAR2011 (162) - 09JUN2011 (235) 4. 02JUN2011 (228) - 17JUN2011 (243) 5. 02JUN2011 (228) - 09JUN2011 (235) 6. 08AUG2011 (295) - --------- (.)
Duration of AE	1. . 2. 35 3. 74 4. 16 5. 8 6. .
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193004

Parameter	Value
	5.
	6.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. IMPROVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/280193009/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/62/WHITE/BELGIUM/YES
Medical history	Aortic aneurysm, Anal fistula, Appendicectomy, Diverticulum intestinal, Chronic obstructive pulmonary disease, Cytomegalovirus infection, Erysipelas, Hepatic cyst, Hiatus hernia, Hypertension, Inguinal hernia repair, Insomnia, Spinal osteoarthritis, Myelopathy, Pleural effusion, Pneumonia chlamydial, Musculoskeletal pain, Tobacco user, Spinal fusion surgery, Bronchitis, Musculoskeletal pain, Arteriosclerosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ABELCET, ACEDICON, ACETYLCYSTEINE, ACTAPULGITE, ALDACTONE [SPIRONOLACTONE], ALIMTA, ALPRAZOLAM, AUGMENTIN, BACTRIM, BEFACT FORTE, BIO-D-MULSION, BIO-K-MULSION, BURINEX, BUSCOPAN, CALCICLO, CIPROXINE, CLEXANE, CO-TRIMOXAZOLE, COENZYME Q10, COMBIVENT, CONTRAMAL, DAFALGAN, DAKTARIN (ORAL), DEXAMETHASONE, DIFLUCAN, DIPRIVAN, DOLZAM, DOLZAM RETARD, DORMICUM, DULCOLAX [BISACODYL], DUOVENT, DUROGESIC, EMEND, ENTEROL [SACCHAROMYCES BOULARDII], EUSAPRIM FORTE, FLEET, FLUIMICIL, FOLAVIT, FUROSEMIDE, GABBRORAL, GELOFUSINE, HALDOL, IMODIUM, KCL, LASIX, LEVOPHED, LEXOTAN, LITICAN, LYSOMUCIL, MAALOX, MAALOX FORTE, MAGNESIUM, MAXIPIME, MEDICA [CHLORHEXIDINE, DICHLORHYDRATE, LIDOCAINE,CHLORHYDRATE], MEDROL, MERONEM, MG SO4, MOTILIUM, MOVICOL, MS DIRECT, NEUROBION, NEXIAM, NIMBEX, NOVALGINE, OLAMINE [COMPLEX VITAMINS AND MINERALS], OMEPRAZOLE, OXYGEN, PANTOZOL, PERFUSALGAN, PLATINOL, PRIMPERAN, PROBACTIOL PLUS, ROCEPHINE, SERETIDE 50/500, SOLU-MEDROL, SPIRIVA, SUFENTANYL, TAMSULOSINE, TEVETEN PLUS, TILDIEM RETARD, ULTRA-K, UREA, VASEXTEN, VERSATIS 5%, VFEND, VOLTAREN, ZALDIAR, ZANTAC, ZOFRAN, ZOMETA
Adverse Events (AE) Preferred term	1. Tremor 2. Bronchitis 3. Constipation 4. Dyspnoea 5. Cough 6. Fatigue 7. Decreased appetite 8. Back pain 9. Abdominal pain upper 10. Anxiety 11. Blood pressure increased 12. Hypoxia 13. Non-small cell lung cancer 14. Haemothorax 15. Dyspnoea 16. Dyspnoea 17. Inflammation 18. Pleural effusion 19. Constipation 20. Lung infection 21. Oliguria 22. Urinary retention

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193009

Parameter	Value
	23. Benign prostatic hyperplasia
	24. Hyponatraemia
	25. Hypokalaemia
	26. Stomatitis
	27. Genital infection fungal
	28. Anaemia
	29. Hypovolaemia
	30. Hypocalcaemia
	31. Hypokalaemia
	32. Hyponatraemia
	33. Pyrexia
	34. Chronic obstructive pulmonary disease
	35. Hypotension
	36. Tachycardia
	37. Hypomagnesaemia
	38. Hypocalcaemia
	39. Hypokalaemia
	40. Anaemia
	41. Oropharyngeal pain
	42. Hyponatraemia
	43. Nausea
	44. Insomnia
	45. Fluid retention
	46. Hyponatraemia
	47. Hypocalcaemia
	48. Bronchopulmonary aspergillosis
	49. Cough
	50. Abdominal distension
	51. Vomiting
	52. Anaemia
	53. Hyponatraemia
	54. Intestinal obstruction
	55. Anaemia
	56. Hypokalaemia
	57. Hypocalcaemia
	58. Epistaxis
	59. Hyponatraemia
	60. Chills
	61. Cataract
	62. Optic disc hyperaemia
	63. Lung infection
	64. Lung infection
	65. Stomatitis
	66. Gastroenteritis

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193009

Parameter	Value
	67. Decreased appetite
	68. Chronic obstructive pulmonary disease
	69. Nausea
	70. Dyspepsia
	71. Decreased appetite
	72. Lung infection
	73. Cytolytic hepatitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MODERATE/NO/NO/YES
	3. MILD/NO/NO/YES
	4. MODERATE/NO/NO/YES
	5. MODERATE/NO/NO/YES
	6. MODERATE/NO/NO/YES
	7. MODERATE/NO/NO/YES
	8. SEVERE/NO/YES/YES
	9. MODERATE/NO/NO/YES
	10. MILD/NO/NO/YES
	11. MODERATE/NO/NO/YES
	12. MODERATE/NO/NO/YES
	13. SEVERE/NO/YES/YES
	14. MILD/YES/NO/YES
	15. SEVERE/NO/NO/YES
	16. MODERATE/NO/NO/YES
	17. MODERATE/NO/NO/YES
	18. SEVERE/NO/YES/YES
	19. MODERATE/NO/NO/YES
	20. MODERATE/NO/NO/YES
	21. MODERATE/NO/NO/YES
	22. MODERATE/NO/NO/YES
	23. MODERATE/NO/NO/YES
	24. SEVERE/NO/NO/YES
	25. MILD/NO/NO/YES
	26. MODERATE/NO/NO/YES
	27. MILD/NO/NO/YES
	28. MODERATE/NO/NO/YES
	29. MODERATE/NO/NO/YES
	30. MODERATE/NO/NO/YES
	31. SEVERE/NO/NO/YES
	32. MILD/NO/NO/YES
	33. MODERATE/NO/NO/YES
	34. SEVERE/NO/YES/YES
	35. MODERATE/NO/NO/YES
	36. MODERATE/NO/NO/YES
	37. MODERATE/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193009

Parameter	Value
	38. SEVERE/NO/NO/YES
	39. MILD/NO/NO/YES
	40. MILD/NO/NO/YES
	41. MODERATE/NO/NO/YES
	42. SEVERE/NO/NO/YES
	43. MODERATE/NO/NO/YES
	44. MODERATE/NO/NO/YES
	45. MODERATE/NO/NO/YES
	46. MILD/NO/NO/YES
	47. MILD/NO/NO/YES
	48. MODERATE/NO/NO/YES
	49. MODERATE/NO/NO/YES
	50. MODERATE/NO/NO/YES
	51. MODERATE/NO/NO/YES
	52. MODERATE/NO/NO/YES
	53. SEVERE/NO/NO/YES
	54. SEVERE/NO/NO/YES
	55. MILD/NO/NO/YES
	56. MILD/NO/NO/YES
	57. MILD/NO/NO/YES
	58. MILD/YES/NO/YES
	59. MILD/NO/NO/YES
	60. MILD/NO/NO/YES
	61. MODERATE/NO/NO/YES
	62. MODERATE/NO/NO/YES
	63. MODERATE/NO/NO/YES
	64. MODERATE/NO/NO/YES
	65. MODERATE/NO/NO/YES
	66. MODERATE/NO/NO/YES
	67. MODERATE/NO/NO/YES
	68. MODERATE/NO/YES/YES
	69. MILD/NO/NO/NO
	70. MODERATE/NO/NO/NO
	71. MODERATE/NO/NO/NO
	72. MODERATE/NO/NO/NO
	73. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --JUN2011 (.) - --------- (.)
	2. 11MAR2011 (4) - --APR2011 (.)
	3. 11MAR2011 (4) - 29APR2011 (53)
	4. 24MAR2011 (17) - 30APR2011 (54)
	5. 24MAR2011 (17) - 30APR2011 (54)
	6. 24MAR2011 (17) - --------- (.)
	7. 24MAR2011 (17) - 08JUL2011 (123)
	8. 10APR2011 (34) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193009

Parameter	Value
	9. 13APR2011 (37) - --------- (.)
	10. 14APR2011 (38) - --------- (.)
	11. 14APR2011 (38) - 14APR2011 (38)
	12. 15APR2011 (39) - --------- (.)
	13. 18APR2011 (42) - --------- (.)
	14. 30APR2011 (54) - 30APR2011 (54)
	15. 30APR2011 (54) - 30APR2011 (54)
	16. 30APR2011 (54) - --------- (.)
	17. 30APR2011 (54) - --------- (.)
	18. 30APR2011 (54) - 05MAY2011 (59)
	19. 30APR2011 (54) - --------- (.)
	20. 08MAY2011 (62) - --JUN2011 (.)
	21. 10MAY2011 (64) - 10MAY2011 (64)
	22. 11MAY2011 (65) - 13MAY2011 (67)
	23. 11MAY2011 (65) - --------- (.)
	24. 16MAY2011 (70) - 26MAY2011 (80)
	25. 16MAY2011 (70) - 26MAY2011 (80)
	26. 23MAY2011 (77) - 04JUL2011 (119)
	27. 23MAY2011 (77) - 26MAY2011 (80)
	28. 26MAY2011 (80) - 28MAY2011 (82)
	29. 26MAY2011 (80) - 27MAY2011 (81)
	30. 26MAY2011 (80) - 27MAY2011 (81)
	31. 26MAY2011 (80) - 27MAY2011 (81)
	32. 26MAY2011 (80) - 26MAY2011 (80)
	33. 26MAY2011 (80) - 28MAY2011 (82)
	34. 26MAY2011 (80) - 04JUL2011 (119)
	35. 26MAY2011 (80) - 27MAY2011 (81)
	36. 26MAY2011 (80) - 27MAY2011 (81)
	37. 27MAY2011 (81) - 16JUN2011 (101)
	38. 27MAY2011 (81) - 31MAY2011 (85)
	39. 27MAY2011 (81) - 28MAY2011 (82)
	40. 28MAY2011 (82) - 14JUN2011 (99)
	41. 28MAY2011 (82) - 10JUN2011 (95)
	42. 28MAY2011 (82) - 31MAY2011 (85)
	43. 29MAY2011 (83) - 04JUL2011 (119)
	44. 29MAY2011 (83) - 04JUL2011 (119)
	45. 30MAY2011 (84) - --------- (.)
	46. 31MAY2011 (85) - 06JUN2011 (91)
	47. 31MAY2011 (85) - 06JUN2011 (91)
	48. 01JUN2011 (86) - --JUN2011 (.)
	49. 03JUN2011 (88) - 03JUN2011 (88)
	50. 11JUN2011 (96) - --JUN2011 (.)
	51. 12JUN2011 (97) - 15JUN2011 (100)
	52. 14JUN2011 (99) - 15JUN2011 (100)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193009

Parameter	Value
	53. 14JUN2011 (99) - 16JUN2011 (101)
	54. 14JUN2011 (99) - 15JUN2011 (100)
	55. 15JUN2011 (100) - --------- (.)
	56. 15JUN2011 (100) - 16JUN2011 (101)
	57. 15JUN2011 (100) - 17JUN2011 (102)
	58. 16JUN2011 (101) - 16JUN2011 (101)
	59. 16JUN2011 (101) - 20JUN2011 (105)
	60. 17JUN2011 (102) - 17JUN2011 (102)
	61. 17JUN2011 (102) - --------- (.)
	62. 17JUN2011 (102) - --------- (.)
	63. 06JUL2011 (121) - 22JUL2011 (137)
	64. 22JUL2011 (137) - 21SEP2011 (198)
	65. 02AUG2011 (148) - 05SEP2011 (182)
	66. 03AUG2011 (149) - 14AUG2011 (160)
	67. 03AUG2011 (149) - 14AUG2011 (160)
	68. 10SEP2011 (187) - 28SEP2011 (205)
	69. 18SEP2011 (195) - 29SEP2011 (206)
	70. 18SEP2011 (195) - 29SEP2011 (206)
	71. 21SEP2011 (198) - 29SEP2011 (206)
	72. 21SEP2011 (198) - --------- (.)
	73. 23SEP2011 (200) - --------- (.)
Duration of AE	1. .
	2. .
	3. 50
	4. 38
	5. 38
	6. .
	7. 107
	8. .
	9. .
	10. .
	11. 1
	12. .
	13. .
	14. 1
	15. 1
	16. .
	17. .
	18. 6
	19. .
	20. .
	21. 1
	22. 3
	23. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193009

Parameter	Value
	24. 11
	25. 11
	26. 43
	27. 4
	28. 3
	29. 2
	30. 2
	31. 2
	32. 1
	33. 3
	34. 40
	35. 2
	36. 2
	37. 21
	38. 5
	39. 2
	40. 18
	41. 14
	42. 4
	43. 37
	44. 37
	45. .
	46. 7
	47. 7
	48. .
	49. 1
	50. .
	51. 4
	52. 2
	53. 3
	54. 2
	55. .
	56. 2
	57. 3
	58. 1
	59. 5
	60. 1
	61. .
	62. .
	63. 17
	64. 62
	65. 35
	66. 12
	67. 12

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193009

Parameter	Value
	68. 19
	69. 12
	70. 12
	71. 9
	72. .
	73. .
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
	22. 20 mg
	23. 20 mg
	24. 20 mg
	25. 20 mg
	26. 20 mg
	27. 20 mg
	28. 20 mg
	29. 20 mg
	30. 20 mg
	31. 20 mg
	32. 20 mg
	33. 20 mg
	34. 20 mg
	35. 20 mg
	36. 20 mg
	37. 20 mg
	38. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193009

Parameter	Value
	39. 20 mg
	40. 20 mg
	41. 20 mg
	42. 20 mg
	43. 20 mg
	44. 20 mg
	45. 20 mg
	46. 20 mg
	47. 20 mg
	48. 20 mg
	49. 20 mg
	50. 20 mg
	51. 20 mg
	52. 20 mg
	53. 20 mg
	54. 20 mg
	55. 20 mg
	56. 20 mg
	57. 20 mg
	58. 20 mg
	59. 20 mg
	60. 20 mg
	61. 20 mg
	62. 20 mg
	63. 20 mg
	64. 20 mg
	65. 20 mg
	66. 20 mg
	67. 20 mg
	68. 20 mg
	69. 20 mg
	70. 20 mg
	71. 20 mg
	72. 20 mg
	73. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193009

Parameter	Value
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
	18. .
	19. .
	20. I
	21. .
	22. .
	23. .
	24. .
	25. .
	26. .
	27. .
	28. .
	29. .
	30. .
	31. .
	32. .
	33. .
	34. .
	35. .
	36. .
	37. .
	38. .
	39. .
	40. .
	41. .
	42. .
	43. .
	44. .
	45. .
	46. .
	47. .
	48. .
	49. .
	50. .
	51. .
	52. .
	53. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193009

Parameter	Value
	54. .
	55. I
	56. I
	57. I
	58. .
	59. .
	60. I
	61. I
	62. I
	63. .
	64. .
	65. .
	66. .
	67. .
	68. F
	69. F
	70. F
	71. F
	72. F
	73. F
Action taken	1. OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY,OTHER
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	19. REMEDIAL DRUG THERAPY
	20. REMEDIAL DRUG THERAPY,OTHER
	21. REMEDIAL DRUG THERAPY
	22. OTHER
	23. REMEDIAL DRUG THERAPY
	24. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193009

Parameter	Value
	25. REMEDIAL DRUG THERAPY
	26. REMEDIAL DRUG THERAPY
	27. NONE
	28. OTHER
	29. REMEDIAL DRUG THERAPY
	30. REMEDIAL DRUG THERAPY
	31. REMEDIAL DRUG THERAPY
	32. NONE
	33. REMEDIAL DRUG THERAPY
	34. REMEDIAL DRUG THERAPY,OTHER
	35. REMEDIAL DRUG THERAPY
	36. NONE
	37. REMEDIAL DRUG THERAPY
	38. REMEDIAL DRUG THERAPY
	39. REMEDIAL DRUG THERAPY
	40. NONE
	41. REMEDIAL DRUG THERAPY
	42. REMEDIAL DRUG THERAPY
	43. REMEDIAL DRUG THERAPY
	44. REMEDIAL DRUG THERAPY
	45. REMEDIAL DRUG THERAPY
	46. REMEDIAL DRUG THERAPY
	47. NONE
	48. REMEDIAL DRUG THERAPY
	49. REMEDIAL DRUG THERAPY
	50. NONE
	51. REMEDIAL DRUG THERAPY
	52. OTHER
	53. REMEDIAL DRUG THERAPY
	54. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	55. NONE
	56. REMEDIAL DRUG THERAPY
	57. REMEDIAL DRUG THERAPY
	58. NONE
	59. NONE
	60. NONE
	61. NONE
	62. NONE
	63. REMEDIAL DRUG THERAPY
	64. REMEDIAL DRUG THERAPY
	65. OTHER
	66. REMEDIAL DRUG THERAPY
	67. NONE
	68. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193009

Parameter	Value
	69. NONE
	70. REMEDIAL DRUG THERAPY
	71. NONE
	72. REMEDIAL DRUG THERAPY
	73. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. WORSENED
	4. WORSENED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. UNCHANGED
	9. UNCHANGED
	10. UNCHANGED
	11. RESOLVED
	12. UNCHANGED
	13. UNCHANGED
	14. RESOLVED
	15. IMPROVED
	16. UNCHANGED
	17. UNCHANGED
	18. RESOLVED
	19. UNCHANGED
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED
	23. UNCHANGED
	24. IMPROVED
	25. RESOLVED
	26. RESOLVED
	27. RESOLVED
	28. IMPROVED
	29. RESOLVED
	30. WORSENED
	31. IMPROVED
	32. RESOLVED
	33. RESOLVED
	34. RESOLVED
	35. RESOLVED
	36. RESOLVED
	37. RESOLVED
	38. IMPROVED
	39. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 280193009

Parameter	Value
	40. WORSENED
	41. RESOLVED
	42. IMPROVED
	43. RESOLVED
	44. RESOLVED
	45. IMPROVED
	46. RESOLVED
	47. RESOLVED
	48. RESOLVED
	49. RESOLVED
	50. RESOLVED
	51. RESOLVED
	52. IMPROVED
	53. IMPROVED
	54. RESOLVED
	55. UNCHANGED
	56. RESOLVED
	57. RESOLVED
	58. RESOLVED
	59. RESOLVED
	60. RESOLVED
	61. UNCHANGED
	62. UNCHANGED
	63. RESOLVED
	64. RESOLVED
	65. RESOLVED
	66. RESOLVED
	67. RESOLVED
	68. RESOLVED
	69. RESOLVED
	70. RESOLVED
	71. RESOLVED
	72. IMPROVED
	73. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300063030

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300063030/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/56/WHITE/NETHERLANDS/YES
Medical history	Adrenal insufficiency, Dyspnoea, Fatigue, Gastritis erosive, Head discomfort, Hypercholesterolaemia, Hypothyroidism, Non-secretory adenoma of pituitary, Pneumonia, Chest pain, Gastric ulcer, Ocular discomfort, Venous insufficiency, Venous insufficiency, Hypogonadism, Tumour excision, Tumour excision, Seborrhoeic dermatitis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AMOXICILLINE/CLAVUL, CEFOTAXIM, DESMOPRESSIN, DESMOPRESSINE, ENOXAPARIN, GLUCOSE 5%, HBVAXPRO, HYDROCORTISON, HYDROCORTISON OINTMENT, INFLUVAC 2008/2009, KALIUMCHLORIDE, LEVOTHYROXINE, MICONAZOLE NITRATE, MOVICOLON, NACL 0.9%, NEXIUM, NORDIFLEX, NORIT, PARACETAMOL, SOMATROPIN INJ, TESTIM, THYRAX, ZOCOR
Adverse Events (AE) Preferred term	1. Diabetes insipidus 2. Diarrhoea 3. International normalised ratio increased 4. Nasopharyngitis 5. Pollakiuria 6. Flank pain 7. Constipation 8. Influenza 9. Headache 10. Muscle spasms 11. Ear infection 12. Influenza 13. Epididymitis
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/YES/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/NO 12. MILD/NO/NO/NO 13. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 28JUL2008 (4) - 01AUG2008 (8) 2. 30JUL2008 (6) - 07AUG2008 (14) 3. 11AUG2008 (18) - 13AUG2008 (20) 4. 11SEP2008 (49) - 15SEP2008 (53) 5. 03NOV2008 (102) - --------- (.) 6. 01FEB2009 (192) - 12JUN2009 (323)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300063030

Parameter	Value
	7. 01FEB2009 (192) - --------- (.)
	8. 05FEB2009 (196) - 10FEB2009 (201)
	9. 15APR2009 (265) - --------- (.)
	10. 14MAY2009 (294) - 12AUG2009 (384)
	11. 23JUL2009 (364) - 03AUG2009 (375)
	12. 01AUG2009 (373) - 06AUG2009 (378)
	13. 08AUG2009 (380) - --------- (.)
Duration of AE	1. 5
	2. 9
	3. 3
	4. 5
	5. .
	6. 132
	7. .
	8. 6
	9. .
	10. 91
	11. 12
	12. 6
	13. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300063030

Parameter	Value
	12.
	13.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300063073

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300063073/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/20/WHITE/NETHERLANDS/YES
Medical history	Asthma, Dyspnoea, Cough, Painful respiration, Tachycardia, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DOXYCYCLINE, HYDROCORTISON EARDROPS, PARACETAMOL, TRAMADOL, XYLOMETAZOLINE
Adverse Events (AE) Preferred term	1. Dizziness 2. Acne 3. Back pain 4. Headache 5. Menorrhagia 6. Nausea 7. Sinusitis 8. Subcutaneous haematoma 9. Haematoma 10. Varicose vein 11. Headache 12. Dizziness 13. Diplopia 14. Intracranial pressure increased 15. Headache
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/YES/NO/YES 9. MODERATE/YES/NO/NO 10. MODERATE/YES/NO/NO 11. SEVERE/NO/YES/NO 12. SEVERE/NO/NO/NO 13. MODERATE/NO/NO/NO 14. MODERATE/NO/NO/NO 15. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 11MAR2009 (2) - 23MAR2009 (14) 2. 11MAR2009 (2) - 25MAR2009 (16) 3. 11MAR2009 (2) - 23MAR2009 (14) 4. 08APR2009 (30) - 14SEP2009 (189) 5. 09APR2009 (31) - --------- (.) 6. 20MAY2009 (72) - 18SEP2009 (193) 7. 30JUN2009 (113) - 20JUL2009 (133) 8. 21JUL2009 (134) - 03AUG2009 (147)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300063073

Parameter	Value
	9. 14SEP2009 (189) - --------- (.)
	10. 14SEP2009 (189) - --------- (.)
	11. 15SEP2009 (190) - 18SEP2009 (193)
	12. 15SEP2009 (190) - --------- (.)
	13. 15SEP2009 (190) - --------- (.)
	14. 16SEP2009 (191) - --------- (.)
	15. 19SEP2009 (194) - --------- (.)
Duration of AE	1. 13
	2. 15
	3. 13
	4. 160
	5. .
	6. 122
	7. 21
	8. 14
	9. .
	10. .
	11. 4
	12. .
	13. .
	14. .
	15. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300063073

Parameter	Value
	8. .
	9. F
	10. F
	11. F
	12. F
	13. F
	14. F
	15. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. NONE
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. OTHER
	13. OTHER
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. WORSENED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. UNCHANGED
	11. IMPROVED
	12. UNCHANGED
	13. UNCHANGED
	14. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300063073

Parameter	Value
	15. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300063096

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300063096/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/72/WHITE/NETHERLANDS/YES
Medical history	Alanine aminotransferase increased, Aspartate aminotransferase increased, Back pain, Dyspnoea, Fatigue, Hypertension, Hyponatraemia, Pain in extremity, Normochromic normocytic anaemia, Constipation, Pneumonia, Decreased appetite
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AMLODIPINE, BENZYLPENICILLINE, CINNARIZINE, CIPROFLOXACINE, DORMICUM, ENOXAPARIN, FENETICILLINE, FENTANYL, KLEAN PREP, LISINOPRIL, LOSARTAN, MICANOZOL HYDROFYL CREAM, TEMAZEPAM
Adverse Events (AE) Preferred term	1. Pneumonia 2. Groin infection 3. Pyrexia 4. Dry mouth 5. Pneumonia 6. Epistaxis 7. Gingival bleeding 8. Cough 9. Influenza 10. Colonic polyp 11. Colonic polyp 12. Rectal polyp 13. Wound haemorrhage 14. Syncope 15. Nausea 16. Dyspepsia 17. Abdominal pain 18. Hypertension 19. Dizziness
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/YES/NO/YES 7. MILD/YES/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/YES/NO/YES 14. MODERATE/NO/NO/YES 15. MILD/NO/NO/YES 16. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300063096

Parameter	Value
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MODERATE/YES/NO/YES
Start/stop date of event with relative date	1. 04MAY2010 (1) - 12MAY2010 (9)
	2. 04MAY2010 (1) - 30MAY2010 (27)
	3. 04MAY2010 (1) - 04MAY2010 (1)
	4. 05MAY2010 (2) - --------- (.)
	5. 12MAY2010 (9) - 15MAY2010 (12)
	6. 19MAY2010 (16) - 19MAY2010 (16)
	7. 21MAY2010 (18) - 28MAY2010 (25)
	8. 05JUN2010 (33) - --------- (.)
	9. 14JUN2010 (42) - 07JUL2010 (65)
	10. 29JUN2010 (57) - 29JUN2010 (57)
	11. 29JUN2010 (57) - 29JUN2010 (57)
	12. 29JUN2010 (57) - 29JUN2010 (57)
	13. 02AUG2010 (91) - 30AUG2010 (119)
	14. 19AUG2010 (108) - 19AUG2010 (108)
	15. 16SEP2010 (136) - --------- (.)
	16. 16SEP2010 (136) - --------- (.)
	17. 16SEP2010 (136) - 01NOV2010 (182)
	18. 16SEP2010 (136) - --------- (.)
	19. 23SEP2010 (143) - --------- (.)
Duration of AE	1. 9
	2. 27
	3. 1
	4. .
	5. 4
	6. 1
	7. 8
	8. .
	9. 24
	10. 1
	11. 1
	12. 1
	13. 29
	14. 1
	15. .
	16. .
	17. 47
	18. .
	19. .
Dose on AE onset	1.
	2.
	3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300063096

Parameter	Value
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
	9. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300063096

Parameter	Value
	10. NONE
	11. NONE
	12. NONE
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. NONE
	16. NONE
	17. NONE
	18. REMEDIAL DRUG THERAPY
	19. NONE
Outcome of event	1. IMPROVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. UNCHANGED
	16. UNCHANGED
	17. RESOLVED
	18. UNCHANGED
	19. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-300063096[1)]	WORSENING OF PNEUMONIA（PT：肺炎） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、合併症と判断し、エノキサパリン又はアセノクマロール投与との因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300063097

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300063097/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/75/WHITE/NETHERLANDS/YES
Medical history	Anaemia, Angina pectoris, Colon cancer, Oedema peripheral, Erysipelas, Pyrexia, Peroneal nerve palsy, Hypertension, Pneumonia, Peripheral sensory neuropathy, Oedema peripheral, Vaginal haemorrhage, Colon cancer metastatic, Postmenopause, Colon cancer metastatic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLAFORAN, FERRO FUMARAAT, NOROXIN, PARACETAMOL, XELODA
Adverse Events (AE) Preferred term	1. Post procedural haemorrhage 2. Dyspnoea 3. Palmar-plantar erythrodysaesthesia syndrome 4. Anal haemorrhage 5. Rectal tenesmus 6. Urinary incontinence 7. Nasopharyngitis 8. Vaginal haemorrhage 9. Vaginal haemorrhage 10. Cervical polyp
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/YES/YES/YES 9. MODERATE/YES/NO/YES 10. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 14JUN2010 (18) - 15JUN2010 (19) 2. 15JUN2010 (19) - --SEP2010 (.) 3. 01JUL2010 (35) - 31AUG2010 (96) 4. 05JUL2010 (39) - 23JUL2010 (57) 5. 05JUL2010 (39) - 31AUG2010 (96) 6. 01OCT2010 (127) - --------- (.) 7. 20OCT2010 (146) - 04NOV2010 (161) 8. 28NOV2010 (185) - 01DEC2010 (188) 9. 05DEC2010 (192) - --------- (.) 10. 05DEC2010 (192) - --------- (.)
Duration of AE	1. 2 2. . 3. 62 4. 19 5. 58 6. . 7. 16

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300063097

Parameter	Value
	8. 4
	9. .
	10. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. F
	10. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. STUDY DRUG DISCONTINUED AND RESTARTED
	10. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300063097

Parameter	Value
	10. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/45/WHITE/NETHERLANDS/YES
Medical history	Appendicectomy, Chordoma, Craniotomy, Hypercholesterolaemia, Constipation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, DICLOFENAC, ENOXAPARIN, LIPITOR, MOVICOLON, PARACETAMOL, SIMVASTATINE
Adverse Events (AE) Preferred term	1. Amnesia 2. Subdural haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 15MAY2007 (12) - --------- (.) 2. 23NOV2007 (204) - 26NOV2007 (207)
Duration of AE	1. . 2. 4
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. IMPROVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-300073001[4)]	SUBDURAL BLEEDING（PT：硬膜下出血） 治験担当医は、アセノクマロール投与中止１か月を経ての発現のため、否定できると判断した。しかしながら弊社は、アセノクマロールが事象発現時も投与中であったとの報告から、アセノクマロール投与と報告事象発現との時間的関連性を考慮し、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073013/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/68/WHITE/NETHERLANDS/YES
Medical history	Barrett's oesophagus, Oesophagectomy, Ileus, Ileus, Oesophageal adenocarcinoma, Varicocele, Hiatus hernia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AUGMENTIN, CIPROFLOXACINE, COMBIVENT, ENOXAPARIN, FLUIMUCIL, HYDROCOBAMINE, LACTULOSE, MORPHINE PCA PUMP, NEXIUM, OMEPRAZOL, PANTOZOL, PARACETAMOL, POTASSIUM CHLORIDE, PRIMPERAN, TEMAZEPAM, TRIMETHOPRIM, VITAMIN K, XYZAL, ZOFRAN
Adverse Events (AE) Preferred term	1. Epididymitis 2. Wound haemorrhage 3. Wound infection 4. International normalised ratio increased 5. Cough 6. Diarrhoea 7. Vomiting 8. Diarrhoea 9. Malnutrition
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. --AUG2007 (.) - 11SEP2007 (78) 2. 28JUN2007 (3) - 01JUL2007 (6) 3. 28JUN2007 (3) - 06JUL2007 (11) 4. 29JUN2007 (4) - 30JUN2007 (5) 5. 30JUN2007 (5) - 02JUL2007 (7) 6. 02JUL2007 (7) - 03JUL2007 (8) 7. 02JUL2007 (7) - 03JUL2007 (8) 8. 08JUL2007 (13) - 09JUL2007 (14) 9. 10JUL2007 (15) - 17JUL2007 (22)
Duration of AE	1. . 2. 4 3. 9 4. 2 5. 3 6. 2 7. 2 8. 2 9. 8

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073013

Parameter	Value
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. OTHER
	3. OTHER
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073013

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073051

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073051/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/79/WHITE/NETHERLANDS/YES
Medical history	Bladder cancer, Cerebrovascular accident, Chronic obstructive pulmonary disease, Dry eye, Dysphagia, Hypothyroidism, Laryngeal cancer, Lung lobectomy, Lung disorder, Lung squamous cell carcinoma stage unspecified
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPHAGAN, THYRAX, XALATAN
Adverse Events (AE) Preferred term	1. Death
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 28NOV2007 (3) - 28NOV2007 (3)
Duration of AE	1. 1
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. NONE
Outcome of event	1. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073058

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073058/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/48/WHITE/NETHERLANDS/YES
Medical history	Bilirubin conjugated increased, Knee arthroplasty, Knee arthroplasty, Knee operation, Limb operation, Device related infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AMOXICILLINE, AUGMENTIN, AVALOX, CLEXANE, DICLOFENAC NA, ENOXAPARIN, FRAXIPARINE, KEFZOL, OMEPRAZOL, PARACETAMOL, RIFAMPICINE, TRAMADOL
Adverse Events (AE) Preferred term	1. Pneumonia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 31MAR2008 (102) - 04APR2008 (106)
Duration of AE	1. 5
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073079

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073079/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/59/WHITE/NETHERLANDS/YES
Medical history	Dyspnoea exertional, Hypertension, Obesity, Pneumonia, Uterine leiomyoma, Postmenopause, Lung neoplasm malignant
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BUPIVACAINE/SUFENTA, CEFUROXIM, CIPROXIN, CLINDAMYCINE, DICLOFENAC, FLUIMICIL, FRAXIPARINE, FUROSEMIDE, IBUPROFEN, IPRAMOL, LACTULOSE, MERONEM, METOCLOPRAMIDE, MISTABRON, MORFINE, MOTILIUM, NITRAZEPAM, OMEPRAZOL, PARACETAMOL, PIPERACILLINE-TAZOBACTAM, POTASSIUM CHLORIDE, PREDNISOLON, SELOKENZOC, SLOW K, SPIRIVA, TEMAZEPAM, TRAMADOL, TRIMETOPRIM, ZOPICLON
Adverse Events (AE) Preferred term	1. Rectal haemorrhage 2. Sarcoma 3. Pleural effusion 4. Nausea 5. Haematuria 6. Weight increased 7. Hypokalaemia 8. Urinary tract infection 9. Wound complication 10. Pyrexia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. SEVERE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 24FEB2008 (28) - 14APR2008 (78) 2. 10JUN2008 (135) - --------- (.) 3. 12JUN2008 (137) - 24JUN2008 (149) 4. 13JUN2008 (138) - 21JUN2008 (146) 5. 15JUN2008 (140) - 15JUN2008 (140) 6. 15JUN2008 (140) - 01JUL2008 (156) 7. 19JUN2008 (144) - 01JUL2008 (156) 8. 19JUN2008 (144) - 22JUN2008 (147) 9. 25JUN2008 (150) - --JUL2008 (.) 10. 10JUL2008 (165) - 23JUL2008 (178)
Duration of AE	1. 51 2. . 3. 13 4. 9

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073079

Parameter	Value
	5. 1
	6. 17
	7. 13
	8. 4
	9. .
	10. 14
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1. .
	2. I
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. I
	10. .
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	3. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073079

Parameter	Value
	9. RESOLVED
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073104

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073104/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/NETHERLANDS/YES
Medical history	Aortic aneurysm, Lung adenocarcinoma, Appendicectomy, Atrial fibrillation, Cataract operation, Lung lobectomy, Obesity, Lung neoplasm malignant
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, BISOPROLOL, BUPIVACAINE/SUFENTANIL, CEFAZOLINE, CO-TRIMOXAZOL, COMBIVENT/IPRATROPIUM/SALBUTAMOL, COVERSYL, DIGOXINE, DOPAMINE, DORMICUM, ENOXAPARINE, ESOMEPRAZOL, FRESH FROZEN PLASMA, FUROSEMIDE, HYDROCORTISON, MAGNESIUM SULFATE, MANNITOL 20%, MIDAZOLAN, NEXIUM, NOREPINEFRINE, PARACETAMOL, PERINDOPRIL, POTASSIUM CHLORIDE, PREDNISOLON, PREDNISON, TEMAZEPAM, THIAMINE, VENOFUNDIN
Adverse Events (AE) Preferred term	1. Skin exfoliation 2. Hypertension 3. Venous haemorrhage 4. Hypotension 5. Blood glucose increased 6. Arterial haemorrhage 7. Hypotension 8. Device related infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. SEVERE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/YES/NO
Start/stop date of event with relative date	1. --SEP2008 (.) - --------- (.) 2. --APR2008 (.) - --------- (.) 3. 09JUN2008 (94) - 09JUN2008 (94) 4. 09JUN2008 (94) - 10JUN2008 (95) 5. 09JUN2008 (94) - 10JUN2008 (95) 6. 03SEP2008 (180) - 03SEP2008 (180) 7. 03SEP2008 (180) - 05SEP2008 (182) 8. 09SEP2008 (186) - 16SEP2008 (193)
Duration of AE	1. . 2. . 3. 1 4. 2 5. 2 6. 1 7. 3 8. 8
Dose on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073104

Parameter	Value
	2.
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1.
	2.
	3. I
	4. I
	5. I
	6. F
	7. F
	8. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. OTHER
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. INSUFFICIENT FOLLOW-UP
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073108

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073108/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/75/WHITE/NETHERLANDS/YES
Medical history	Angina unstable, Coronary artery bypass, Cervix carcinoma, Diabetes mellitus, Pyrexia, Gout, Hypertension, Menopause, Pneumonia, Polyneuropathy, Vascular graft occlusion, Aortic dilatation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ACUPRIL, AMITRIPTYLINE, AMOXICILLIN/CLAVULAMIC ACID, ASCAL, AUGMENTIN, CIPROXIN, CODEINE, COFACT, ENOXAPARIN, HYDROCHLOORTHIAZIDE, INSULATARD, LYRICA, METFORMINE, MS CONTIN, OMEPRAZOL, SIMVASTATINE, TEMAZEPAM, TRIMETHOPRIM, VERAPAMIL RETARD
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Urinary retention 3. Pneumonia 4. Urinary tract infection 5. Cough 6. Protein C deficiency
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. SEVERE/NO/NO/YES 6. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 18MAR2008 (6) - 21MAR2008 (9) 2. 19MAR2008 (7) - 17JUL2008 (127) 3. 05MAY2008 (54) - 10MAY2008 (59) 4. 05MAY2008 (54) - 10MAY2008 (59) 5. 27AUG2008 (168) - 01OCT2008 (203) 6. 01OCT2008 (203) - --------- (.)
Duration of AE	1. 4 2. 121 3. 6 4. 6 5. 36 6. .
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073108

Parameter	Value
	6.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073113

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073113/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/57/WHITE/NETHERLANDS/YES
Medical history	Angina unstable, Intermittent claudication, Diverticulitis, Epididymitis, Hydrocele, Obesity, Prostatitis, Tinea pedis, Bladder neck operation, Rash generalised, Hydrocele operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ADRENALINE, ADRENALINE 10 MG/50 ML, ASCAL, ATROPINE, ATROVENT, AUGMENTIN, CORDARONE, DIAZEPAM, DOPAMINE 200 MG/50 ML, ENOXAPARIN, FLUMAZENIL, FRAXIPARIN, HAES, LIPITOR, MAGNESIUM OXIDE SULFATE, MORPHINE, MORPHINE 50 MG/50 ML, PLAVIX, PRIMPERAN, PROPOFOL 2%, REOPRO, SELOKEEN
Adverse Events (AE) Preferred term	1. International normalised ratio increased 2. International normalised ratio increased 3. Acute myocardial infarction 4. Pneumonia 5. Thrombocytopenia 6. Renal tubular necrosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. SEVERE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. SEVERE/NO/NO/YES
Start/stop date of event with relative date	1. 30MAR2008 (12) - 01APR2008 (14) 2. 16APR2008 (29) - 18APR2008 (31) 3. 14JUN2008 (88) - 27JUN2008 (101) 4. 14JUN2008 (88) - --------- (.) 5. 14JUN2008 (88) - 21JUN2008 (95) 6. 15JUN2008 (89) - --------- (.)
Duration of AE	1. 3 2. 3 3. 14 4. . 5. 8 6. .
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073113

Parameter	Value
	6.
Action taken	1. DOSE OF STUDY DRUG REDUCED
	2. DOSE OF STUDY DRUG REDUCED
	3. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. DEATH
	4. INSUFFICIENT FOLLOW-UP
	5. RESOLVED
	6. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073125

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073125/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/31/WHITE/NETHERLANDS/YES
Medical history	Appendicectomy, Cystitis, Mammoplasty, Depression, Hydrocephalus, Hypertension, Hypoxia, Kyphoscoliosis, Nephrolithiasis, Obesity, Paralysis, Pneumonia, Renal tubular acidosis, Spina bifida, Latex allergy, Bladder repair
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BETADINE BLADDER WASH, DESOGESTREL/ETHINYLESTRADIOL, DURATEARS [DEXTRAN, HYPROMELLOSE, BORAX.,POLYQUATERNIUM], ENALAPRIL, HYDROCOBAMINE, LACTULOSE, MEDROXYPROGESTERON, NADROPARIN, NATRIUM BICARBONAT, NITROFURANTOINE, OXYGEN THERAPY, PARACETAMOL, RISPERDAL, SODIUMCHLORIDE BLADDER WASH
Adverse Events (AE) Preferred term	1. Death
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 15SEP2008 (165) - 15SEP2008 (165)
Duration of AE	1. 1
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. NONE
Outcome of event	1. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073134

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073134/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/26/WHITE/NETHERLANDS/YES
Medical history	Anaemia, Anxiety, Appendicectomy, Crohn's disease, Ileectomy, Ileostomy, Muscular dystrophy, Urinary tract infection, Vitamin B12 deficiency, Candidiasis, Ileostomy, Ileostomy, Ileostomy, Proctocolectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMITRIPTYLINE, CHLORHEXEDINE, CO-TRIMOXAZOL, FENTANYL MATRIX PLASTER, HALOPERIDOL, IMURAN, KYTRIL, LORAZEPAM, LYRICA, MICONAZOLNITRATE CREME, NADROPARIN, NATRIUM CHLORIDE INFUSION, NEXIUM, NYSTATINE, ORAMORPH, OXAZEPAM, PARACETAMOL, PRIMPERAN, TRIMETHOPRIM, VITAMIN B12 INJECTION, ZOFRAN
Adverse Events (AE) Preferred term	1. Dyshidrosis 2. Urinary tract infection 3. Dehydration 4. Candidiasis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 20APR2008 (3) - --APR2008 (.) 2. 26APR2008 (9) - --MAY2008 (.) 3. 12MAY2008 (25) - 15MAY2008 (28) 4. 01JUN2008 (45) - --JUN2008 (.)
Duration of AE	1. . 2. . 3. 4 4. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073134

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073144

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073144/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/NETHERLANDS/YES
Medical history	Microcytic anaemia, Angina pectoris, Chronic obstructive pulmonary disease, Hypercholesterolaemia, Hypertension, Hyponatraemia, Obesity, Oedema peripheral, Dyspepsia, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AMIODARONE, COZAAR, ENOXAPARIN, FERROFUMARAAT, HYDROCHLORTHIAZIDE, ISOSORBIDEDINITRAAT RETARD, LASIX, LERDIP, OMEPRAZOL, SELOKEEN ZOC, SIMVASTATINE, SYMBICORT
Adverse Events (AE) Preferred term	1. Aortic aneurysm 2. Hiatus hernia 3. Gastrooesophageal reflux disease 4. Renal impairment 5. Wound haemorrhage 6. Atrial fibrillation
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 14MAY2008 (4) - --------- (.) 2. 15MAY2008 (5) - --------- (.) 3. 15MAY2008 (5) - --------- (.) 4. 16MAY2008 (6) - 09OCT2008 (152) 5. 22MAY2008 (12) - 22MAY2008 (12) 6. 09OCT2008 (152) - 10OCT2008 (153)
Duration of AE	1. . 2. . 3. . 4. 147 5. 1 6. 2
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073144

Parameter	Value
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073151

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073151/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/52/WHITE/NETHERLANDS/YES
Medical history	VIIth nerve paralysis, Breast cancer, Menorrhagia, Mastectomy, Anaemia postoperative
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CYCLOPHOSFAMIDE, DEXAMETHASON, EPIRUBICINE, FLUOROURACIL, METFORMIN, NEURONTIN, PARACETAMOL, TAXOTERE, ZOFRAN
Adverse Events (AE) Preferred term	1. Epistaxis 2. Neuralgia 3. Pyrexia 4. Respiratory tract infection 5. Diabetes mellitus
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 01JUL2008 (29) - 08NOV2008 (159) 2. 07OCT2008 (127) - --------- (.) 3. 19OCT2008 (139) - 21OCT2008 (141) 4. 20OCT2008 (140) - 21OCT2008 (141) 5. 11NOV2008 (162) - --------- (.)
Duration of AE	1. 131 2. . 3. 3 4. 2 5. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. NONE 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. IMPROVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073151

Parameter	Value
	4. RESOLVED
	5. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073190

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073190/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/79/WHITE/NETHERLANDS/YES
Medical history	Appendicectomy, Arteriosclerosis, Bursa removal, Intermittent claudication, Diabetes mellitus, Gastrointestinal angiodysplasia, Haemorrhoids, Hypertension, Iron deficiency anaemia, Lung squamous cell carcinoma stage unspecified, Pneumothorax, Transurethral prostatectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CIPROFLOXACIN, DICLOFENAC, DORMICUM, FERROFUMARAAT, GLUCOSE 5%, IPRAMOL STERI-NEB 0.2-1.0 MG/ML, METFORMIN, MORPHIN PCA PUMP 1MG/ML, NEXIUM, NORMISON, PARACETAMOL, SIMVASTATINE, ZOFRAN
Adverse Events (AE) Preferred term	1. Dizziness 2. Lung disorder 3. Blood glucose increased 4. Haematuria traumatic 5. Urinary retention
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --DEC2008 (.) - --------- (.) 2. 08SEP2008 (22) - 23SEP2008 (37) 3. 11SEP2008 (25) - -----2008 (.) 4. 14SEP2008 (28) - 20SEP2008 (34) 5. 14SEP2008 (28) - 19SEP2008 (33)
Duration of AE	1. . 2. 16 3. . 4. 7 5. 6
Dose on AE onset	1. 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. . 5. .
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY,OTHER 3. REMEDIAL DRUG THERAPY 4. NONE 5. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073190

Parameter	Value
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073198

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073198/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/67/WHITE/NETHERLANDS/YES
Medical history	Gastrooesophageal reflux disease, Gout, Hyperkalaemia, Hypertension, Inguinal hernia repair, Inguinal hernia repair, Nephrotic syndrome, Transurethral prostatectomy, Prostatism, Proteinuria, Renal failure chronic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ACTRAPID, ALLOPURINOL, ATROVENT, AUGMENTIN, CEFUROXIM, DICLOFENAC, ENOXAPARIN, FENTANYL, FLUIMICIL, HEPARIN, HYDROCHLORATHIAZIDE, HYDROCHLOROTHIAZIDE, IPRAMOL, KEFZOL, LASIX, LISINOPRIL, MAGNESIUM SULPHATE, MIDAZOLAM, MISTABRON, MORPHINE, MORPHINE PCA PUMP, NADROPARIN, NEXIUM, NORADRENALINE, OMEPRAZOL, OXYNORM, PARACETAMOL, POTASSIUM CHLORIDE, PRIMPERAN, PROPOFOL 2%, PROTAMINE, RESONIUM, SODIUM BICARBONATE 8.4%, TAMSOLUSIN, TRAMADOL, VENTOLIN, ZOCOR
Adverse Events (AE) Preferred term	1. Haematuria 2. Haematuria 3. Inguinal hernia 4. Gastroenteritis 5. Aortic aneurysm rupture 6. Hyperkalaemia 7. Pneumonia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. SEVERE/NO/YES/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 17SEP2008 (4) - 18SEP2008 (5) 2. 31OCT2008 (48) - 31OCT2008 (48) 3. 01NOV2008 (49) - --JAN2009 (.) 4. 13DEC2008 (91) - 15DEC2008 (93) 5. 13JAN2009 (122) - 14JAN2009 (123) 6. 13JAN2009 (122) - 15JAN2009 (124) 7. 14JAN2009 (123) - 28JAN2009 (137)
Duration of AE	1. 2 2. 1 3. . 4. 3 5. 2 6. 3 7. 15
Dose on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073198

Parameter	Value
	5.
	6.
	7.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. STUDY DRUG DISCONTINUED AND RESTARTED
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073213

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073213/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/57/WHITE/NETHERLANDS/YES
Medical history	Resection of rectum, Bradycardia, Colostomy, Incisional hernia, Metastases to lung, Obesity, Umbilical hernia, Rectal cancer metastatic, Coronary artery bypass, Omentopexy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ASCAL, ATENOLOL, DICLOFENAC, ENOXAPARIN, LACTULOSE, LISINOPRIL, MOVICOLON, NADROPARINE, OMEPRAZOL, OXYCONTIN, OXYNORM, PARACETAMOL, PRIMPERAN, SIMVASTATINE, TRAMADOL, VITAMIN K
Adverse Events (AE) Preferred term	1. International normalised ratio increased 2. Rectal cancer metastatic 3. Dyspnoea 4. Cough 5. Subcutaneous haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 14OCT2008 (5) - 17OCT2008 (8) 2. 14NOV2008 (36) - 14FEB2009 (128) 3. 04JAN2009 (87) - --------- (.) 4. 07JAN2009 (90) - 12JAN2009 (95) 5. 11JAN2009 (94) - --------- (.)
Duration of AE	1. 4 2. 93 3. . 4. 6 5. .
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER 3. OTHER 4. NONE 5. NONE
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073213

Parameter	Value
	2. DEATH
	3. UNCHANGED
	4. RESOLVED
	5. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073216

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073216/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/49/WHITE/NETHERLANDS/YES
Medical history	Acne, Asthma, Back pain, Nasopharyngitis, Depression, Diaphragmatic hernia, Eczema, Epicondylitis, Irritable bowel syndrome, Rhinitis, Varicose vein, Radicular syndrome, Bronchial hyperreactivity, Intervertebral discitis, Intervertebral disc operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ATROVENT, CYPROTERONE/ETHINYLESTRADIOL, DIAZEPAM, EFEXOR, ENOXAPARIN, ENOXAPARIN, 1.0MG/KG, FLIXONASE, OMEPRAZOL, OXYCONTIN, PARACETAMOL, PREDNISOLON, SEROQUEL, SINGULAIR, SYMBICORT
Adverse Events (AE) Preferred term	1. Suicide attempt 2. International normalised ratio decreased 3. Fatigue 4. Dyspnoea 5. Chest pain 6. Asthma 7. Vaginal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/NO 5. MILD/NO/NO/NO 6. MODERATE/NO/YES/NO 7. MILD/YES/NO/NO
Start/stop date of event with relative date	1. --APR2009 (.) - --APR2009 (.) 2. 27OCT2008 (13) - 26NOV2008 (43) 3. 10NOV2008 (27) - 20JAN2009 (98) 4. 01DEC2008 (48) - --JAN2009 (.) 5. 01DEC2008 (48) - --JAN2009 (.) 6. 16FEB2009 (125) - 19FEB2009 (128) 7. 20MAR2009 (157) - --------- (.)
Duration of AE	1. . 2. 31 3. 72 4. . 5. . 6. 4 7. .
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073216

Parameter	Value
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. OTHER
	2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	3. NONE
	4. OTHER
	5. OTHER
	6. REMEDIAL DRUG THERAPY,OTHER
	7. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073217

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073217/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/49/WHITE/NETHERLANDS/YES
Medical history	Retinal detachment, Pneumonia, Pleural effusion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ATROPIN SULFATE 1%, AUGMENTIN, CHLORAMPHENICOL 0.4%, CLEXANE, COSOPT, DEXAMETHASON 0.1%, ENOXAPARIN, FENYLEFRIN HCL 2,5%, OXYBUPROCAINE HCL 0.2%, PARACETAMOL, TEMAZEPAM, TIMOPTOL 0.5%, TROPICAMIDE 0.5%
Adverse Events (AE) Preferred term	1. Pleural effusion 2. Retinal detachment 3. Retinal detachment
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 28OCT2008 (14) - 10NOV2008 (27) 2. 07NOV2008 (24) - 07NOV2008 (24) 3. 19NOV2008 (36) - 19NOV2008 (36)
Duration of AE	1. 14 2. 1 3. 1
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. OTHER 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 3. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073219

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073219/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/78/WHITE/NETHERLANDS/YES
Medical history	Diverticulitis, Benign prostatic hyperplasia, Essential hypertension, Gout, Hepatic cyst, Large intestine perforation, Normochromic normocytic anaemia, Obesity, Renal cyst, Splenomegaly, Renal failure acute
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENALAPRIL, FLUIMUCIL, FUROSEMIDE, NADROPARIN, OMEPRAZOL
Adverse Events (AE) Preferred term	1. Diarrhoea 2. Diarrhoea 3. Myelofibrosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/NO
Start/stop date of event with relative date	1. --OCT2008 (.) - --------- (.) 2. 03NOV2008 (17) - 03NOV2008 (17) 3. 11MAY2009 (206) - --------- (.)
Duration of AE	1. . 2. 1 3. .
Dose on AE onset	1. 2. 15 mg 3. 20 mg
Dose status on AE onset	1. 2. . 3. F
Action taken	1. NONE 2. NONE 3. OTHER
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. RESOLVED 3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073246

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073246/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/45/WHITE/NETHERLANDS/YES
Medical history	Hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AUGMENTIN, CIPROFLOXACIN, DICLOFENAC, ENOXAPARIN, FRAXODI, HYDROCHLORTHIAZIDE, MOVICOLON, OMEPRAZOL, ORAL CONTRACEPTIVE, OXINORM, OXYCONTIN, PARACETAMOL, PRIMPERAN, VIT K
Adverse Events (AE) Preferred term	1. Influenza 2. Diarrhoea 3. Lung infection 4. International normalised ratio increased 5. Nausea 6. Decreased appetite 7. Hyperhidrosis 8. Palpitations 9. Pulmonary congestion 10. Hyperthyroidism
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/YES/YES/YES 10. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --JAN2009 (.) - --JAN2009 (.) 2. --DEC2008 (.) - --JAN2009 (.) 3. 23NOV2008 (1) - 01DEC2008 (9) 4. 21DEC2008 (29) - 22DEC2008 (30) 5. 21DEC2008 (29) - 21DEC2008 (29) 6. 22DEC2008 (30) - --JAN2009 (.) 7. 22DEC2008 (30) - --JAN2009 (.) 8. 22DEC2008 (30) - --------- (.) 9. 15JAN2009 (54) - 16JAN2009 (55) 10. 11FEB2009 (81) - --------- (.)
Duration of AE	1. . 2. . 3. 9 4. 2 5. 1 6. . 7. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073246

Parameter	Value
	8. .
	9. 2
	10. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
	9. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073246

Parameter	Value
	10. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073282

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073282/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/44/WHITE/NETHERLANDS/YES
Medical history	Asthma, Obesity, Dyspnoea
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTILYSE, ADRENALINE, ATROPINE, MICROGYNON 30, NASONEX, OXYGEN, SALBUTAMOL, SERETIDE, XYZAL
Adverse Events (AE) Preferred term	1. Pulmonary embolism
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 09MAR2009 (1) - 10MAR2009 (2)
Duration of AE	1. 2
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073283

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073283/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/75/WHITE/NETHERLANDS/YES
Medical history	Appendicectomy, Cholecystectomy, Chronic obstructive pulmonary disease, Benign prostatic hyperplasia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ACETYLCYSTEINE, ADRENALINE, AMOXICILLINE, ASCAL, CLEXANE, COFACT, DORMICUM, ENOXAPARIN, ERYTHROMYCINE, FERROFUMARAAT, FUROSEMIDE, METOPROLOL, NEXIUM, OMEPRAZOL, PERINDOPRIL, PLAVIX, PREDNISOLON, ROSUVASTATINE, SERETIDE, SIMVASTATINE, SPIRIVA
Adverse Events (AE) Preferred term	1. Diarrhoea 2. Chronic obstructive pulmonary disease 3. Haemoptysis 4. Acute myocardial infarction 5. Oesophageal ulcer haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/YES/NO/YES 4. SEVERE/NO/YES/YES 5. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. --JUL2009 (.) - --AUG2009 (.) 2. 19MAR2009 (8) - 27MAR2009 (16) 3. 21MAR2009 (10) - --MAR2009 (.) 4. 05MAY2009 (55) - 09MAY2009 (59) 5. 09MAY2009 (59) - 15MAY2009 (65)
Duration of AE	1. . 2. 9 3. . 4. 5 5. 7
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY 3. NONE 4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073283

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-300073283[2)]	OESOPHAGEAL ULCER（PT：食道潰瘍） 治験担当医はエノキサパリン及びワルファリンと報告事象との関連性があると判断した。弊社は、エノキサパリン及びワルファリン投与終了 2 か月後の発現であり、また併用薬（Ascal）による可能性も考えられることから、エノキサパリン及びワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073296

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073296/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/50/WHITE/NETHERLANDS/YES
Medical history	Obesity, Joint dislocation, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	METFORMINE, NOVOMIX 30 FLEXPEN
Adverse Events (AE) Preferred term	1. Tooth loss
	2. Type 2 diabetes mellitus
	3. Type 2 diabetes mellitus
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
	2. MILD/NO/NO/YES
	3. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --JUL2009 (.) - 06OCT2009 (140)
	2. --AUG2009 (.) - --------- (.)
	3. 20MAY2009 (1) - --AUG2009 (.)
Duration of AE	1. .
	2. .
	3. .
Dose on AE onset	1.
	2.
	3. 15 mg
Dose status on AE onset	1.
	2.
	3. .
Action taken	1. OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073298

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073298/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/21/WHITE/NETHERLANDS/YES
Medical history	Cough
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AMOXYCILLINE/CLAVULAANZUUR, CODEINE, DICLOFENAC A.N., ENOXAPARIN, ENOXAPARIN 1.0MG/KG, MICROGYNON 30, MIRENA, PARACETAMOL, PREDNISOLON
Adverse Events (AE) Preferred term	1. Cystitis 2. Muscle haemorrhage 3. Alanine aminotransferase increased 4. Chest pain 5. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/YES/YES 3. MODERATE/YES/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 31MAY2009 (6) - 10JUN2009 (16) 2. 01JUN2009 (7) - 07JUN2009 (13) 3. 08JUN2009 (14) - 17JUN2009 (23) 4. 08JUN2009 (14) - 09JUN2009 (15) 5. 08JUN2009 (14) - 09JUN2009 (15)
Duration of AE	1. 11 2. 7 3. 10 4. 2 5. 2
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. DOSE OF STUDY DRUG REDUCED,OTHER 3. NONE 4. OTHER 5. OTHER
Outcome of event	1. RESOLVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073298

Parameter	Value
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073299

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073299/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/62/WHITE/NETHERLANDS/YES
Medical history	Gout, Hip arthroplasty, Hip fracture, Hypertension, Nephrolithiasis, Nephrolithiasis, Obesity, Osteosarcoma metastatic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPINE, DEXAMETHASON, DICLOFENAC, HYDROCHLOROTHIAZIDE, LACTULOSE, MS-CONTIN, NADROPARINE, NEXIUM, OXYCODON, PARACETAMOL, TAMSOLUSINE, X-PRAEP
Adverse Events (AE) Preferred term	1. Urinary retention 2. Cauda equina syndrome
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. --JUN2009 (.) - --------- (.) 2. 12JUN2009 (15) - 19JUN2009 (22)
Duration of AE	1. . 2. 8
Dose on AE onset	1. 2. 15 mg
Dose status on AE onset	1. 2. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073321

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073321/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/NETHERLANDS/YES
Medical history	Basal cell carcinoma, Eczema
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, DIAZEPAM, DICLOFENAC, ENOXAPARIN, H1N1 VACCINATION, H1N1 VACINATION, NERISONA CREAM 0.1%, OMEPRAZOL, PARACETAMOL, TEMAZEPAM, TRAMADOL, TRAMAL
Adverse Events (AE) Preferred term	1. Rash 2. Gingival bleeding 3. Haematoma 4. Wound haemorrhage 5. Anaemia 6. Post-traumatic pain 7. Subcutaneous haematoma 8. Back pain 9. Arthralgia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. SEVERE/YES/YES/YES 4. MILD/YES/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/YES/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 25SEP2009 (1) - --APR2010 (.) 2. 25SEP2009 (1) - 20MAR2010 (177) 3. 08OCT2009 (14) - --FEB2010 (.) 4. 08OCT2009 (14) - 22OCT2009 (28) 5. 08OCT2009 (14) - 28DEC2009 (95) 6. 09JAN2010 (107) - --------- (.) 7. 09JAN2010 (107) - 30MAR2010 (187) 8. 09JAN2010 (107) - --------- (.) 9. 09JAN2010 (107) - --------- (.)
Duration of AE	1. . 2. 177 3. . 4. 15 5. 82 6. . 7. 81 8. . 9. .
Dose on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073321

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. UNCHANGED
	9. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-300073321[3)]	ANEMIA（PT：出血性貧血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症（足部血腫）の合併症と考え、エノキサパリン及びアセノクマロール投与との因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073327

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073327/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/73/WHITE/NETHERLANDS/YES
Medical history	Oedema peripheral, Bronchiectasis, Chronic sinusitis, Large intestine perforation, Chronic obstructive pulmonary disease, Diverticulitis, Hiatus hernia, Hypertension, Hypogammaglobulinaemia, Staphylococcal infection, Hypergammaglobulinaemia benign monoclonal, Myasthenia gravis, Obesity, Thymectomy, Postmenopause, Hyperlipidaemia, Microscopic polyangiitis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AMLODIPINE, AZATHIOPRIN, AZITHROMYCINE, CALCICHEW D3, COTRIMOXAZOL, CRESTOR, DOXAZOSINE, ENDOXAN, ENOXAPARIN, EZETROL, FLUCONAZOL, FLUIMUCIL, FOSAMAX, FUROSEMIDE, METFORMINE, NANOGAM (IMMUNOGLOBULINE), OMEPRAZOL, PREDNISOLON, PRIMPERAN, SALBUTAMOL/IPRATROPIUM, SERETIDE, SPIRONOLACTON
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Cardiac failure congestive 3. Gastroenteritis norovirus 4. Dyspnoea 5. Cardiac failure congestive 6. Influenza 7. Type 2 diabetes mellitus
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 15JAN2010 (57) - 22FEB2010 (95) 2. 23FEB2010 (96) - 05MAR2010 (106) 3. 26FEB2010 (99) - 28FEB2010 (101) 4. 05MAR2010 (106) - --------- (.) 5. 06MAR2010 (107) - --------- (.) 6. 15APR2010 (147) - 20APR2010 (152) 7. 28APR2010 (160) - --------- (.)
Duration of AE	1. 39 2. 11 3. 3 4. . 5. . 6. 6 7. .
Dose on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073327

Parameter	Value
	5.
	6.
	7.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. WORSENED
	2. IMPROVED
	3. RESOLVED
	4. UNCHANGED
	5. IMPROVED
	6. RESOLVED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073328

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073328/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/64/WHITE/NETHERLANDS/YES
Medical history	Hypertension, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AMOXICILLIN, AUGMENTIN, CODEINE PHOSPHATE, COTRIMOXAZOL, DOXYCYCLINE, ENOXAPARIN, FLUIMUCIL, FRAXIPARIN, HYDROCHLORTHIAZIDE, IPRAMOL 0.2-1.0 MG/ML, IPRAMOL STERI-NEB 0.2-1.0 MG/ML, MELATONINE, METOPROLOL, NASONEX 0,5 MG/G, PARACETAMOL/CODEINE, PREDNISOLON, PULMICORT 200, SLOW-K, SYMBICORT 200/ 6 MCG, SYMBICORT 400/12 MCG, TEMAZEPAM, TRIMETHOPRIM, VASELINE, VITAMIN K, XYLOMETAZOLINE HCL 0.1%
Adverse Events (AE) Preferred term	1. Rash 2. Eczema 3. Dyspnoea 4. Cough 5. Dyspnoea exertional 6. Rash 7. Bronchial obstruction 8. Sinusitis 9. International normalised ratio increased 10. Hypokalaemia 11. Rash 12. Bronchial obstruction 13. Urinary tract infection 14. Erythema 15. Swelling face
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/YES/NO/YES 7. MODERATE/NO/YES/YES 8. MODERATE/NO/NO/YES 9. MILD/YES/NO/YES 10. MILD/NO/NO/YES 11. MILD/YES/NO/YES 12. MODERATE/NO/YES/YES 13. MILD/NO/NO/YES 14. MILD/YES/NO/YES 15. MILD/YES/NO/YES
Start/stop date of event with relative date	1. --MAR2010 (.) - 15MAR2010 (90) 2. --MAR2010 (.) - --MAY2010 (.) 3. --JAN2010 (.) - 10FEB2010 (57) 4. --JAN2010 (.) - 10FEB2010 (57)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073328

Parameter	Value
	5. --MAY2010 (.) - --------- (.)
	6. 21DEC2009 (6) - 28DEC2009 (13)
	7. 11FEB2010 (58) - 23FEB2010 (70)
	8. 11FEB2010 (58) - 15MAR2010 (90)
	9. 11FEB2010 (58) - 17FEB2010 (64)
	10. 17FEB2010 (64) - 22FEB2010 (69)
	11. 18MAR2010 (93) - 26MAR2010 (101)
	12. 29MAR2010 (104) - 16APR2010 (122)
	13. 06APR2010 (112) - --MAY2010 (.)
	14. 10APR2010 (116) - 11APR2010 (117)
	15. 10APR2010 (116) - 11APR2010 (117)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. 8
	7. 13
	8. 33
	9. 7
	10. 6
	11. 9
	12. 19
	13. .
	14. 2
	15. 2
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Dose status on AE onset	1.
	2.
	3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073328

Parameter	Value
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED PERMANENTLY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. STUDY DRUG DISCONTINUED AND RESTARTED
	10. REMEDIAL DRUG THERAPY,OTHER
	11. NONE
	12. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. WORSENED
	4. WORSENED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073328

Parameter	Value
	15. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-300073328[1),1)]	BRONCHUS OBSTRUCTION（PT：気管支閉塞） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、投与終了約 7 週間後の発現であり、時間的関連性がないため、エノキサパリンとの因果関係は否定できると考える。 RECURRENT BRONCHUS OBSTRUCTION（PT：気管支閉塞） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、投与終了約 3 か月後の発現であり、時間的関連性がないため、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073335

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073335/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/59/WHITE/NETHERLANDS/YES
Medical history	Back pain, Chest pain, Chronic obstructive pulmonary disease, Cytomegalovirus infection, Emphysema, Gastrooesophageal reflux disease, Hypercholesterolaemia, Incisional hernia repair, Lung transplant, Migraine, Pneumonia, Respiratory syncytial virus bronchiolitis, Tinnitus, Osteopenia, Meniscus operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ACTONEL, AZITROMYCINE, BETAHISTINE, CALCI CHEW, CELLCEPT, CIPROXIN, CODEINE PHOSPHATE, COTRIMOXAZOL, ENOXAPARIN, IMIGRAN, LIPITOR, MAGNESIUM HYDROXIDE, OMEPRAZOL, PARACETAMOL, PREDNISOLON, PROGRAFT, TRAMADOL, VALCYTE
Adverse Events (AE) Preferred term	1. Cough 2. Respiratory tract infection 3. Oropharyngitis fungal 4. Tendonitis 5. Hypophosphataemia 6. Complications of transplant surgery 7. Pneumothorax 8. Diarrhoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/YES/YES 8. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --JUL2010 (.) - --------- (.) 2. 26APR2010 (70) - 17MAY2010 (91) 3. 03MAY2010 (77) - --------- (.) 4. 09MAY2010 (83) - --------- (.) 5. 11MAY2010 (85) - --------- (.) 6. 14JUL2010 (149) - --------- (.) 7. 10AUG2010 (176) - 13AUG2010 (179) 8. 21AUG2010 (187) - 29AUG2010 (195)
Duration of AE	1. . 2. 22 3. . 4. . 5. . 6. . 7. 4 8. 9
Dose on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073335

Parameter	Value
	3.
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. OTHER
	6. REMEDIAL DRUG THERAPY,OTHER
	7. REMEDIAL DRUG THERAPY
	8. OTHER
Outcome of event	1. IMPROVED
	2. RESOLVED
	3. INSUFFICIENT FOLLOW-UP
	4. IMPROVED
	5. UNCHANGED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073338

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073338/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/63/WHITE/NETHERLANDS/YES
Medical history	Electrocardiogram abnormal, Influenza, Pneumonia, Rectal haemorrhage
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADRENALIN, ASCAL, COLEX KLYSMA, COLOFORT, DORMICUM, FRAXIPARIN, HEPATITIS A VACCINE, KLEAN-PREP, MOLAXOLE, MOVICOLON, PARACETAMOL, PETHIDINE, POTASSIUM CHLORIDE
Adverse Events (AE) Preferred term	1. Muscle spasms 2. Rectal haemorrhage 3. Haemorrhoids
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/YES/YES 3. MILD/YES/NO/NO
Start/stop date of event with relative date	1. --JUL2010 (.) - --------- (.) 2. 25JUN2010 (106) - 27JUN2010 (108) 3. 27SEP2010 (200) - --------- (.)
Duration of AE	1. . 2. 3 3. .
Dose on AE onset	1. 2. 20 mg 3. 20 mg
Dose status on AE onset	1. 2. . 3. F
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 3. NONE
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. RESOLVED 3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073351

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073351/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/61/WHITE/NETHERLANDS/YES
Medical history	Atrial fibrillation, Catheterisation cardiac, Cholecystectomy, Chronic obstructive pulmonary disease, Chronic obstructive pulmonary disease, Chronic obstructive pulmonary disease, Chronic obstructive pulmonary disease, Gastrooesophageal reflux disease, Hyperthyroidism, Pain in extremity, Lung transplant, Muscle atrophy, Pneumonia, Osteopenia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALENDRONINE ACID, CALCI CHEW, CELLCEPT, CERTICAN, CO-TRIMOXAZOL, FLUCONAZOL, GLUCOSE 2.5% / NACL 0.45%, MAGNESIUM HYDROXIDE, MAGNESIUMHYDROXIDE, METOPROLOL, NEXIUM, PREDNISOLON, PROGRAFT, STRUMAZOL, TAMSULOSINE, TEMAZEPAM, VALCYTE
Adverse Events (AE) Preferred term	1. Gastric cancer 2. Oedema peripheral 3. Pain in extremity 4. Pain in extremity 5. Oesophageal candidiasis 6. Renal impairment 7. Renal impairment
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. SEVERE/NO/YES/YES 7. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --MAR2011 (.) - --------- (.) 2. 28NOV2010 (27) - 29NOV2010 (28) 3. 28NOV2010 (27) - 29NOV2010 (28) 4. 10JAN2011 (70) - --------- (.) 5. 29MAR2011 (148) - 26APR2011 (176) 6. 26APR2011 (176) - 06MAY2011 (186) 7. 07MAY2011 (187) - --------- (.)
Duration of AE	1. . 2. 2 3. 2 4. . 5. 29 6. 11 7. .
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073351

Parameter	Value
	6. 20 mg
	7. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. F
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	2. NONE
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY,OTHER
	7. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. IMPROVED
	7. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073353

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300073353/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/79/WHITE/NETHERLANDS/YES
Medical history	Tendon rupture, Drug hypersensitivity, Anaemia, Aortic arteriosclerosis, Asthma, Diverticulum intestinal, Diverticulum intestinal, Diabetes mellitus, Hypercholesterolaemia, Hypertension, Hyperthyroidism, Hypocalcaemia, Hypothyroidism, Hysterectomy, Melaena, Melaena, Normochromic normocytic anaemia, Obesity, Oedema, Hiatus hernia, Gastrooesophageal reflux disease, Spinal osteoarthritis, Hip arthroplasty, Knee arthroplasty, Knee arthroplasty, Thyroidectomy, Hip surgery, Prolapse repair, Infective exacerbation of bronchiectasis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ACTONEL, AZITROMYCINE, CALCI CHEW 1.25G, CALCI CHEW D, CALCI CHEW D3, CEFUROXIM, CIPROXIN, ENOXAPARIN, ETALPHA, FERROFUMERATE, FLUCONAZOL, FOSTER, FUROSEMIDE, IPRAMOL STERI-NEB, LANTUS, MEROPENEM, METFORMINE, NOVORAPID, OMEPRAZOL, PREDNISOLON, RAMIPRIL, SIMVASTATINE, TAMIFLU, THYRAX DUOTAB
Adverse Events (AE) Preferred term	1. Occult blood positive 2. Respiratory tract infection 3. Haematoma 4. Cystitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/NO
Start/stop date of event with relative date	1. -----2011 (.) - 22JUL2011 (211) 2. 28FEB2011 (67) - 05MAR2011 (72) 3. 01MAR2011 (68) - --APR2011 (.) 4. 01JUL2011 (190) - 09JUL2011 (198)
Duration of AE	1. . 2. 6 3. . 4. 9
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER 2. REMEDIAL DRUG THERAPY 3. NONE 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300073353

Parameter	Value
	3. RESOLVED
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300083044

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300083044/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/62/WHITE/NETHERLANDS/YES
Medical history	Diverticulitis, Gout, Haematuria, Hydronephrosis, Hydronephrosis, Hypertension, Renal transplant, Myocardial infarction, Congenital cystic kidney disease, Pyelonephritis, Urine cytology abnormal, Arterial stent insertion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AMOXICILLIN/CLAVULANIC ACID, CALCIUM CARBONATE, CARBASALATE CALCIUM, CEFTRIAXON, COLCHICINE, COTRIMOXAZOL, ENALAPRIL MALEATE, ENOXAPARIN, LIPITOR, NEXIUM, PANTOZOL, PARACETAMOL, PREDNISOLON, PROGRAFT, SELOKEEN, UNFRACTIONATED HEPARIN, UROKINASE
Adverse Events (AE) Preferred term	1. Post procedural haemorrhage 2. Iliac artery thrombosis 3. Haematoma 4. Pain in extremity 5. Urinary tract infection 6. Headache
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. SEVERE/NO/YES/YES 3. SEVERE/YES/NO/YES 4. MODERATE/YES/NO/YES 5. MODERATE/NO/YES/NO 6. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 31AUG2009 (7) - 01SEP2009 (8) 2. 16SEP2009 (23) - 17SEP2009 (24) 3. 17SEP2009 (24) - 12OCT2009 (49) 4. 25SEP2009 (32) - 13OCT2009 (50) 5. 14OCT2009 (51) - 21OCT2009 (58) 6. 20OCT2009 (57) - 20OCT2009 (57)
Duration of AE	1. 2 2. 2 3. 26 4. 19 5. 8 6. 1
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300083044

Parameter	Value
	6.
Action taken	1. OTHER
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	3. OTHER
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300083048

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300083048/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/51/BLACK/NETHERLANDS/YES
Medical history	Anaemia, Depression, Drug hypersensitivity, Menorrhagia, Menstruation irregular, Uterine leiomyoma, Varicose vein, Sterilisation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, LACTULOSE SIRUP 50%, METOPROLOL ZOC, MORFINE, NITROGLYCERINE SPRAY, OMEPRAZOL, PARACETAMOL, VITAMINE B COMPLEX
Adverse Events (AE) Preferred term	1. Alopecia 2. Nausea 3. Headache 4. Hyperventilation 5. Haemoptysis 6. Visual acuity reduced 7. Abnormal sensation in eye 8. Pain in extremity 9. Menorrhagia 10. Conjunctival haemorrhage 11. Haemoptysis 12. Chest discomfort 13. Cough 14. Subcutaneous haematoma 15. Pruritus 16. Chest pain 17. Gastroenteritis 18. Influenza
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. MILD/YES/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/YES/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/YES/NO/YES 10. MILD/YES/NO/YES 11. MILD/YES/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/YES 14. MILD/YES/NO/YES 15. MILD/NO/NO/YES 16. MODERATE/NO/NO/YES 17. MILD/NO/NO/NO 18. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --DEC2009 (.) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300083048

Parameter	Value
	2. 23OCT2009 (1) - 24MAR2010 (153)
	3. 30OCT2009 (8) - 12NOV2009 (21)
	4. 01NOV2009 (10) - 06NOV2009 (15)
	5. 16NOV2009 (25) - 16NOV2009 (25)
	6. 01DEC2009 (40) - --------- (.)
	7. 01DEC2009 (40) - 30DEC2009 (69)
	8. 05DEC2009 (44) - 30DEC2009 (69)
	9. 07DEC2009 (46) - 14DEC2009 (53)
	10. 11DEC2009 (50) - 14DEC2009 (53)
	11. 11DEC2009 (50) - 11DEC2009 (50)
	12. 12DEC2009 (51) - 12DEC2009 (51)
	13. 12DEC2009 (51) - 12DEC2009 (51)
	14. 04JAN2010 (74) - 09JAN2010 (79)
	15. 01FEB2010 (102) - --------- (.)
	16. 04FEB2010 (105) - --SEP2010 (.)
	17. 04APR2010 (164) - 05APR2010 (165)
	18. 14SEP2010 (327) - 30SEP2010 (343)
Duration of AE	1. .
	2. 153
	3. 14
	4. 6
	5. 1
	6. .
	7. 30
	8. 26
	9. 8
	10. 4
	11. 1
	12. 1
	13. 1
	14. 6
	15. .
	16. .
	17. 2
	18. 17
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300083048

Parameter	Value
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. F
	18. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. OTHER
	13. NONE
	14. NONE
	15. NONE
	16. REMEDIAL DRUG THERAPY,OTHER
	17. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300083048

Parameter	Value
	18. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. UNCHANGED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300083049

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300083049/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/74/WHITE/NETHERLANDS/YES
Medical history	Appendicectomy, Metastases to bone, Chronic obstructive pulmonary disease, Diverticulum, Haematuria, Haemorrhoids, Hydronephrosis, Hypertension, Metastases to liver, Metastases to lung, Lymphadenopathy, Bladder cancer, Osteoarthritis, Back pain, Pleurisy, Prostate cancer, Brachytherapy, Tremor, Varicose vein, Varicose vein, Bilateral orchidectomy, Lymphadenectomy, Lower limb fracture, Urinary cystectomy, Lower urinary tract symptoms, Lower urinary tract symptoms
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPINE SANDOZ RETARD, AUGMENTIN, CARBOPLATIN, CYCLOKAPRON, DICLOFENAC, DIOVAN, ERYTHROCINE, ETOPOSIDE, FORTUM, FUROSEMIDE, METOPROLOL, MORFINE, MOVICOLON COMPOUND, OMNIC, PARACETAMOL, TEMAZEPAM, TRAMADOL, VENTOLIN INHALER
Adverse Events (AE) Preferred term	1. Medical observation 2. Haematuria 3. Pneumonia 4. Haematuria 5. Rectal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/YES/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/YES/NO/YES 5. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 13NOV2009 (17) - 14NOV2009 (18) 2. 13NOV2009 (17) - 19NOV2009 (23) 3. 29NOV2009 (33) - 10DEC2009 (44) 4. 30NOV2009 (34) - --------- (.) 5. 07DEC2009 (41) - 08DEC2009 (42)
Duration of AE	1. 2 2. 7 3. 12 4. . 5. 2
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. OTHER 2. OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300083049

Parameter	Value
	3. REMEDIAL DRUG THERAPY
	4. OTHER
	5. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300103003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/300103003/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/66/WHITE/NETHERLANDS/YES
Medical history	Anaemia, Headache, Dyspepsia, Leukocytosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, KALIUMCHLORIDE, LANSOPRAZOL, PANTOPRAZOL, PARACETAMOL, PETHIDINE, SARIDON [PROPYFENAZON, PARACETAMOL, COFFEINE], ZOFRAN
Adverse Events (AE) Preferred term	1. Cyst 2. Dry mouth 3. Constipation 4. Adrenal haemorrhage 5. Haematemesis 6. Nausea 7. Constipation 8. Oesophagitis 9. Addison's disease 10. Bacterial test positive
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/YES/YES/YES 5. MODERATE/YES/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. SEVERE/YES/YES/YES 10. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 06JUL2007 (3) - --------- (.) 2. 06JUL2007 (3) - 18JUL2007 (15) 3. 01AUG2007 (29) - 03SEP2007 (62) 4. 02SEP2007 (61) - 11SEP2007 (70) 5. 02SEP2007 (61) - 02SEP2007 (61) 6. 02SEP2007 (61) - 06SEP2007 (65) 7. 03SEP2007 (62) - 10SEP2007 (69) 8. 03SEP2007 (62) - --------- (.) 9. 05SEP2007 (64) - --------- (.) 10. 05SEP2007 (64) - 06SEP2007 (65)
Duration of AE	1. . 2. 13 3. 34 4. 10 5. 1 6. 5 7. 8 8. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300103003

Parameter	Value
	9. .
	10. 2
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. F
	10. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. WORSENED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 300103003

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-300103003[3)]	HEMATEMESIS OF OLD BLOOD（PT：吐血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、リバーロキサバン投与と報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340013001/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/24/WHITE/SWEDEN/YES
Medical history	Anxiety, Appendicectomy, Cervical dysplasia, Depression, Insomnia, Pneumonia, Tonsillectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	COCILLANA-ETYFIN, DOXYFERM, MINI-PE, MOLLIPECT, NEOVLETTA, PROPAVAN, STILNOCT, TIKACILLIN
Adverse Events (AE) Preferred term	1. Menorrhagia 2. Nasopharyngitis 3. Nasopharyngitis 4. Bronchopneumonia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. SEVERE/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 29MAY2007 (14) - 21AUG2007 (98) 2. 30MAY2007 (15) - --JUN2007 (.) 3. 10SEP2007 (118) - 17SEP2007 (125) 4. 17SEP2007 (125) - 04OCT2007 (142)
Duration of AE	1. 85 2. . 3. 8 4. 18
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013001

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340013013/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/85/WHITE/SWEDEN/YES
Medical history	Bronchitis, Hypertension, Insomnia, Osteoarthritis, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT, CLOXACILLIN, ENOXAPARIN, FLUNITRAZEPAM, FRAGMIN, GLUCOSINE, IMDUR, IMOVANE, KONAKION, LASIX RETARD, OESTRIOL, PANODIL, SELOKEN ZOC, SUSCARD, TRADOLAN, TRIATEC, TROMBYL, WARFARIN
Adverse Events (AE) Preferred term	1. Sick sinus syndrome 2. Procedural pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 01JUL2008 (133) - 05JUL2008 (137) 2. 04JUL2008 (136) - 04JUL2008 (136)
Duration of AE	1. 5 2. 1
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013019

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340013019/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/38/WHITE/SWEDEN/YES
Medical history	Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CITODON, DICLOFENAC, ENOXAPARIN, KLEXANE, KÅVEPENIN, OXASCAND, PANOCOD, PARACETAMOL, TRINETTA, WARFARIN
Adverse Events (AE) Preferred term	1. Pleuritic pain 2. Pneumonia mycoplasmal 3. Pneumonia mycoplasmal
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 13APR2008 (4) - 16APR2008 (7) 2. 15APR2008 (6) - 18APR2008 (9) 3. 19APR2008 (10) - 09MAY2008 (30)
Duration of AE	1. 4 2. 4 3. 21
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. NONE 3. NONE
Outcome of event	1. RESOLVED 2. IMPROVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013025

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340013025/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/60/WHITE/SWEDEN/YES
Medical history	Pneumonia, Prostate cancer, Obstructive airways disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BENZYLPENICILLIN, CASODEX, FUROSEMID, KAVEPENIN, PAMOL, PROCREN DEPOT, SYMBICORT
Adverse Events (AE) Preferred term	1. Chest pain 2. Cough 3. Nephrotic syndrome
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 23NOV2008 (19) - -----2009 (.) 2. 29APR2009 (176) - --------- (.) 3. 17MAY2009 (194) - --JUL2009 (.)
Duration of AE	1. . 2. . 3. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. OTHER 2. NONE 3. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. INSUFFICIENT FOLLOW-UP 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013034

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340013034/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/56/WHITE/SWEDEN/YES
Medical history	Diabetes mellitus, Hypercholesterolaemia, Hypertension, Inguinal hernia, Colitis ulcerative, Umbilical hernia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPIN, ASACOL, DALACIN [CLINDAMYCIN], DIKLOFENAK, DIKOLOFENAK, ENALAPRIL COMP, EUSAPRIM FORTE, FRAGMIN, INSULATARD FLEXIPEN, METFORMIN, NOVO NORM, OXYNORM, PANODIL, SELOKEN, SIMVASTATIN
Adverse Events (AE) Preferred term	1. Wound haemorrhage 2. Renal colic 3. Nephrolithiasis 4. Blood urine present 5. Wound infection 6. Rash 7. Poor dental condition 8. Umbilical hernia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 05APR2009 (30) - 05APR2009 (30) 2. 09APR2009 (34) - 11APR2009 (36) 3. 09APR2009 (34) - 02SEP2009 (180) 4. 10APR2009 (35) - 11APR2009 (36) 5. 16APR2009 (41) - 09JUN2009 (95) 6. 28MAY2009 (83) - 11JUN2009 (97) 7. 27AUG2009 (174) - 27AUG2009 (174) 8. 04NOV2009 (243) - 05NOV2009 (244)
Duration of AE	1. 1 2. 3 3. 147 4. 2 5. 55 6. 15 7. 1 8. 2
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013034

Parameter	Value
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. I
Action taken	1. OTHER
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	8. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013037

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340013037/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/SWEDEN/YES
Medical history	Depression, Diabetes mellitus, Obstructive airways disorder, Gastritis, Hypothyroidism, Insomnia, Knee arthroplasty, Vitamin B complex deficiency, Osteoarthritis, Myocardial ischaemia, Diarrhoea
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLCYSTEINE, BISOPROLOL, CITALOPRAM, ENALAPRIL, ENOXAPARIN, FLUNITRAZEPAM, FURIX, KALEORID, LEVAXIN, LOPERAMID, MIANSERIN, NOVO MIX PEN, OMEPRAZOL, OXIS TURBUL,INHAL, OXYCONTIN, OXYNORM, PANODIL, PREDNISOLON, PULMICORT, TRIOBE, WARFARIN
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Dyspnoea 3. Diarrhoea 4. Vomiting 5. Retroperitoneal haemorrhage 6. Melaena 7. General physical health deterioration 8. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. SEVERE/YES/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. SEVERE/YES/YES/NO 6. MODERATE/YES/YES/NO 7. SEVERE/NO/NO/NO 8. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 18APR2009 (2) - 20APR2009 (4) 2. 20APR2009 (4) - 22APR2009 (6) 3. 24APR2009 (8) - --MAY2009 (.) 4. 24APR2009 (8) - 28APR2009 (12) 5. 04MAY2009 (18) - 29MAY2009 (43) 6. 04MAY2009 (18) - 29MAY2009 (43) 7. 04MAY2009 (18) - 29MAY2009 (43) 8. 26MAY2009 (40) - 05JUN2009 (50)
Duration of AE	1. 3 2. 3 3. . 4. 5 5. 26 6. 26 7. 26 8. 11
Dose on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013037

Parameter	Value
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. OTHER
	3. STUDY DRUG DISCONTINUED PERMANENTLY
	4. NONE
	5. REMEDIAL DRUG THERAPY,OTHER
	6. OTHER
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. WORSENED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-340013037[2),2)]	MELENA（PT：メレナ） 治験担当医はエノキサパリンと報告事象との関連性があると判断した。弊社は、エノキサパリン投与終了 2 週間後の発現であり、時間的関連性がないことから、エノキサパリンとの因果関係は否定できると考える。 SUDDEN DYSPNEA（PT：呼吸困難） 治験担当医は原疾患（肺塞栓症）及び合併症（虚血性心疾患）による可能性も考えられるが、エノキサパリン及びワルファリンと報告事象との関連性があると判断した。弊社は、原疾患（肺塞栓症）及び合併症（虚血性心疾患）によるものとし、エノキサパリン及びワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013040

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340013040/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/85/WHITE/SWEDEN/YES
Medical history	Chronic obstructive pulmonary disease, Hypothyroidism, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	LEVAXIN, PLENDIL, SPIRIVA, SYMBICORT FORTE
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Vertigo 3. Atrial fibrillation 4. Conjunctival haemorrhage 5. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/YES/YES 4. MILD/YES/NO/YES 5. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --JUN2010 (.) - 11JUN2010 (367) 2. 04JUL2009 (25) - 06JUL2009 (27) 3. 14JUL2009 (35) - 15JUL2009 (36) 4. 28AUG2009 (80) - 01SEP2009 (84) 5. 02DEC2009 (176) - 10DEC2009 (184)
Duration of AE	1. . 2. 3 3. 2 4. 5 5. 9
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. . 5. .
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY,OTHER 3. OTHER 4. NONE 5. OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED 4. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013040

Parameter	Value
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013042

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340013042/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/38/WHITE/SWEDEN/YES
Medical history	Seasonal allergy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DALTEPARIN, ENOXAPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Liver function test abnormal
	2. Headache
	3. Rash
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/YES/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 11NOV2009 (14) - 19NOV2009 (22)
	2. 08FEB2010 (103) - 12FEB2010 (107)
	3. 02APR2010 (156) - 25APR2010 (179)
Duration of AE	1. 9
	2. 5
	3. 24
Dose on AE onset	1.
	2.
	3.
Dose status on AE onset	1.
	2.
	3.
Action taken	1. NONE
	2. NONE
	3. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-340013042[1)]	HIGH LIVER FUNCTION TEST（PT：肝機能検査異常） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、ワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013047

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340013047/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/59/WHITE/SWEDEN/YES
Medical history	Depression, Crohn's disease, Ileostomy, Thrombophlebitis, Postmenopause, Varicose vein operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CITALOPRAM, KALSIPOS D, PANODIL, ZOLPIDEM
Adverse Events (AE) Preferred term	1. Post procedural haemorrhage
	2. Dyspnoea
	3. Dyspnoea
	4. Liver function test abnormal
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES
	2. MILD/NO/NO/YES
	3. MODERATE/NO/YES/YES
	4. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 22APR2010 (1) - --------- (.)
	2. 30APR2010 (9) - 03MAY2010 (12)
	3. 03MAY2010 (12) - 05MAY2010 (14)
	4. 20SEP2010 (152) - --------- (.)
Duration of AE	1. .
	2. 4
	3. 3
	4. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
Action taken	1. NONE
	2. NONE
	3. OTHER
	4. OTHER
Outcome of event	1. UNCHANGED
	2. WORSENED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013047

Parameter	Value
	4. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013048

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340013048/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/64/WHITE/SWEDEN/YES
Medical history	Hypertension, Obesity, Rheumatoid arthritis, Rotator cuff syndrome, Torticollis, Venous thrombosis, Osteoarthritis, Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLCYSTEIN, AMLODIPIN, ATACAND PLUS, BRICANYL TURBOHALER, CITODON, COCILLANA-ETYFIN, COMBIVENT, DOXYFERM, ENOXAPARIN, FELODIPIN, FRAGMIN, IMOVANE, INNOHEP, LOSARTAN, METOJECT, MOLLIPECT, ORUDIS GEL, OXASCAND, PAMOL, PREDNISOLON, SPIRIVA, STESOLID, SYMBICORT FORTE TURBOHALER, TIPAROL, WARFARIN
Adverse Events (AE) Preferred term	1. Chronic obstructive pulmonary disease 2. Balance disorder 3. Bronchitis 4. Haemoptysis 5. Pulmonary fibrosis 6. Anxiety 7. Pulmonary fibrosis 8. Headache 9. Myalgia 10. Blood pressure increased 11. Tongue haemorrhage 12. Contusion 13. Atrial fibrillation 14. Haemoglobin increased
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/YES/NO/YES 5. MODERATE/NO/YES/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/YES/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/YES/NO/YES 12. MILD/YES/NO/YES 13. MODERATE/NO/YES/YES 14. MILD/NO/NO/YES
Start/stop date of event with relative date	1. -----2010 (.) - --------- (.) 2. --------- (.) - --------- (.) 3. 02SEP2010 (23) - 27OCT2010 (78) 4. 23SEP2010 (44) - 08NOV2010 (90) 5. 30SEP2010 (51) - 07OCT2010 (58) 6. 03OCT2010 (54) - 03OCT2010 (54) 7. 08OCT2010 (59) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013048

Parameter	Value
	8. 13NOV2010 (95) - 17NOV2010 (99)
	9. 13NOV2010 (95) - --------- (.)
	10. 13NOV2010 (95) - 14NOV2010 (96)
	11. 22NOV2010 (104) - 22NOV2010 (104)
	12. 08JAN2011 (151) - -----2011 (.)
	13. 01FEB2011 (175) - 09FEB2011 (183)
	14. 01FEB2011 (175) - --------- (.)
Duration of AE	1. .
	2. .
	3. 56
	4. 47
	5. 8
	6. 1
	7. .
	8. 5
	9. .
	10. 2
	11. 1
	12. .
	13. 9
	14. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013048

Parameter	Value
	10.
	11.
	12.
	13.
	14.
Action taken	1. REMEDIAL DRUG THERAPY
	2. OTHER
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. DOSE OF STUDY DRUG REDUCED,REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	9. REMEDIAL DRUG THERAPY,OTHER
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. NONE
	13. OTHER
	14. OTHER
Outcome of event	1. IMPROVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED
	9. IMPROVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-340013048[3),1)]	HEMOPTYSIS（PT：喀血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、ワルファリンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリン投与中止 5 週間後の発現であり、時間的関連性がないため、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013051

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340013051/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/65/WHITE/SWEDEN/YES
Medical history	Abdominal pain, Cholecystitis, Cholelithiasis, Gastrooesophageal reflux disease, Pneumonia, Skin ulcer, Varicose vein operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	KÅVEPENIN, OMEPRAZOL, VOLTAREN
Adverse Events (AE) Preferred term	1. Cholecystitis 2. Chest pain 3. Cholelithiasis 4. Cholelithiasis 5. Cholelithiasis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 11OCT2010 (1) - 15OCT2010 (5) 2. 14FEB2011 (127) - 14FEB2011 (127) 3. 14FEB2011 (127) - 14FEB2011 (127) 4. 18FEB2011 (131) - 18FEB2011 (131) 5. 21FEB2011 (134) - 21FEB2011 (134)
Duration of AE	1. 5 2. 1 3. 1 4. 1 5. 1
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. OTHER 2. OTHER 3. OTHER 4. REMEDIAL DRUG THERAPY 5. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340013051

Parameter	Value
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340043003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/81/WHITE/SWEDEN/YES
Medical history	Asthma, Depression, Hypercholesterolaemia, Osteoporosis, Cataract, Joint swelling, Transient ischaemic attack, Vitamin B12 deficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLCYSTEIN, ATROVENT, BEHEPAN, BETAPRED, BRICANYL TURBOHALER, CALCICHEW-D3, COCILLANA-ETYFIN, COMBIVENT, DELTISON, ENOXAPARIN, FLUORESCEIN SODIUM, IMOVANE, IMPUGAN, KALIUM RETARD, LIDOKAIN HYDROCHLORID, PANODIL, PHENYLEPRINE HYDROCHLORIDE, SIMVASTATIN, SYMBICORT TURBOHALER, TROPIKAMID, VENTOLINE, WARFARIN
Adverse Events (AE) Preferred term	1. Insomnia 2. Haematoma 3. Epistaxis 4. Fatigue 5. Nasopharyngitis 6. Eye haemorrhage 7. Epistaxis 8. Epistaxis 9. Asthma 10. Asthma 11. Asthma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/YES/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/YES/NO/YES 7. SEVERE/YES/NO/YES 8. MODERATE/YES/NO/YES 9. SEVERE/NO/NO/YES 10. SEVERE/NO/YES/NO 11. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 09JAN2008 (1) - 11JAN2008 (3) 2. 13JAN2008 (5) - 16JAN2008 (8) 3. 08APR2008 (91) - 08APR2008 (91) 4. 09APR2008 (92) - 16MAY2008 (129) 5. 25JUL2008 (199) - 10AUG2008 (215) 6. 25JUL2008 (199) - 23AUG2008 (228) 7. 05DEC2008 (332) - 09DEC2008 (336) 8. 12DEC2008 (339) - 12DEC2008 (339) 9. 23DEC2008 (350) - 08JAN2009 (366) 10. 09JAN2009 (367) - 13JAN2009 (371) 11. 14JAN2009 (372) - 20JAN2009 (378)
Duration of AE	1. 3

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043003

Parameter	Value
	2. 4
	3. 1
	4. 38
	5. 17
	6. 30
	7. 5
	8. 1
	9. 17
	10. 5
	11. 7
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. OTHER
	4. NONE
	5. NONE
	6. OTHER
	7. OTHER
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043003

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. WORSENED
	10. IMPROVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340043009/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/36/WHITE/SWEDEN/YES
Medical history	Vision blurred, Hypoaesthesia, Cardiac failure, Palpitations, Wolff-Parkinson-White syndrome
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BETAMETASON, DALACIN [CLINDAMYCIN], DEPO-PROVERA, EMCONCOR CHF, HYDROCORTISONE 1%, LEPHETON, LOPERAMID, SELEXID, TRIATEC
Adverse Events (AE) Preferred term	1. Subcutaneous abscess 2. Urinary tract infection 3. Cough 4. Chest pain 5. Pyrexia 6. Nasopharyngitis 7. Nasopharyngitis 8. Eczema 9. Nasopharyngitis 10. Diarrhoea 11. Back pain 12. Brain neoplasm
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES 10. MODERATE/NO/NO/YES 11. SEVERE/NO/NO/YES 12. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. --SEP2008 (.) - 10OCT2008 (212) 2. 09JUN2008 (89) - 15JUN2008 (95) 3. 05JUL2008 (115) - 23JUL2008 (133) 4. 05JUL2008 (115) - 23JUL2008 (133) 5. 18JUL2008 (128) - --JUL2008 (.) 6. 29AUG2008 (170) - 04SEP2008 (176) 7. 18OCT2008 (220) - 21OCT2008 (223) 8. 24OCT2008 (226) - --FEB2009 (.) 9. 30NOV2008 (263) - 05DEC2008 (268) 10. 20DEC2008 (283) - 25JAN2009 (319) 11. 01FEB2009 (326) - 02FEB2009 (327) 12. 15FEB2009 (340) - --------- (.)
Duration of AE	1. . 2. 7

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043009

Parameter	Value
	3. 19
	4. 19
	5. .
	6. 7
	7. 4
	8. .
	9. 6
	10. 37
	11. 2
	12. .
Dose on AE onset	1.
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. OTHER
	5. NONE
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043009

Parameter	Value
	11. NONE
	12. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340043017/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/59/WHITE/SWEDEN/YES
Medical history	Chronic obstructive pulmonary disease, Hypoalbuminaemia, Oedema peripheral, Thrombocytopenia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	FUROSEMID, SYMBICORT FORTE
Adverse Events (AE) Preferred term	1. Headache 2. Thrombocytopenia 3. Thrombocytopenia 4. Haematoma 5. Epistaxis 6. Haematuria 7. Mouth haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/YES/NO/YES 3. SEVERE/YES/YES/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/NO 6. MILD/YES/NO/NO 7. MILD/YES/NO/NO
Start/stop date of event with relative date	1. --APR2009 (.) - 18MAY2009 (46) 2. 16APR2009 (14) - 20APR2009 (18) 3. 20APR2009 (18) - 27JUL2009 (116) 4. 22APR2009 (20) - --MAY2009 (.) 5. 27APR2009 (25) - --JUN2009 (.) 6. 01MAY2009 (29) - --MAY2009 (.) 7. 01MAY2009 (29) - --MAY2009 (.)
Duration of AE	1. . 2. 5 3. 99 4. . 5. . 6. . 7. .
Dose on AE onset	1. 2. 15 mg 3. 15 mg 4. 15 mg 5. 15 mg 6. 15 mg 7. 15 mg
Dose status on AE onset	1. 2. . 3. . 4. F

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043017

Parameter	Value
	5. F
	6. F
	7. F
Action taken	1. NONE
	2. OTHER
	3. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	4. NONE
	5. REMEDIAL DRUG THERAPY,OTHER
	6. NONE
	7. NONE
Outcome of event	1. RESOLVED
	2. WORSENED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340043020/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/64/WHITE/SWEDEN/YES
Medical history	Osteoarthritis, Migraine, Hyperparathyroidism primary
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, IBUMETIN, OMEGA 3, PAMOL, WARFARIN
Adverse Events (AE) Preferred term	1. Nasopharyngitis
	2. Diarrhoea
	3. Hyperparathyroidism primary
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MILD/NO/NO/YES
	3. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 23OCT2009 (169) - 30OCT2009 (176)
	2. 26NOV2009 (203) - 28NOV2009 (205)
	3. 26MAY2010 (384) - 27MAY2010 (385)
Duration of AE	1. 8
	2. 3
	3. 2
Dose on AE onset	1.
	2.
	3.
Dose status on AE onset	1.
	2.
	3.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043024

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340043024/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/66/WHITE/SWEDEN/YES
Medical history	Hypothyroidism, Visual acuity reduced, Ear infection, Psoriasis, Urethritis, Postmenopause, Hypertension, Lichen sclerosus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BETAPRED, BETNOVAT, CANODERM, CYCLOPENTOLATE PHENYLEPHRINE, DAIVOBET, ELOCON, EMOVAT, ENOXAPARIN, FRAGMIN, FUCITHALMIC 1%, ISOPTO-MAXIDEX, LEVAXIN, MAXIDEX 1MG/ML, NEVANAC, PANDEMRIX, REPLENS, RINGER-ACETAT, SALICYLSYRE VASELINE, WARFARIN
Adverse Events (AE) Preferred term	1. Paraesthesia 2. Cataract 3. Conjunctival haemorrhage 4. Retinal degeneration 5. Nasopharyngitis 6. Urticaria
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/YES/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --NOV2009 (.) - --------- (.) 2. --NOV2009 (.) - 24MAY2010 (251) 3. 28MAR2010 (194) - 28MAR2010 (194) 4. 16JUN2010 (274) - 18JUN2010 (276) 5. 01AUG2010 (320) - 08AUG2010 (327) 6. 21AUG2010 (340) - 23AUG2010 (342)
Duration of AE	1. . 2. . 3. 1 4. 3 5. 8 6. 3
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043024

Parameter	Value
	6.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY,OTHER
	3. NONE
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. NONE
	6. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043027

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340043027/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/72/WHITE/SWEDEN/YES
Medical history	Anaemia, Cholecystectomy, Pneumonia, Thyroidectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLCYSTEIN, DUROFERON, KÅVEPENIN, MOLLIPECT, PARACETAMOL, TROMBYL
Adverse Events (AE) Preferred term	1. Occult blood positive 2. Renal neoplasm
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. --DEC2009 (.) - --------- (.) 2. 22JAN2010 (59) - --------- (.)
Duration of AE	1. . 2. .
Dose on AE onset	1. 2. 20 mg
Dose status on AE onset	1. 2. .
Action taken	1. OTHER 2. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. UNCHANGED 2. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043028

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340043028/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/55/WHITE/SWEDEN/YES
Medical history	Depression, Insomnia, Migraine, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANERVAN, COCILLANA-ETYFIN, DIKLOFENAK, KLEXANE, MIRTAZAPIN, OMEPRAZOL, ONDANSETRON, PANODIL, POSTAFEN, PRIMPERAN, RINGER-ACETAT, WARAN
Adverse Events (AE) Preferred term	1. Nausea 2. Depression 3. Nausea 4. Nausea 5. Wound haemorrhage 6. Groin pain 7. Nasopharyngitis 8. Groin pain 9. Nasopharyngitis 10. Diarrhoea
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/YES/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 04FEB2010 (1) - 10MAR2010 (35) 2. 04FEB2010 (1) - --------- (.) 3. 10MAR2010 (35) - 12MAR2010 (37) 4. 13MAR2010 (38) - ---------- (.) 5. 18SEP2010 (227) - 18SEP2010 (227) 6. 26OCT2010 (265) - 02NOV2010 (272) 7. 31OCT2010 (270) - 11NOV2010 (281) 8. 06NOV2010 (276) - 09NOV2010 (279) 9. 21NOV2010 (291) - 13DEC2010 (313) 10. 20FEB2011 (382) - 21FEB2011 (383)
Duration of AE	1. 35 2. . 3. 3 4. . 5. 1 6. 8 7. 12 8. 4

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043028

Parameter	Value
	9. 23
	10. 2
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1. .
	2. .
	3. I
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. F
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. NONE
	5. OTHER
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
Outcome of event	1. WORSENED
	2. IMPROVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340043028

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340053006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340053006/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/56/WHITE/SWEDEN/YES
Medical history	Inguinal hernia repair
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Haematuria
	2. Urinary tract infection
	3. Urosepsis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES
	2. MODERATE/NO/NO/NO
	3. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 30AUG2009 (5) - 08SEP2009 (14)
	2. 10SEP2009 (16) - --OCT2009 (.)
	3. 11SEP2009 (17) - 14SEP2009 (20)
Duration of AE	1. 10
	2. .
	3. 4
Dose on AE onset	1.
	2.
	3.
Dose status on AE onset	1.
	2.
	3.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340083002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/340083002/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/65/WHITE/SWEDEN/YES
Medical history	Hypersensitivity, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALVEDON, BROMHEXIN, CETIRIZIN MYLAN, CITODON, LAKTULOS, NASOMET, NICORETTE, NICOTINELL, NOSKAPIN, TRADOLAN, VOLTAREN
Adverse Events (AE) Preferred term	1. Cough 2. Cough 3. Localised oedema 4. Liver function test abnormal 5. Chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JUN2010 (.) - 21JUN2010 (54) 2. --SEP2010 (.) - --SEP2010 (.) 3. 30MAY2010 (32) - 31MAY2010 (33) 4. 22JUN2010 (55) - 02AUG2010 (96) 5. 03SEP2010 (128) - --------- (.)
Duration of AE	1. . 2. . 3. 2 4. 42 5. .
Dose on AE onset	1. 2. 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. 2. 3. . 4. . 5. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. NONE 4. NONE 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 340083002

Parameter	Value
	4. RESOLVED
	5. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-340083002[4)]	HIGH LIVER TEST VALUES（PT：肝機能検査異常） 治験担当医は、投与前後の検査値は正常であったと判断し、否定できると判断した。弊社は、リバーロキサバン投与と報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360013001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/360013001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/24/WHITE/NORWAY/YES
Medical history	
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DICLOFENAC, ENOXAPARIN, PARALGIN FORTE, ROCEPHALIN, WARFARIN
Adverse Events (AE) Preferred term	1. Pyrexia
	2. Respiratory tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
	2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 27FEB2008 (8) - 03MAR2008 (13)
	2. 27FEB2008 (8) - 03MAR2008 (13)
Duration of AE	1. 6
	2. 6
Dose on AE onset	1.
	2.
Dose status on AE onset	1.
	2.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360013017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/360013017/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/61/WHITE/NORWAY/YES
Medical history	Aortic aneurysm, Hypercholesterolaemia, Hypothyroidism, Intervertebral disc protrusion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	LEVOTHYROXIN, SIMVASTATIN
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Vein pain 3. Pyrexia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 20MAR2009 (19) - 24MAR2009 (23) 2. 20MAR2009 (19) - 24MAR2009 (23) 3. 09MAY2009 (69) - 11MAY2009 (71)
Duration of AE	1. 5 2. 5 3. 3
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. NONE 2. NONE 3. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360013029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/360013029/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/57/WHITE/NORWAY/YES
Medical history	Hypersensitivity, Epistaxis, Myalgia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CETERIZIN, ENOXAPARIN, IBUX, WARFARIN, ZOPIKLON
Adverse Events (AE) Preferred term	1. Chest pain
	2. Haemoptysis
	3. Cough
	4. Epistaxis
	5. Insomnia
	6. Epistaxis
	7. Dyspnoea
	8. Chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/NO/YES
	4. MILD/NO/NO/YES
	5. MILD/NO/NO/YES
	6. MILD/NO/NO/YES
	7. MILD/NO/NO/YES
	8. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 14JAN2010 (9) - 22FEB2010 (48)
	2. 16JAN2010 (11) - 16JAN2010 (11)
	3. 16JAN2010 (11) - 19JAN2010 (14)
	4. 21JAN2010 (16) - 21JAN2010 (16)
	5. 26JAN2010 (21) - 07FEB2010 (33)
	6. 28JAN2010 (23) - 28JAN2010 (23)
	7. 28JAN2010 (23) - 22FEB2010 (48)
	8. 12JUN2010 (158) - 17JUN2010 (163)
Duration of AE	1. 40
	2. 1
	3. 4
	4. 1
	5. 13
	6. 1
	7. 26
	8. 6
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360013029

Parameter	Value
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. OTHER
	2. NONE
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. OTHER
	7. OTHER
	8. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360013035

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/360013035/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/74/WHITE/NORWAY/YES
Medical history	Insomnia, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, IMOVANE, KETORAX, KLEXANE, KONAKION, PARACETAMOL, PERFALGAN, SOBRIL, WARFARIN
Adverse Events (AE) Preferred term	1. Humerus fracture 2. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 22AUG2010 (109) - 27AUG2010 (114) 2. 31AUG2010 (118) - 03SEP2010 (121)
Duration of AE	1. 6 2. 4
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. OTHER
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360023007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/360023007/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/33/WHITE/NORWAY/YES
Medical history	
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DALTEPARIN, PARACET, PARALGIN FORTE
Adverse Events (AE) Preferred term	1. Nasopharyngitis 2. Chest pain 3. Chest pain 4. Syncope
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --JAN2010 (.) - 15MAR2010 (216) 2. 11AUG2009 (0) - 15MAR2010 (216) 3. 14AUG2009 (3) - 15AUG2009 (4) 4. 14AUG2009 (3) - 15AUG2009 (4)
Duration of AE	1. . 2. 217 3. 2 4. 2
Dose on AE onset	1. 2. 3. 15 mg 4. 15 mg
Dose status on AE onset	1. 2. 3. . 4. .
Action taken	1. OTHER 2. NONE 3. REMEDIAL DRUG THERAPY 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360023007

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360023010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/360023010/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/71/WHITE/NORWAY/YES
Medical history	Cholelithiasis, Hepatic steatosis, Hypertension, Bursitis, Urge incontinence, Ovarian neoplasm
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	MORFIN, PARACETAMOL, SELO-ZOK, TOVIAZ
Adverse Events (AE) Preferred term	1. Fatigue
	2. Haematemesis
	3. Myalgia
	4. Nausea
	5. C-reactive protein increased
	6. Alanine aminotransferase increased
	7. Blood alkaline phosphatase increased
	8. Chest pain
	9. Aspartate aminotransferase increased
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/NO
	2. MODERATE/YES/YES/YES
	3. SEVERE/NO/YES/YES
	4. MODERATE/NO/NO/YES
	5. MILD/NO/NO/YES
	6. SEVERE/YES/YES/YES
	7. SEVERE/YES/NO/YES
	8. SEVERE/NO/YES/YES
	9. SEVERE/YES/NO/NO
Start/stop date of event with relative date	1. 19AUG2010 (1) - 14OCT2010 (57)
	2. 25AUG2010 (7) - 30AUG2010 (12)
	3. 25AUG2010 (7) - 30AUG2010 (12)
	4. 25AUG2010 (7) - 25AUG2010 (7)
	5. 29AUG2010 (11) - 14SEP2010 (27)
	6. 10SEP2010 (23) - 18NOV2010 (92)
	7. 10SEP2010 (23) - 18NOV2010 (92)
	8. 10SEP2010 (23) - 14SEP2010 (27)
	9. 13SEP2010 (26) - 18NOV2010 (92)
Duration of AE	1. 57
	2. 6
	3. 6
	4. 1
	5. 17
	6. 70
	7. 70
	8. 5
	9. 67
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360023010

Parameter	Value
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. F
	7. F
	8. F
	9. F
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY
	2. OTHER
	3. REMEDIAL DRUG THERAPY,OTHER
	4. NONE
	5. NONE
	6. STUDY DRUG DISCONTINUED AND RESTARTED
	7. STUDY DRUG DISCONTINUED AND RESTARTED
	8. REMEDIAL DRUG THERAPY
	9. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360043003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/360043003/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/NORWAY/YES
Medical history	Compression fracture, Fungal infection, Hypercholesterolaemia, Hypertension, Constipation, Osteoporosis, Pneumonia, Urinary tract infection, Weight decreased, Wrist fracture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALENDRONATE, AMLODIPIN, SIMVASTATIN
Adverse Events (AE) Preferred term	1. Haematuria 2. Bladder cancer 3. Pain in extremity 4. Oedema
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/NO 3. MODERATE/NO/NO/NO 4. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 23NOV2007 (2) - 28NOV2007 (7) 2. 12DEC2007 (21) - --------- (.) 3. 26DEC2007 (35) - --------- (.) 4. 26DEC2007 (35) - --------- (.)
Duration of AE	1. 6 2. . 3. . 4. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg
Dose status on AE onset	1. . 2. F 3. F 4. F
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. OTHER 4. OTHER
Outcome of event	1. RESOLVED 2. UNCHANGED 3. INSUFFICIENT FOLLOW-UP

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360043003

Parameter	Value
	4. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360043005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/360043005/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/83/WHITE/NORWAY/YES
Medical history	Drug hypersensitivity, Appendicectomy, Hypertension, Oophorectomy bilateral, Drug hypersensitivity, Perfume sensitivity, Toe operation, Gallbladder operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AFIPRAN, CEFUROXIM, CIPROXIM, DALACIN [CLINDAMYCIN PHOSPHATE], DEHYDREX, DUROFERON, FLAGYL, FRAGMIN, FURIX, GAVISCON, GLUCOSE 50 MG/ML, KALIUMCLORID, LACTULOSE, LASIX, NACL, NEXIUM, OXYNORM, PARACET, RAX NOS, RINGERACETAT, ZESTRIL, ZOPICLONE
Adverse Events (AE) Preferred term	1. Alopecia 2. Cough 3. Chest discomfort 4. Rash 5. Anaemia 6. Colon cancer 7. Melaena 8. Dyspnoea 9. Pyrexia 10. Nausea 11. Blood urine present 12. Abdominal pain upper 13. Bacterial test positive 14. Thrombocytopenia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. SEVERE/NO/YES/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MILD/NO/NO/YES 12. MODERATE/NO/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --SEP2008 (.) - --------- (.) 2. --APR2008 (.) - --MAY2008 (.) 3. 06FEB2008 (14) - 23APR2008 (91) 4. 27FEB2008 (35) - 27MAR2008 (64) 5. 05JUN2008 (134) - 12FEB2009 (386) 6. 05JUN2008 (134) - 08JUL2008 (167) 7. 05JUN2008 (134) - 08JUL2008 (167)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360043005

Parameter	Value
	8. 05JUN2008 (134) - --JUL2008 (.)
	9. 06JUN2008 (135) - --JUN2008 (.)
	10. 11JUL2008 (170) - 16JUL2008 (175)
	11. 01AUG2008 (191) - --AUG2008 (.)
	12. 08AUG2008 (198) - 18AUG2008 (208)
	13. 09AUG2008 (199) - 27AUG2008 (217)
	14. 12FEB2009 (386) - --------- (.)
Duration of AE	1. .
	2. .
	3. 78
	4. 30
	5. 253
	6. 34
	7. 34
	8. .
	9. .
	10. 6
	11. .
	12. 11
	13. 19
	14. .
Dose on AE onset	1.
	2.
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360043005

Parameter	Value
	10. I
	11. .
	12. .
	13. .
	14. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	7. OTHER
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. NONE
	12. NONE
	13. NONE
	14. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360043010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/360043010/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/65/WHITE/NORWAY/YES
Medical history	Gouty arthritis, Depression, Meniere's disease, Pericarditis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPUR, CITALOPRAM, ENOXAPARIN, FRAGMIN, METOPROLOL, WARFARIN
Adverse Events (AE) Preferred term	1. Bladder cancer 2. Hypertension 3. Pain in extremity 4. Oedema 5. Haematuria 6. Contusion 7. Syncope 8. Traumatic haemorrhage 9. Haematuria
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --JAN2009 (.) - 20MAR2009 (351) 2. --FEB2009 (.) - --------- (.) 3. 05APR2008 (2) - 11APR2008 (8) 4. 05APR2008 (2) - 11APR2008 (8) 5. 01OCT2008 (181) - 29OCT2008 (209) 6. 01OCT2008 (181) - --OCT2008 (.) 7. 19DEC2008 (260) - 19DEC2008 (260) 8. 16JAN2009 (288) - 16JAN2009 (288) 9. 16JAN2009 (288) - 16JAN2009 (288)
Duration of AE	1. . 2. . 3. 7 4. 7 5. 29 6. . 7. 1 8. 1 9. 1
Dose on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360043010

Parameter	Value
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. OTHER
	6. NONE
	7. OTHER
	8. OTHER
	9. OTHER
Outcome of event	1. RESOLVED
	2. INSUFFICIENT FOLLOW-UP
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360043019

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/360043019/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/54/WHITE/NORWAY/YES
Medical history	Asthma, Insomnia, Gingivitis, Guillain-Barre syndrome, Allergy to metals, Pneumonia, Postmenopause, Fibroadenoma of breast
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CORAL CALK EXTRA [THIS IS NATURAL REMEDY, VITAMIN SUPPLEMENT. INGREDIENTS NOT KN, ENOXAPARIN, ERY MAX, IMOVANE, JONI JUICE [THIS IS NATURAL REMEDY, VITAMIN SUPPLEMENT. INGREDIENTS NOT KNOWN], KLEXANE, MULTIPOWER [THIS IS VITAMIN SUPPLENT.INGREDIENTS NOT KNOWN], OMEGA 3, SOLVIPECT COMP, SYMBICORT, TOFUPILL, WARFARIN
Adverse Events (AE) Preferred term	1. Oedema peripheral 2. Syncope 3. Transaminases increased 4. Dyspnoea 5. Cough 6. Haemorrhage subcutaneous 7. Road traffic accident 8. Limb injury 9. Dizziness 10. Nausea 11. Gingival bleeding 12. Cough 13. Dyspnoea 14. Pain in extremity 15. Oedema
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/NO 13. MILD/NO/NO/NO 14. MILD/NO/NO/NO 15. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --MAR2009 (.) - --------- (.) 2. 12DEC2008 (9) - 13DEC2008 (10) 3. 12DEC2008 (9) - 19JAN2009 (47) 4. 02MAR2009 (89) - 09MAR2009 (96)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360043019

Parameter	Value
	5. 02MAR2009 (89) - 09MAR2009 (96)
	6. 29MAR2009 (116) - 31MAR2009 (118)
	7. 29MAR2009 (116) - 29MAR2009 (116)
	8. 29MAR2009 (116) - --------- (.)
	9. 11MAY2009 (159) - --------- (.)
	10. 11MAY2009 (159) - --JUL2009 (.)
	11. 01OCT2009 (302) - --OCT2009 (.)
	12. 17DEC2009 (379) - --------- (.)
	13. 17DEC2009 (379) - --------- (.)
	14. 17DEC2009 (379) - --------- (.)
	15. 17DEC2009 (379) - --------- (.)
Duration of AE	1. .
	2. 2
	3. 39
	4. 8
	5. 8
	6. 3
	7. 1
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Dose status on AE onset	1.
	2.
	3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360043019

Parameter	Value
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. OTHER
	7. NONE
	8. OTHER
	9. NONE
	10. NONE
	11. NONE
	12. NONE
	13. NONE
	14. NONE
	15. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. IMPROVED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED
	13. UNCHANGED
	14. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 360043019

Parameter	Value
	15. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-360043019[3)]	INCREASED TRANSAMINASES（PT：トランスアミナーゼ上昇） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、ワルファリン投与と報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370013005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370013005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/88/WHITE/SOUTH AFRICA/YES
Medical history	Bronchospasm, Constipation, Chronic obstructive pulmonary disease, Hyperkeratosis, Osteoarthritis, Oedema peripheral, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AVELON, BEROTEC, COMBIVENT, COMBIVENT NEBS, DIFLUCAN, DULCOLAX[BISACODYL], ENOXAPARIN, GLYCERINE, IMIPENEM, IMOVANE, MERONEM, MOVICOL, NEXIUM, PLENISH K, PROCYDON, PULMISON, ROLAB FUROSEMIDE, SERETIDE, SERETIDE ACCUHALER, SOLICORTEV, SOLU-CORTEF, SYNAP FORTE, TARGACID, VIT K, WARFARIN
Adverse Events (AE) Preferred term	1. Pyrexia 2. Pneumonia 3. Haemoptysis 4. Aspartate aminotransferase increased 5. Alanine aminotransferase increased 6. Subdural haemorrhage 7. Arrhythmia 8. Hyperkeratosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. SEVERE/YES/YES/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 06APR2008 (8) - 10APR2008 (12) 2. 06APR2008 (8) - 15APR2008 (17) 3. 14APR2008 (16) - 01JUN2008 (64) 4. 14APR2008 (16) - 06JUN2008 (69) 5. 14APR2008 (16) - 06JUN2008 (69) 6. 15JUL2008 (108) - 23JUL2008 (116) 7. 23JUL2008 (116) - 23JUL2008 (116) 8. 03SEP2008 (158) - 04SEP2008 (159)
Duration of AE	1. 5 2. 10 3. 49 4. 54 5. 54 6. 9 7. 1 8. 2
Dose on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370013005

Parameter	Value
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. NONE
	6. STUDY DRUG DISCONTINUED PERMANENTLY
	7. REMEDIAL DRUG THERAPY
	8. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370013010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370013010/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/70/WHITE/SOUTH AFRICA/YES
Medical history	Colon cancer, Colon cancer, Hypertension, Pneumonia, Procedural pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BUSCOPAN, COVERSYL, GAVISCON, IMODIUM, NEXIAM, OMNOPON, PERFALGAN, PETHIDINE, STILNOX, SYNAP FORTE, TAZOCIN, VANCOMYCIN, ZIAK, ZOFRAN
Adverse Events (AE) Preferred term	1. Abdominal pain 2. Hypertension 3. Dyspepsia 4. Vomiting 5. Nausea 6. Diarrhoea 7. Pyrexia 8. Abdominal distension 9. Large intestinal obstruction 10. Urine output decreased 11. Scrotal oedema 12. Pyrexia 13. Abdominal abscess 14. Tachycardia 15. Confusional state 16. Haemoglobin decreased 17. Tachypnoea 18. Hypotension 19. Acidosis 20. Pyrexia 21. Renal failure 22. Atrial fibrillation 23. Ventricular fibrillation
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. SEVERE/NO/YES/YES 10. MODERATE/NO/NO/YES 11. MILD/NO/NO/NO 12. MILD/NO/NO/NO 13. MODERATE/NO/NO/NO 14. MODERATE/NO/NO/NO 15. MILD/NO/NO/NO

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370013010

Parameter	Value
	16. MODERATE/NO/NO/NO
	17. MILD/NO/NO/NO
	18. MILD/NO/NO/NO
	19. MILD/NO/NO/NO
	20. MILD/NO/NO/NO
	21. MODERATE/NO/NO/NO
	22. MODERATE/NO/NO/NO
	23. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 25OCT2008 (1) - 12NOV2008 (19)
	2. 25OCT2008 (1) - 27OCT2008 (3)
	3. 26OCT2008 (2) - 26OCT2008 (2)
	4. 27OCT2008 (3) - 29OCT2008 (5)
	5. 27OCT2008 (3) - 08NOV2008 (15)
	6. 28OCT2008 (4) - 01NOV2008 (8)
	7. 31OCT2008 (7) - 31OCT2008 (7)
	8. 02NOV2008 (9) - 12NOV2008 (19)
	9. 03NOV2008 (10) - --------- (.)
	10. 04NOV2008 (11) - 12NOV2008 (19)
	11. 06NOV2008 (13) - 12NOV2008 (19)
	12. 06NOV2008 (13) - 07NOV2008 (14)
	13. 06NOV2008 (13) - 10NOV2008 (17)
	14. 06NOV2008 (13) - 12NOV2008 (19)
	15. 07NOV2008 (14) - 08NOV2008 (15)
	16. 07NOV2008 (14) - 12NOV2008 (19)
	17. 07NOV2008 (14) - 08NOV2008 (15)
	18. 07NOV2008 (14) - 09NOV2008 (16)
	19. 08NOV2008 (15) - 12NOV2008 (19)
	20. 09NOV2008 (16) - 10NOV2008 (17)
	21. 09NOV2008 (16) - 12NOV2008 (19)
	22. 09NOV2008 (16) - 12NOV2008 (19)
	23. 12NOV2008 (19) - 12NOV2008 (19)
Duration of AE	1. 19
	2. 3
	3. 1
	4. 3
	5. 13
	6. 5
	7. 1
	8. 11
	9. .
	10. 9
	11. 7
	12. 2
	13. 5

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370013010

Parameter	Value
	14. 7
	15. 2
	16. 6
	17. 2
	18. 3
	19. 5
	20. 2
	21. 4
	22. 4
	23. 1
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 15 mg
	12. 15 mg
	13. 15 mg
	14. 15 mg
	15. 15 mg
	16. 15 mg
	17. 15 mg
	18. 15 mg
	19. 15 mg
	20. 15 mg
	21. 15 mg
	22. 15 mg
	23. 15 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. F
	11. F

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370013010

Parameter	Value
	12. F
	13. F
	14. F
	15. F
	16. F
	17. F
	18. F
	19. F
	20. F
	21. F
	22. F
	23. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. OTHER
	9. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	10. REMEDIAL DRUG THERAPY,OTHER
	11. NONE
	12. NONE
	13. REMEDIAL DRUG THERAPY,OTHER
	14. REMEDIAL DRUG THERAPY
	15. NONE
	16. OTHER
	17. NONE
	18. REMEDIAL DRUG THERAPY
	19. REMEDIAL DRUG THERAPY
	20. NONE
	21. OTHER
	22. REMEDIAL DRUG THERAPY
	23. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370013010

Parameter	Value
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. WORSENED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. WORSENED
	23. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-370013010[1),1),1),1),1),1),1),1),1),1)]	ACIDOSIS（PT：アシドーシス） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症（大腸閉塞）による合併症と判断し、リバーロキサバンとの因果関係は否定できると考える。 DECREASED URINARY OUTPUT（PT：尿量減少） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症（大腸閉塞）による合併症と判断し、リバーロキサバンとの因果関係は否定できると考える。 DISTENDED ABDOMEN（PT：腹部膨満） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症（大腸閉塞）による合併症と判断し、リバーロキサバンとの因果関係は否定できると考える。 EXACERBATION OF ABDOMINAL CRAMP（PT：腹痛） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症（大腸閉塞）による合併症と判断し、リバーロキサバンとの因果関係は否定できると考える。 LOW HAEMOGLOBIN（PT：ヘモグロビン減少） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症（大腸閉塞）による合併症と判断し、リバーロキサバンとの因果関係は否定できると考える。 RENAL FAILURE（PT：腎不全） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症（大腸閉塞）による合併症と判断し、リバーロキサバンとの因果関係は否定できると考える。 SCROTAL OEDEMA（PT：陰嚢浮腫） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症（大腸閉塞）による合併症と判断し、リバーロキサバンとの因果関係は否定できると考える。 TACHYCARDIA（PT：頻脈） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症（大腸閉塞）による合併症と判断し、リバーロキサバンとの因果関係は否定できると考える

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合

2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合

3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370023029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370023029/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/74/WHITE/SOUTH AFRICA/YES
Medical history	Cardiogenic shock, Cor pulmonale, Oesophagogastric fundoplasty, Hypertension, Myocardial infarction, Pneumonia, Cerebrovascular accident, Cerebrovascular accident, Tobacco user, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADALAT, ASPIRIN, ATROVENT, BEROTEC, CIPROBAY, CORDARONE X, DIGOXIN, DISPRIN, ENOXAPARIN, HEXARONE, HYDROCHLOROTHIAZIDE, LASIX, PREDNISONE, ROCEPHIN, SABAX POTASIUM CHLORIDE 15% - 15 MEQ/20 ML, SEREPAX, SOLU-CORTEF, ULSANIC, WARFARIN, ZOCOR
Adverse Events (AE) Preferred term	1. International normalised ratio increased 2. Abdominal wall haematoma 3. Haematemesis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. SEVERE/YES/YES/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 20JAN2010 (6) - 23JAN2010 (9) 2. 06FEB2010 (23) - 06FEB2010 (23) 3. 06FEB2010 (23) - 06FEB2010 (23)
Duration of AE	1. 4 2. 1 3. 1
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED 2. NONE 3. NONE
Outcome of event	1. RESOLVED 2. DEATH 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号：11702-370023029

死亡に至るまでの経過

被験者は 74 歳、白人女性。2010 年 1 月 14 日に肺塞栓症と診断され、1 月 15 日にエノキサパリン（160mg）の投与を、1 月 16 日に用量調節ワルファリンの投与を開始した。

2010 年 1 月 20 日、被験者は INR 増加（PT-INR 増加）を発現した。本事象は非重篤な事象として報告された。被験者の PT-INR は、2010 年 1 月 20 日 6.37、2010 年 1 月 21 日 6.71、2010 年 1 月 22 日 5.27 であったが、2010 年 1 月 23 日には目標範囲内まで減少し 2.12 となった。

2010 年 2 月 6 日、介護施設において呼吸困難及び腹部膨張を呈し、コーヒー残渣様嘔吐〔吐血（出血：コーヒー残渣様嘔吐）〕を 1 回発現した。吐血は非重篤な事象として報告された。

2010 年 2 月 6 日、被験者は腹壁血腫（出血：腹壁血腫）を発現した。本事象は生命を脅かす事象であり重大な医学的事象と考えられ、また被験者が死亡に至ったため、重篤とされた。治験責任（分担）医師は、本事象の重症度は高度で、治験薬との因果関係は「あり」と判断した。被験者は、心筋梗塞、心原性ショック、高血圧、肺性心及び脳卒中の病歴を有していた。本事象に対して臨床検査やその他の検査は実施されず、治療も行われなかった。2010 年 2 月 6 日、本事象により被験者は死亡に至った。剖検を実施し、死亡原因を腹壁血腫及び後腹膜出血に伴う循環血液量減少性ショックと判定した（それ以前は肺塞栓症としていた）。また、これにはおそらく抗凝固療法も関与していると考えられた。

CIAC は吐血（出血：コーヒー残渣様嘔吐）を「重大ではないが臨床的に問題となる出血事象」と判定した。また腹壁血腫（出血：腹壁血腫）を「重大な出血事象」及び「致死的出血」とし、死亡原因を出血と判定した。

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
Hemoglobin	Local: 12.0-16.0 g/dL	15 Jan 2010	12.9 g/dL				
Platelets	Local: 150-450 giga/L	15 Jan 2010	326 giga/L				
Alkaline Phosphatase	Central: 36-118 U/L	15 Jan 2010	84 U/L	28 Jan 2010	54 U/L		
Amylase	Central: 28-100 U/L	15 Jan 2010	**20 U/L (L)**				
Bilirubin, Direct	Central: 0.10-0.32 mg/dL	15 Jan 2010	0.20 mg/dL	28 Jan 2010	**0.34 mg/dL (H)**		
Bilirubin, Total	Central: 0.22-1.28 mg/dL	15 Jan 2010	0.51 mg/dL	28 Jan 2010	0.87 mg/dL		
Creatinine	Local: 0.60-1.20 mg/dL	15 Jan 2010	**0.59 mg/dL (L)**				
SGOT/AST	Central: 11-37 U/L	15 Jan 2010	20 U/L	28 Jan 2010	34 U/L		

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
SGPT/ALT	Central: 8-43 U/L [a] Local: 10-28 U/L	15 Jan 2010	**41 U/L (H)** [a]	15 Jan 2010	35 U/L	28 Jan 2010	30 U/L
PICT Seconds	Central: 24.80-36.40 S	15 Jan 2010	**>158.50 S (H)**				
Prothrombin Time (PT)	Central: 11.80-15.50 S	15 Jan 2010	**18.40 S (H)**				
PT Ratio	Central: 0.70-1.20 %	15 Jan 2010	**0.52 % (L)**				
PT, INR	Central: 0.9-1.2	15 Jan 2010	**1.6 (H)**				

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370023031

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370023031/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/75/WHITE/SOUTH AFRICA/YES
Medical history	Hypertension, Hysterectomy, Nausea, Pollakiuria, Polyuria, Tonsillectomy, Vaginal discharge, Weight decreased, Ovarian mass, Ovarian mass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPHANE, ADALAT XL, COVERSYL, DULCOLAX [BISACODYL], ENOXAPARIN, FLAGYL, FRESH FROZEN PLASMA, IMODIUM, LIGNOCAINE, MAXOLON, OMNOPON FRESENIUS, PHARMAPRESS, RIDAQ, VOLUVEN, WARFARIN, ZINACEF
Adverse Events (AE) Preferred term	1. Operative haemorrhage 2. Hyperglycaemia 3. Haemorrhagic anaemia 4. Coagulopathy 5. Hypovolaemia 6. Constipation 7. Diarrhoea 8. Respiratory failure 9. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/YES/YES/YES 4. SEVERE/YES/YES/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. SEVERE/NO/YES/NO 9. MODERATE/YES/NO/NO
Start/stop date of event with relative date	1. 09JUL2010 (1) - 09JUL2010 (1) 2. 10JUL2010 (2) - 17JUL2010 (9) 3. 11JUL2010 (3) - --------- (.) 4. 12JUL2010 (4) - --------- (.) 5. 12JUL2010 (4) - 12JUL2010 (4) 6. 13JUL2010 (5) - 13JUL2010 (5) 7. 15JUL2010 (7) - 17JUL2010 (9) 8. 18JUL2010 (10) - 18JUL2010 (10) 9. 18JUL2010 (10) - 18JUL2010 (10)
Duration of AE	1. 1 2. 8 3. . 4. . 5. 1 6. 1 7. 3 8. 1 9. 1

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370023031

Parameter	Value
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. OTHER
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. DOSE OF STUDY DRUG REDUCED,STUDY DRUG DISCONTINUED AND RESTARTED,STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY,OTHER
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. DEATH

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370023031

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370043004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370043004/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/71/WHITE/SOUTH AFRICA/YES
Medical history	Osteoarthritis, Cholecystectomy, Chronic obstructive pulmonary disease, Gastrooesophageal reflux disease, Insomnia, Obesity, Spinal osteoarthritis, Renal impairment
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALZAM, CELEBREX, ENOXAPARIN, NEXIUM, PREDNISONE, PURESIS, SERETIDE, TRAMACET, TRANQUIPAM, TREPILINE, VITAMIN K, WARFARIN, ZITHROMAX
Adverse Events (AE) Preferred term	1. Haemorrhage subcutaneous
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 29JAN2009 (128) - 02FEB2009 (132)
Duration of AE	1. 5
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370043007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370043007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/60/UNCODABLE/SOUTH AFRICA/YES
Medical history	Coronary artery bypass, Cardiac failure chronic, Constipation, Depression, Diabetes mellitus, Hypertension, Myocardial ischaemia, Oedema peripheral, Peripheral vascular disorder, Localised oedema, Coronary arterial stent insertion, Dyslipidaemia, Radiation skin injury
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADCO ZOLPIDEM, AVELON, CARDURA, CILIFT, ENOXAPARIN, FUROSEMIDE, GLYCOMIN, LASIX, METFORMIN, PHARMAPRESS, SIMVASTATIN, SOLMUCOL, SPIRACTIN, WARFARIN, ZOPIMED
Adverse Events (AE) Preferred term	1. Hyperbilirubinaemia 2. Cardiac failure 3. Cardiac failure
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 27MAY2009 (1) - --------- (.) 2. 17JUN2009 (22) - 18JUN2009 (23) 3. 21DEC2009 (209) - 03JAN2010 (222)
Duration of AE	1. . 2. 2 3. 14
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370043011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370043011/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/SOUTH AFRICA/YES
Medical history	Breast cancer, Cholecystectomy, Hypercholesterolaemia, Hypertension, Hysterectomy, Mass excision, Systemic sclerosis, Pulmonary fibrosis, Type 2 diabetes mellitus, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALTOSEC, AUGMENTIN, AVELON, AZAPRESS, COVERSYL, COXFLAM, ENDOXAN, METFORMIN, NOVOMIX 30, PRAVA STATIN, PREDNISONE, PURESIS, RAVAMIL SR, SOLMUCOL, TAREG, TRAMACET
Adverse Events (AE) Preferred term	1. Gastrooesophageal reflux disease 2. Cellulitis 3. Ecchymosis 4. Contusion 5. Rib fracture 6. Conjunctival haemorrhage 7. Ecchymosis 8. Pain in extremity
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --MAR2010 (.) - --------- (.) 2. 05NOV2009 (84) - 08NOV2009 (87) 3. 12NOV2009 (91) - 30NOV2009 (109) 4. 12NOV2009 (91) - 30NOV2009 (109) 5. 13NOV2009 (92) - 13DEC2009 (122) 6. 14NOV2009 (93) - 18NOV2009 (97) 7. 01FEB2010 (172) - --JUL2010 (.) 8. 05JUN2010 (296) - 10JUL2010 (331)
Duration of AE	1. . 2. 4 3. 19 4. 19 5. 31 6. 5 7. . 8. 36
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370043011

Parameter	Value
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370043026

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370043026/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/79/WHITE/SOUTH AFRICA/YES
Medical history	Hypertension, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AVELON, CARBOPLATTIN, CILIFT, CIPROFLOXACIN, COMBIVENT NEBS, DORMINOCT, DRAINAGE OF PLEURAL EFFUSION, ENOXAPARIN, FERIMED, FILTER VENA CAVA, GEMZOR, INVANZ, NEXIUM, PARACETAMOL, PERFALGON, PURESIS, REUTERI, SENEKOT, STILNOX, SYNAP FORTE, TRAMAZET, TRIPLEN FORTE, VENOFER, WARFARIN
Adverse Events (AE) Preferred term	1. Respiratory tract infection 2. Insomnia 3. Occult blood positive 4. Iron deficiency anaemia 5. Lung adenocarcinoma 6. Depression 7. Constipation 8. Skin mass
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 04AUG2010 (27) - 16AUG2010 (39) 2. 12AUG2010 (35) - 30NOV2010 (145) 3. 01SEP2010 (55) - 15OCT2010 (99) 4. 01SEP2010 (55) - 15OCT2010 (99) 5. 28OCT2010 (112) - 18SEP2011 (437) 6. 28OCT2010 (112) - --------- (.) 7. 31OCT2010 (115) - 15NOV2010 (130) 8. 25JUN2011 (352) - --------- (.)
Duration of AE	1. 13 2. 111 3. 45 4. 45 5. 326 6. . 7. 16 8. .
Dose on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370043026

Parameter	Value
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. OTHER
	4. REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. DEATH
	6. UNCHANGED
	7. RESOLVED
	8. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370043027

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370043027/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/62/WHITE/SOUTH AFRICA/YES
Medical history	Liver disorder, Hypertension, Insomnia, Macrocytosis, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AREM, CONCOR, DORMINOCT, FOLATE, FUROSEMIDE, LANZOR, MICARDIS, RIDAQ, SPIRACTIN
Adverse Events (AE) Preferred term	1. Fatigue 2. Orthostatic hypotension 3. Toothache 4. Gastritis 5. Tachycardia 6. Hyponatraemia 7. Pericardial effusion 8. Wound haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. SEVERE/NO/YES/YES 7. MODERATE/NO/YES/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 20NOV2010 (3) - 23MAR2011 (126) 2. 25NOV2010 (8) - 23MAR2011 (126) 3. 08DEC2010 (21) - 08DEC2010 (21) 4. 16DEC2010 (29) - 23MAR2011 (126) 5. 18JAN2011 (62) - --------- (.) 6. 18JAN2011 (62) - 02FEB2011 (77) 7. 21FEB2011 (96) - 23FEB2011 (98) 8. 23JUL2011 (248) - 14SEP2011 (301)
Duration of AE	1. 124 2. 119 3. 1 4. 98 5. . 6. 16 7. 3 8. 54
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370043027

Parameter	Value
	8. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
Action taken	1. NONE
	2. NONE
	3. OTHER
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY,OTHER
	8. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053012/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/62/WHITE/SOUTH AFRICA/YES
Medical history	Anaemia, Conjunctivitis, Diabetes mellitus, Dyspepsia, Systemic lupus erythematosus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTONEL, AZATHIOPRINE, CELECOXIB, CHLORAMEX OINTMENT, CLOPAMON, DUOLIN NEBULIZATION, DUROGESIC, EPILIM, FUROSEMIDE, IMURAN, LENTOGESIC [PARACETAMOL,DEXROPROPOXYPHENE,DIPHENHYDRAMINE,CAFFEINE], METFORMIN, METOCLOPRAMIDE, MORPHINE, OMEPRAZOLE, PLENISH K, POTASSIUM, PREDNISONE, PROPANOLOL, PURESIS, RISPERDAL, ROCEPHIN, TRAMAL, VITAMIN B, CALCIUM
Adverse Events (AE) Preferred term	1. Haemoptysis 2. T-cell lymphoma 3. Spinal compression fracture 4. Nausea 5. Osteoporosis 6. Tachycardia 7. Oedema 8. Histiocytosis haematophagic 9. Anaemia 10. Guillain-Barre syndrome 11. Multi-organ failure 12. Neutropenic sepsis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. SEVERE/NO/YES/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. SEVERE/NO/YES/YES 9. MODERATE/NO/NO/YES 10. SEVERE/NO/YES/YES 11. SEVERE/NO/YES/NO 12. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 09MAY2008 (3) - 09MAY2008 (3) 2. 21MAY2008 (15) - --------- (.) 3. 22MAY2008 (16) - 31MAY2008 (25) 4. 23MAY2008 (17) - 31MAY2008 (25) 5. 05JUN2008 (30) - --------- (.) 6. 15JUL2008 (70) - 15AUG2008 (101) 7. 15JUL2008 (70) - 09SEP2008 (126) 8. 28JUL2008 (83) - --------- (.) 9. 04SEP2008 (121) - 06NOV2008 (184) 10. 04SEP2008 (121) - --------- (.) 11. 06NOV2008 (184) - 06NOV2008 (184)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053012

Parameter	Value
	12. 06NOV2008 (184) - --------- (.)
Duration of AE	1. 1
	2. .
	3. 10
	4. 9
	5. .
	6. 32
	7. 57
	8. .
	9. 64
	10. .
	11. 1
	12. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. F
	12. F
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053012

Parameter	Value
	8. NONE
	9. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
	10. OTHER
	11. NONE
	12. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED
	10. UNCHANGED
	11. DEATH
	12. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-370053012[4)]	HEMOPTYSIS（PT：喀血） 治験担当医は、因果関係を否定できると判断した。弊社は、原疾患（肺塞栓症）及び併発症（T細胞性リンパ腫及び血小板減少を含む二血球減少症）による影響とも考えられるが、リバーロキサバン投与と報告事象発現との時間的関連性及び抗凝固作用から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053015/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/41/BLACK/SOUTH AFRICA/YES
Medical history	Anxiety, Asthma, Epistaxis, Insomnia, Pneumonia, Sterilisation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BENYLIN WITH CODEINE, CEFTRIAXONE, DIFLUCAN, ENOXAPARIN, ESOMEPRAZOLE, HYDROCORTISONE, HYDROXIZINE, IPATROPIUM BROMIDE+SALBUTAMOL, SYNAP FORTE(PARACETAMOL,DEXTROPROPOXYPHENE,DIPHENHYDRAMINE,CAFFEINE), TELITHROMYCIN, WARFARIN, ZOLPIDEM TARTRATE
Adverse Events (AE) Preferred term	1. Epistaxis 2. Candidiasis 3. Cough
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 14JUN2008 (2) - 14JUN2008 (2) 2. 25JUN2008 (13) - 29JUN2008 (17) 3. 12JUL2008 (30) - 19JUL2008 (37)
Duration of AE	1. 1 2. 5 3. 8
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-370053015[4)]	EPISTAXIS（PT：鼻出血） 治験担当医は、既往の鼻出血を有することから、否定できると判断した。弊社は、エノキサパリンの抗凝固作用を考慮し、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053016

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053016/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/63/WHITE/SOUTH AFRICA/YES
Medical history	Anxiety, Arrhythmia, Bronchospasm, Bunion operation, Dehydration, Depression, Haemoglobin decreased, Hysterectomy, Insomnia, Nausea, Pain in extremity, Pneumonia, Tachycardia, Oedema peripheral, Gastric bypass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALZAM, BUSCOPAN, CHELA FUR [IRON], CLINDAMYCIN, CORDARONE, ENOXAPARIN, ETOMINE, FOLIC ACID, IPRATROPIUM BROMIDE/SALBUTAMOL, KONAKION, LEVOFLOXACIN, LORIEN, PARACETAMOL,DEXTROPROPOXYPHENE,DIPHENHYDRAMINE,CAFFEINE, PERFALGAN, TRAMAL, VITAMIN B12, VITAMIN BCO, WARFARIN
Adverse Events (AE) Preferred term	1. Abdominal pain 2. International normalised ratio increased 3. Haematemesis 4. Fatigue
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/NO/YES 3. MODERATE/YES/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 01JUL2008 (0) - 01JUL2008 (0) 2. 09JUL2008 (8) - 13JUL2008 (12) 3. 12JUL2008 (11) - 13JUL2008 (12) 4. 30JUL2008 (29) - 16JAN2009 (199)
Duration of AE	1. 1 2. 5 3. 2 4. 171
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053016

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053017/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/74/WHITE/SOUTH AFRICA/YES
Medical history	Atrial fibrillation, Drug hypersensitivity, Hypertension, Oral candidiasis, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, AMLODIPINE, ATERAX, BISOCOR, COLCHICINE, CORDARONE, DIGOXIN, FRAGMIN, IPATROPIUM BROMIDE/SALBUTAMOL, LACTEOL FORTE, LORATADINE, METICORTEN, NEXIAM, PHENERGAN, PULMISON, ROCEPHIN, SEREPAX, SOLU CORTEF, SOLUCORTEF, TARGOCID, TAZOCIN, VERAPAMIL
Adverse Events (AE) Preferred term	1. Gout 2. Hypertension 3. Insomnia 4. Hypersensitivity
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 04JUL2008 (2) - 17JUL2008 (15) 2. 04JUL2008 (2) - 05JUL2008 (3) 3. 06JUL2008 (4) - 08OCT2008 (98) 4. 18JUL2008 (16) - 19JUL2008 (17)
Duration of AE	1. 14 2. 2 3. 95 4. 2
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053017

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053020/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/41/BLACK/SOUTH AFRICA/YES
Medical history	Bronchospasm, Constipation, Depression, HIV test positive, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMITRIPTYLINE, AUGMENTIN, CATAFLAM, CHELAFUR, CIPRAMIL, DUPHALAC [LACTULOSE], FLUANXOL, FOLIC ACID, IBUPROFEN,PARACETAMOL,CODEINE, LAMZID-ZIDOVUDINE,LAMIVUDINE, MAGNESIUM SULPHATE, NA VALPROATE, NEVIRAPINE, PARACETAMOL,DEXTROPROPOXYPHENE,DIPHENHYDRAMINE,CAFFEINE, PULMISON, SACCHAROMYCES BOULARDII, SERETIDE-SALMETEROL/FLUTICASONE, SINGULAR, VERAMINE [VIRAMINE-NEVIRAPINE], XANOR
Adverse Events (AE) Preferred term	1. Syncope 2. Dizziness 3. Tooth abscess 4. Oedema 5. Weight increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --SEP2008 (.) - --SEP2008 (.) 2. 29JUL2008 (12) - 12DEC2008 (148) 3. 15SEP2008 (60) - 20SEP2008 (65) 4. 08OCT2008 (83) - 04FEB2009 (202) 5. 08OCT2008 (83) - 04FEB2009 (202)
Duration of AE	1. . 2. 137 3. 6 4. 120 5. 120
Dose on AE onset	1. 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. . 5. .
Action taken	1. NONE 2. NONE 3. REMEDIAL DRUG THERAPY 4. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053020

Parameter	Value
Outcome of event	5. NONE 1. RESOLVED 2. RESOLVED 3. RESOLVED 4. RESOLVED 5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053023/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/56/WHITE/SOUTH AFRICA/YES
Medical history	Anxiety, Asthma, Chronic obstructive pulmonary disease, Depression, Diabetes mellitus, Hypertension, Myocardial infarction, Overweight, Upper respiratory tract infection, Postmenopause, Coronary artery bypass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPAVOR, BUPROPION, DORMICUM, ECOTRIN, ENOXAPARIN, FUROSEMIDE, GLICLAZIDE, IMDUR, INSULIN ASPART, IPATROPIUM BROMIDE/SALBUTAMOL, IPRATROPIUM /SALBUTAMOL, ISOSORBIDE MONONITRATE, KONAKION, METFORMIN, MOXIFLOXACIN, OXYGEN, PARACETAMOL, PSEUDOEPHEDRINE, DEXTROMOTHORPHAN, CHLORPHENIRAMINE, POTASSIUM, PREDNISONE, PULMISON, SALMETEROL/FLUTICASONE, SOLUCORTEF, TELITHROMYCIN, TRAZODONE, VERAPAMIL/TRANDOLAPRIL, WARFARIN, ZOLPIDEM
Adverse Events (AE) Preferred term	1. Influenza 2. Haematuria 3. Bronchitis 4. Angina unstable 5. Chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/YES/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 18SEP2008 (49) - 05OCT2008 (66) 2. 23OCT2008 (84) - 25OCT2008 (86) 3. 23OCT2008 (84) - 25OCT2008 (86) 4. 12NOV2008 (104) - 12NOV2008 (104) 5. 22DEC2008 (144) - 29DEC2008 (151)
Duration of AE	1. 18 2. 3 3. 3 4. 1 5. 8
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053023

Parameter	Value
	4. OTHER
	5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053024

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053024/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/SOUTH AFRICA/YES
Medical history	Cerebrovascular accident, Constipation, Depression, Fatigue, Generalised oedema, Hyperlipidaemia, Hypertension, Menopause, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, CLONIDINE, DIPYRIDAMOLE/ASPIRIN, ESCITALOPRAM OXALATE, FUROSEMIDE, ISPAGHULA HUSK, PARACETAMOL/DEXTROPROPOXYPHENE,DIPHENHYDRAMINE,CAFFEINE, PERINDOPRIL, POTASSIUM, RABEPRAZOLE, SIMVASTATIN, SPIRACTIN, VITAMIN B12
Adverse Events (AE) Preferred term	1. Cor pulmonale 2. Oedema peripheral 3. Dyspepsia 4. Soft tissue infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 22SEP2008 (53) - --------- (.) 2. 22SEP2008 (53) - 01NOV2008 (93) 3. 24JAN2009 (177) - 12FEB2009 (196) 4. 12FEB2009 (196) - 18FEB2009 (202)
Duration of AE	1. . 2. 41 3. 20 4. 7
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. F
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY,OTHER 4. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053024

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053028

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053028/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/26/WHITE/SOUTH AFRICA/YES
Medical history	Bronchospasm, Depression, Dysfunctional uterine bleeding, Dyspnoea, Epilepsy, Headache, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CEFUROXIME, CELEBREX, DORMICUM, HYDROXYZINE, LAMICTIN, LENTOGESIC ["DEXTROPROPOXYPHENE HCl, PARACETAMOL, L-GLUTAMINE"], MIRENA, NEXIAM, PANTOCID, PREDNISONE, RIVOTRIL, SYNAP FORTE, TRAMADOL, TRANSACT PATCHES, VENLOR XR, YASMIN
Adverse Events (AE) Preferred term	1. Headache 2. Hyperhidrosis 3. Menorrhagia 4. Chest pain 5. Cholelithiasis 6. Dermatitis allergic 7. Menorrhagia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/YES/YES/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 10SEP2008 (2) - 13OCT2008 (35) 2. 13OCT2008 (35) - 31OCT2008 (53) 3. 16OCT2008 (38) - 20NOV2008 (73) 4. 10DEC2008 (93) - 20JAN2009 (134) 5. 30DEC2008 (113) - 10JAN2009 (124) 6. 12FEB2009 (157) - 14FEB2009 (159) 7. 17MAR2009 (190) - 03APR2009 (207)
Duration of AE	1. 34 2. 19 3. 36 4. 42 5. 12 6. 3 7. 18
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg
Dose status on AE onset	1. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053028

Parameter	Value
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
Action taken	1. NONE
	2. NONE
	3. OTHER
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. OTHER
	7. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053030

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053030/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/61/WHITE/SOUTH AFRICA/YES
Medical history	Chest pain, Hypertension, Insomnia, Nausea
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BISOLVON, CLAVULANIC ACID/AMOXYCILLIN, DORMICUM, ENOXAPARIN, ESOMEPRAZOLE, ILIADIN - 0.100MG/ML, KONAKION, NEXIAM, NITROCINE, PANTOPRAZOLE, PARACETAMOL/DEXTROPROPOXYPHENE NAPSYLATE/DIPHENHYDRAMINE HCL/CAFFEINE, PREXUM, RAPIFEN, TORADOL, TRAMAL, VITAMIN BCO, WARFARIN, ZOFRAN, ZOLPIDEM
Adverse Events (AE) Preferred term	1. Cough 2. Nasal congestion 3. Fatigue 4. Melaena 5. Chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/YES/YES/YES 5. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 10OCT2008 (15) - 20OCT2008 (25) 2. 10OCT2008 (15) - 20OCT2008 (25) 3. 27OCT2008 (32) - 29JAN2009 (126) 4. 22NOV2008 (58) - 23NOV2008 (59) 5. 20MAR2009 (176) - 21MAR2009 (177)
Duration of AE	1. 11 2. 11 3. 95 4. 2 5. 2
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053030

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053041

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053041/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/37/WHITE/SOUTH AFRICA/YES
Medical history	Sinus operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALFENTANIL, BUDESONIDE, CEFAZOLIN, CLOTHIAPINE, ESOMEPRAZOLE, GRANISETRON, HYDROCORTISONE, LACTEOL FORTE (BACILLUS), LORATADINE, MELOXICAM, MOXIFLOXACIN, PARACETAMOL/DEXTROPROPOXYPHENE/DIPHENHYDRAMINE/CAFFEINE, PARACOXIB, PERFALGAN, PROPOFOL, SODIUM CHLORIDE, TRAMADOL, TRAZODONE, VITAMIN BCO, ZOPICLONE
Adverse Events (AE) Preferred term	1. Sinusitis 2. Chest pain 3. Dyspnoea 4. Depression 5. Haematoma 6. Influenza
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 19NOV2008 (1) - 26NOV2008 (8) 2. 23NOV2008 (5) - 26NOV2008 (8) 3. 23NOV2008 (5) - 26NOV2008 (8) 4. 23JAN2009 (66) - --------- (.) 5. 01FEB2009 (75) - 06FEB2009 (80) 6. 16MAR2009 (118) - 19MAR2009 (121)
Duration of AE	1. 8 2. 4 3. 4 4. . 5. 6 6. 4
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053041

Parameter	Value
	6. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. INSUFFICIENT FOLLOW-UP
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053046

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053046/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/65/WHITE/SOUTH AFRICA/YES
Medical history	Diabetes mellitus, Hypertension, Hypothyroidism, Arthralgia, Convulsion, Postmenopause, Bipolar disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADALAT, ADALAT XL, ADCO-CAPTOMAX, CIPROBAY, COMCOLIT, DIAGLUCIDE, ELTROXIN, EPANUTIN, EPITEC, ESPIRIDE, ETOMINE, GLUCOPHAGE, IMOVANE, LAMOTTRIGINE, PREXUM PLUS(PERINDOPRIL,INDAPAMIDE), PURBLOKA, SEROQUEL, ZYPREXA
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Confusional state 3. Death
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 23JAN2009 (7) - 01FEB2009 (16) 2. 01FEB2009 (16) - 20FEB2009 (35) 3. 13MAR2009 (56) - 13MAR2009 (56)
Duration of AE	1. 10 2. 20 3. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. RESOLVED 2. RESOLVED 3. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053049

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053049/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/74/BLACK/SOUTH AFRICA/YES
Medical history	Cerebrovascular accident, Confusional state, Gastrooesophageal reflux disease, Gouty arthritis, Hip fracture, Hip arthroplasty, Hyperlipidaemia, Hypertension, Hypokalaemia, Peripheral ischaemia, Microcytic anaemia, Postmenopause, Vascular occlusion, Peripheral arterial occlusive disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, ASPRIN, ATENOLOL, CEFUROXINE, CIPROFLOXACIN, ESOMEPRAZOLE, FOLIC ACID, HYOSCINE - N - BUTYLBROMIDE, LANSOPRAZOLE, LENTOGESIC ["DEXTROPROPXYPHENE, LEVOGLUTAMIDE, PARACETAMOL, PEMOLINE"], MOVICOL, PANTOPRAZOLE, PREXUM, RISPERIDONE, SEEDS OF PLANTAGO OVATA, ISPAGHULA HUSK, TINNEVELLY SENNA PODS, SIMVASTATIN
Adverse Events (AE) Preferred term	1. Pain in extremity 2. Constipation 3. Urinary tract infection 4. Gastritis 5. Constipation 6. Pleural effusion 7. Tuberculosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 07MAR2009 (36) - 16APR2009 (76) 2. 07MAY2009 (97) - 10JUN2009 (131) 3. 08MAY2009 (98) - 13MAY2009 (103) 4. 07JUN2009 (128) - 10JUN2009 (131) 5. 20JUL2009 (171) - --------- (.) 6. 11AUG2009 (193) - 21AUG2009 (203) 7. 20AUG2009 (202) - --------- (.)
Duration of AE	1. 41 2. 35 3. 6 4. 4 5. . 6. 11 7. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053049

Parameter	Value
	6. 20 mg
	7. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. F
Action taken	1. OTHER
	2. OTHER
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY,OTHER
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053055

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053055/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/45/WHITE/SOUTH AFRICA/YES
Medical history	Tension headache
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	COXFLAM, ENOXAPARIN, IMOVANE, SYNAP FORTE, TRANSACT, WARFARIN, XANOR SR
Adverse Events (AE) Preferred term	1. Liver function test abnormal 2. Anxiety 3. Pain in extremity 4. Back pain 5. Chest pain 6. Chest pain 7. Hypercholesterolaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/YES/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 13FEB2009 (1) - 16MAR2009 (32) 2. 10MAR2009 (26) - 22MAR2009 (38) 3. 22MAR2009 (38) - 25MAR2009 (41) 4. 09JUL2009 (147) - 15JUL2009 (153) 5. 26NOV2009 (287) - 28NOV2009 (289) 6. 20JAN2010 (342) - 02FEB2010 (355) 7. 02FEB2010 (355) - --------- (.)
Duration of AE	1. 32 2. 13 3. 4 4. 7 5. 3 6. 14 7. .
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053055

Parameter	Value
	5.
	6.
	7.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. OTHER
	7. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053058

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053058/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/77/WHITE/SOUTH AFRICA/YES
Medical history	Bronchitis, Angina pectoris, Aortic aneurysm repair, Chronic obstructive pulmonary disease, Intervertebral disc operation, Hyperlipidaemia, Hypertension, Insomnia, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALZAM, BUDEFLAM, ECOTRIN, ENOXAPARIN, IMOVANE, PERFALGAN, RISPERDAL, SEREVENT, SIMVASTATIN, SYNAP FORTE, TAVANIC, THEOPLUS, WARFARIN, XANOR SR, ZILDEM, ZINACEF, ZITHROMAX, ZOFRAN
Adverse Events (AE) Preferred term	1. Haematoma 2. Dyspnoea 3. Anxiety 4. Dizziness 5. Sinobronchitis 6. Perirenal haematoma 7. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/YES/YES/YES 7. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 28FEB2009 (4) - 05MAR2009 (9) 2. 03MAR2009 (7) - 05MAR2009 (9) 3. 03MAR2009 (7) - --------- (.) 4. 20MAR2009 (24) - 05MAY2009 (70) 5. 04APR2009 (39) - 07APR2009 (42) 6. 14APR2009 (49) - 03MAY2009 (68) 7. 18AUG2009 (175) - --------- (.)
Duration of AE	1. 6 2. 3 3. . 4. 47 5. 4 6. 20 7. .
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053058

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	7. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. IMPROVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053059

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053059/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/82/WHITE/SOUTH AFRICA/YES
Medical history	Cerebrovascular accident, Hypercholesterolaemia, Hypertension, Hypothyroidism, Automatic bladder, Postmenopause, Anxiety disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOC, ANGISED, ATERAX, CARLOC, CIPLAVASC, DAPTRIL (INDAPAMIDE), ELTROXIN, ENOXAPARIN, LENDITRO, SIMVACOR, WARFARIN, XANOR
Adverse Events (AE) Preferred term	1. Dyspepsia 2. Tension headache 3. Angina unstable
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 03APR2009 (31) - 07MAY2009 (65) 2. 18APR2009 (46) - 17JUN2009 (106) 3. 07MAY2009 (65) - 12MAY2009 (70)
Duration of AE	1. 35 2. 61 3. 6
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. NONE 3. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053061

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053061/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/46/WHITE/SOUTH AFRICA/YES
Medical history	Hysterectomy, Anxiety, Depression, Hypertension, Obesity, Procedural pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPRAZOLAM, AMLODIPINE MALEATE, BISOPROLOL HEMIFUMARATE, DICLOFENAC SDIUM, ENOXAPARIN, INTERFLORA, MEFENAMIC ACID, ORPIC, PETHIDINE, SEREPAX, SYNAP FORTE, VALSTRATAN, ZIAK, ZOFRAN
Adverse Events (AE) Preferred term	1. Subcutaneous haematoma 2. Chest pain 3. Upper respiratory tract infection 4. Myalgia 5. Hypertension 6. Haemorrhoidal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/YES/NO/YES 6. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 26MAR2009 (7) - 29MAR2009 (10) 2. 04APR2009 (16) - 08APR2009 (20) 3. 19APR2009 (31) - 22APR2009 (34) 4. 28MAY2009 (70) - 28JUL2009 (131) 5. 19JUN2009 (92) - --------- (.) 6. 14AUG2009 (148) - 17AUG2009 (151)
Duration of AE	1. 4 2. 5 3. 4 4. 62 5. . 6. 4
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053061

Parameter	Value
	2. NONE
	3. NONE
	4. NONE
	5. OTHER
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. INSUFFICIENT FOLLOW-UP
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053066

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053066/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/25/WHITE/SOUTH AFRICA/YES
Medical history	Caesarean section, Depression, Gastrooesophageal reflux disease, Gastroenteritis, Insomnia, Bipolar disorder, Abdominal sepsis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATERAX, BENYLIN ["DEXTROMETHORPHAN HBR, PSEUDOEPHEDRINE HCI"], EPILIM, ETOMINE, FLAGYL, FLUOXETINE, GESTODENE, ETHINYLESTRADIOL, LAMICTIN, LORAZEPAM, MERONEM, NEXIAM, PERFALGAN, PLACEBO, SEREPAX, SEROQUEL, STILLNOX, SYNAP FORTE, TAVANIC, TRAMAL, ULSANIC, VOLTAREN EMUGEL, XANOR SR, ZOFRAN
Adverse Events (AE) Preferred term	1. Infusion site inflammation 2. Thyroid cyst 3. Depression 4. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 11APR2009 (4) - 12APR2009 (5) 2. 12MAY2009 (35) - --------- (.) 3. 07SEP2009 (153) - 16SEP2009 (162) 4. 07SEP2009 (153) - 11SEP2009 (157)
Duration of AE	1. 2 2. . 3. 10 4. 5
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. UNCHANGED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053066

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053070

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053070/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/SOUTH AFRICA/YES
Medical history	Dyspepsia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CITALOPRAM HYDROBROMIDE, FUROSEMIDE, LACTULOSE, METOCHLOPRAMIDE MONOHYDROCLOR, PANTOPRAZOLE, PARACETAMOL, DEXTROPROPOXYPHENE NAPSYLATE, DIPHENHYDRAMINE HCL, CAFFEINE, PARECOXIB, POTASSIUM CHLORIDE, PREDNISONE, THALIDOMIDE, ZOLEDRONIC ACID
Adverse Events (AE) Preferred term	1. Pain 2. Dyspnoea 3. Hypotension 4. Multiple myeloma 5. Nausea 6. Oedema peripheral 7. Constipation 8. Dyspnoea 9. Tremor 10. Oedema peripheral 11. Lethargy 12. Orthopnoea 13. Exercise tolerance decreased 14. Depression
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. SEVERE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 22APR2009 (2) - 23APR2009 (3) 2. 28APR2009 (8) - 06MAY2009 (16) 3. 06MAY2009 (16) - 07MAY2009 (17) 4. 06MAY2009 (16) - --------- (.) 5. 06MAY2009 (16) - 06MAY2009 (16) 6. 25JUN2009 (66) - 21OCT2009 (184) 7. 25JUN2009 (66) - 01JUL2009 (72) 8. 18JUL2009 (89) - 21OCT2009 (184)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053070

Parameter	Value
	9. 20JUL2009 (91) - 21OCT2009 (184)
	10. 07SEP2009 (140) - --------- (.)
	11. 16SEP2009 (149) - 21OCT2009 (184)
	12. 16SEP2009 (149) - 21OCT2009 (184)
	13. 16SEP2009 (149) - 12NOV2009 (206)
	14. 21OCT2009 (184) - --------- (.)
Duration of AE	1. 2
	2. 9
	3. 2
	4. .
	5. 1
	6. 119
	7. 7
	8. 96
	9. 94
	10. .
	11. 36
	12. 36
	13. 58
	14. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053070

Parameter	Value
	11. .
	12. .
	13. .
	14. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. OTHER
	10. REMEDIAL DRUG THERAPY
	11. OTHER
	12. OTHER
	13. OTHER
	14. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. UNCHANGED
	11. RESOLVED
	12. RESOLVED
	13. IMPROVED
	14. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053073

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053073/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/97/WHITE/SOUTH AFRICA/YES
Medical history	Angina pectoris, Benign prostatic hyperplasia, Hypertension, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMITRIPTYLINE, COLCHICINE, COMBIVENT, ELTROXIN, ENOXAPARIN, ESOMEPRAZOLE, ISOSORBIDE MONONITRATE, PANTOPRAZOLE, PARACETAMOL/DEXTROPROPOXYPHENE/DIPHENHYDRAMINE/CAFFEINE, PERFALGAN, PROPRANOLOL, TAMSULOSIN, TAZOCIN, VITAMIN K, WARFARIN
Adverse Events (AE) Preferred term	1. International normalised ratio increased 2. Gout 3. Hypothyroidism 4. Pneumonia 5. Acute respiratory distress syndrome
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 02MAY2009 (5) - 06MAY2009 (9) 2. 12MAY2009 (15) - --------- (.) 3. 13MAY2009 (16) - --------- (.) 4. 14MAY2009 (17) - --------- (.) 5. 30MAY2009 (33) - 30MAY2009 (33)
Duration of AE	1. 5 2. . 3. . 4. . 5. 1
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. DOSE OF STUDY DRUG REDUCED,REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053073

Parameter	Value
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053079

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053079/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/65/WHITE/SOUTH AFRICA/YES
Medical history	Rhinitis allergic, Anxiety, Insomnia, Herpes zoster, Spinal fusion surgery, Spinal fusion surgery, Prostatectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATERAX, ENOXAPARIN, IMOVANE, NASONEX, NEXIAM, SUDAFED, SYNAP FORTE, WARFARIN, XANOR
Adverse Events (AE) Preferred term	1. Chest pain 2. Gastrooesophageal reflux disease 3. Upper respiratory tract infection 4. Eczema 5. Sinusitis 6. Angina pectoris
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 19JUN2009 (13) - 01JUL2009 (25) 2. 24JUN2009 (18) - --------- (.) 3. 01JUL2009 (25) - 07JUL2009 (31) 4. 01AUG2009 (56) - --------- (.) 5. 23AUG2009 (78) - 02OCT2009 (118) 6. 22NOV2009 (169) - 01DEC2009 (178)
Duration of AE	1. 13 2. . 3. 7 4. . 5. 41 6. 10
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY,OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053079

Parameter	Value
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. IMPROVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053081

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053081/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/34/WHITE/SOUTH AFRICA/YES
Medical history	Bronchospasm, Depression, Endoscopy upper gastrointestinal tract, Hysterectomy, Osteoarthritis, Gastric ulcer, Thyroidectomy, Migraine
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPRAZOLAM, AMNILTRIPTYLIN, ATORVASTATIN, CILIFT, COXFLAM, CYMBALTHA, DUOLIN, ENOXAPARIN, EPILIM, ESOMEPRAZOLE, HYDROCORTISONE, KETEK, MAXOLON, OLANZAPINE, ONDANSETRON, PREDNISONE, RAYZON, RISPERDAL, RIZATRIPTAN, SINGULAIR, SYNAP FORTE, TOPAMAX, TRAMAL, WARFARIN, ZOPICLONE
Adverse Events (AE) Preferred term	1. Haematemesis 2. Bronchospasm 3. Vomiting 4. Nausea 5. Migraine 6. Bronchopneumonia 7. Hypercholesterolaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/YES/YES 2. MILD/NO/YES/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MODERATE/NO/YES/YES 7. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 23JUN2009 (6) - 23JUN2009 (6) 2. 28JUN2009 (11) - 04JUL2009 (17) 3. 03SEP2009 (78) - 07SEP2009 (82) 4. 03SEP2009 (78) - 07SEP2009 (82) 5. 05OCT2009 (110) - 08OCT2009 (113) 6. 27OCT2009 (132) - 01NOV2009 (137) 7. 09NOV2009 (145) - --------- (.)
Duration of AE	1. 1 2. 7 3. 5 4. 5 5. 4 6. 6 7. .
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053081

Parameter	Value
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	2. REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053087

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053087/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/83/WHITE/SOUTH AFRICA/YES
Medical history	Anxiety, Constipation, Hypertension, Hypothyroidism, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADRENALINE, ALPRAZOLAM, AMIODARONE, CIPROFLOXACIN, DIPYRONE, DOBUTREX, DORMICUM, ELTROXIN, EPANUTIN, ESOMEPRAZOLE, FUROSEMIDE, HYOSCINE BROMIDE, INVANZ, LANOXIN, LISINOPRIL,HYDROCHLOROTHIAZIDE, LYRICA, MAGNESIUM SULPHATE, MELOXICAM, METOCLOPRAMIDE, MONOSOD PHOSPH,DISOD PHOSPH, ONDANSERTON, PARACETAMOL,DEXTROPROPOXYPHENE,DIPHENHYDRAMINE,CAFFEINE, PHENYLEPHEDRINE, POTASSIUM, POTASSIUM PHOSPHATE DIBASIC, PREMARIN, RAPIFEN, RISPERIDONE, SLOW K, TRAMAL, ZOFRAN, ZOPICLONE
Adverse Events (AE) Preferred term	1. Arthralgia 2. Hypertensive heart disease 3. Left ventricular hypertrophy 4. Diastolic dysfunction 5. Diarrhoea 6. Convulsion 7. Supraventricular tachycardia 8. Fluid overload 9. Arthralgia 10. Diarrhoea 11. Vomiting 12. Hiatus hernia 13. Gastrooesophageal reflux disease 14. Thrombocytopenia 15. Gastroenteritis 16. Anxiety 17. Contusion 18. Infectious peritonitis 19. Acidosis 20. Intestinal infarction 21. Sepsis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/YES/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/YES/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. SEVERE/NO/YES/YES 11. SEVERE/NO/YES/YES 12. SEVERE/NO/YES/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053087

Parameter	Value
	13. SEVERE/NO/YES/YES
	14. SEVERE/NO/YES/YES
	15. SEVERE/NO/YES/YES
	16. MILD/NO/NO/YES
	17. MILD/NO/NO/YES
	18. MODERATE/NO/YES/YES
	19. MODERATE/NO/YES/YES
	20. SEVERE/NO/YES/YES
	21. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 10AUG2009 (18) - 01SEP2009 (40)
	2. 21AUG2009 (29) - 20NOV2009 (120)
	3. 21AUG2009 (29) - 20NOV2009 (120)
	4. 21AUG2009 (29) - 20NOV2009 (120)
	5. 27AUG2009 (35) - 28AUG2009 (36)
	6. 28AUG2009 (36) - 28AUG2009 (36)
	7. 29AUG2009 (37) - 30AUG2009 (38)
	8. 30AUG2009 (38) - 20NOV2009 (120)
	9. 02SEP2009 (41) - 20NOV2009 (120)
	10. 12OCT2009 (81) - 22OCT2009 (91)
	11. 12OCT2009 (81) - 22OCT2009 (91)
	12. 20OCT2009 (89) - --------- (.)
	13. 20OCT2009 (89) - --------- (.)
	14. 11NOV2009 (111) - --------- (.)
	15. 11NOV2009 (111) - --------- (.)
	16. 11NOV2009 (111) - 15NOV2009 (115)
	17. 13NOV2009 (113) - 20NOV2009 (120)
	18. 16NOV2009 (116) - --------- (.)
	19. 17NOV2009 (117) - --------- (.)
	20. 18NOV2009 (118) - 20NOV2009 (120)
	21. 20NOV2009 (120) - 20NOV2009 (120)
Duration of AE	1. 23
	2. 92
	3. 92
	4. 92
	5. 2
	6. 1
	7. 2
	8. 83
	9. 80
	10. 11
	11. 11
	12. .
	13. .
	14. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053087

Parameter	Value
	15. .
	16. 5
	17. 8
	18. .
	19. .
	20. 3
	21. 1
Dose on AE onset	1. 15 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053087

Parameter	Value
	17. .
	18. .
	19. F
	20. F
	21. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. NONE
	14. NONE
	15. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. NONE
	18. REMEDIAL DRUG THERAPY
	19. REMEDIAL DRUG THERAPY
	20. NONE
	21. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED
	13. UNCHANGED
	14. UNCHANGED
	15. UNCHANGED
	16. RESOLVED
	17. RESOLVED
	18. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053087

Parameter	Value
	19. UNCHANGED
	20. DEATH
	21. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053093

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053093/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/58/WHITE/SOUTH AFRICA/YES
Medical history	Asthma, Hypertension, Hypothyroidism, Nausea, Thrombocytopenia, Varicose vein, Postmenopause, Parkinson's disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	(NEUROBION)VITAMIN B1,VITAMINB6,VITAMINB12, AMINOPHYLLIN, ASPIRIN, ATENOLOL, ATENOLOL,CHLORTHALIDONE, BISOLVON LINCTUS, CARBIDOPA,LEVODOPA, DUOLIN RESPULES, ELTROXIN, ENALAPRIL, ENOXAPARIN, EPANUTIN, FUROSEMIDE, LASIX, MOXIFLOXACIN, PERFALGAN, POTASSIUM CHLORIDE SLOW RELEASE, PREXUM, WARFARIN, ZINACEF, ZINNAT
Adverse Events (AE) Preferred term	1. Oedema peripheral 2. Urinary tract infection 3. Asthenia 4. Thrombocytopenia 5. Epistaxis 6. Cor pulmonale 7. Lower respiratory tract infection 8. Hypertension 9. Chronic obstructive pulmonary disease 10. Cor pulmonale 11. Dystonia 12. Vaginal haemorrhage 13. Encephalopathy 14. Anxiety 15. Hypokalaemia 16. Confusional state 17. Hepatic failure 18. Hepatic cirrhosis 19. Portal hypertension 20. Endometrial cancer 21. Constipation
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MODERATE/NO/YES/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. SEVERE/NO/NO/YES 13. MODERATE/NO/YES/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053093

Parameter	Value
	14. MILD/NO/NO/YES
	15. MILD/NO/NO/YES
	16. MILD/NO/NO/YES
	17. MODERATE/NO/YES/NO
	18. MILD/NO/NO/NO
	19. MILD/NO/NO/NO
	20. MILD/NO/NO/NO
	21. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --JAN2010 (.) - --------- (.)
	2. 21DEC2009 (38) - 23DEC2009 (40)
	3. 21DEC2009 (38) - 23DEC2009 (40)
	4. 21DEC2009 (38) - --------- (.)
	5. 01FEB2010 (80) - 19MAR2010 (126)
	6. 26APR2010 (164) - 05MAY2010 (173)
	7. 26APR2010 (164) - 05MAY2010 (173)
	8. 26APR2010 (164) - 19MAY2010 (187)
	9. 03MAY2010 (171) - --------- (.)
	10. 06MAY2010 (174) - --------- (.)
	11. 13MAY2010 (181) - 14MAY2010 (182)
	12. 14MAY2010 (182) - 23MAY2010 (191)
	13. 14MAY2010 (182) - 24MAY2010 (192)
	14. 14MAY2010 (182) - 15MAY2010 (183)
	15. 14MAY2010 (182) - --------- (.)
	16. 15MAY2010 (183) - 03JUN2010 (202)
	17. 18MAY2010 (186) - --------- (.)
	18. 18MAY2010 (186) - --------- (.)
	19. 18MAY2010 (186) - --------- (.)
	20. 18MAY2010 (186) - --------- (.)
	21. 20MAY2010 (188) - 24MAY2010 (192)
Duration of AE	1. .
	2. 3
	3. 3
	4. .
	5. 47
	6. 10
	7. 10
	8. 24
	9. .
	10. .
	11. 2
	12. 10
	13. 11
	14. 2
	15. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053093

Parameter	Value
	16. 20
	17. .
	18. .
	19. .
	20. .
	21. 5
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053093

Parameter	Value
	18.
	19.
	20.
	21.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY,OTHER
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. OTHER
	18. NONE
	19. NONE
	20. NONE
	21. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. IMPROVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. UNCHANGED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. IMPROVED
	16. RESOLVED
	17. UNCHANGED
	18. UNCHANGED
	19. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053093

Parameter	Value
	20. UNCHANGED
	21. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053095

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053095/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/24/ASIAN/SOUTH AFRICA/YES
Medical history	Lower respiratory tract infection, Hydronephrosis, Nephrolithiasis, Urethral stenosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMIKACIN, ARCOXIA, ATERAX, AUGMENTIN, CIPROFLOXACIN, EVRA PATCH, IMOVANE, NEXIAM, PERFALGAN, RAYZON, SHERIPROCT OINTMENT ["PREDNISOLONE CAPROATE,CINCHOCAINE HCl"], SYNAP FORTE, TAVANIC, TRAMAL, XANOR SR
Adverse Events (AE) Preferred term	1. International normalised ratio increased 2. Activated partial thromboplastin time prolonged 3. Pneumonia 4. Pleural effusion 5. Haematuria 6. Anxiety 7. Fatigue 8. Menorrhagia 9. Haemorrhoids 10. Depression 11. Urinary tract infection 12. Lower respiratory tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/YES/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/YES/NO/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 23NOV2009 (3) - 28NOV2009 (8) 2. 23NOV2009 (3) - 28NOV2009 (8) 3. 24NOV2009 (4) - 28NOV2009 (8) 4. 24NOV2009 (4) - 28NOV2009 (8) 5. 25NOV2009 (5) - 29NOV2009 (9) 6. 25NOV2009 (5) - 28NOV2009 (8) 7. 18DEC2009 (28) - 30DEC2009 (40) 8. 20DEC2009 (30) - 24DEC2009 (34) 9. 18JAN2010 (59) - 25FEB2010 (97) 10. 02MAR2010 (102) - 16APR2010 (147) 11. 05MAR2010 (105) - 16MAR2010 (116) 12. 18MAY2010 (179) - 28MAY2010 (189)
Duration of AE	1. 6

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053095

Parameter	Value
	2. 6
	3. 5
	4. 5
	5. 5
	6. 4
	7. 13
	8. 5
	9. 39
	10. 46
	11. 12
	12. 11
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
Dose status on AE onset	1. .
	2. .
	3. I
	4. I
	5. I
	6. I
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED
	2. STUDY DRUG DISCONTINUED AND RESTARTED
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY,OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053095

Parameter	Value
	10. OTHER
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053097

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053097/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/42/BLACK/SOUTH AFRICA/YES
Medical history	Benign breast neoplasm, Caesarean section, Gestational diabetes, Hypothyroidism, Migraine, Obesity, Muscle spasms
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANDOLEX, ARCOXIA, ARIXTRA, AUGMENTIN, CELESTONE, CLOXACILLIN, COXFLAM, DIAMACRON MR, DUOLIN, ELTROXIN, EPILIM, GLUCOPHAGE, GLUCOPHAGE XR, IMOVANE, LENTOGESIC ["DEXTROPROPOXYPHENE HCI, PARACETAMOL, L-GLUTAMINE"], MARCAINE, MICROVAL, MORPHINE, NEXIAM, NOVOMIX 30, NOVORAPID, PANTOCID, PURBLOKA, RAYZON, ROCEPHIN, SLOW MAG, STILNOX, STOPAYNE ["PARACETAMOL, CODEINE PHOSPHATE, MEPROBAMATE, CAFFEINE"], SYNAP FORTE, TRAMACET, TREPELINE, ULSANIC, XANOR SR, ZOFRAN
Adverse Events (AE) Preferred term	1. Migraine 2. Chest pain 3. Rotator cuff syndrome 4. Mastitis 5. Weight increased 6. Hyperhidrosis 7. Type 2 diabetes mellitus 8. Menorrhagia 9. Liver function test abnormal 10. Menorrhagia 11. Haematuria 12. Epistaxis 13. Type 2 diabetes mellitus 14. Diabetes mellitus 15. Fibroadenoma of breast 16. Rotator cuff syndrome 17. Neck pain 18. Cervical spinal stenosis 19. Nausea 20. Tachycardia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES 5. MILD/YES/NO/YES 6. MILD/YES/NO/YES 7. MILD/NO/NO/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES 10. MILD/YES/YES/YES 11. MILD/YES/YES/YES 12. MILD/YES/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053097

Parameter	Value
	13. MILD/NO/YES/YES
	14. MODERATE/NO/NO/YES
	15. MODERATE/NO/YES/YES
	16. MILD/NO/YES/YES
	17. MILD/NO/NO/YES
	18. MILD/NO/YES/YES
	19. MILD/NO/YES/YES
	20. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --APR2010 (.) - --APR2010 (.)
	2. 18JAN2010 (2) - 21JAN2010 (5)
	3. 28JAN2010 (12) - --------- (.)
	4. 28JAN2010 (12) - 01FEB2010 (16)
	5. 01FEB2010 (16) - 16MAR2010 (59)
	6. 02FEB2010 (17) - 16MAR2010 (59)
	7. 23FEB2010 (38) - 05MAY2010 (109)
	8. 26MAR2010 (69) - 06APR2010 (80)
	9. 23APR2010 (97) - 05MAY2010 (109)
	10. 05MAY2010 (109) - 08MAY2010 (112)
	11. 05MAY2010 (109) - 08MAY2010 (112)
	12. 06MAY2010 (110) - 07MAY2010 (111)
	13. 06MAY2010 (110) - 11MAY2010 (115)
	14. 12MAY2010 (116) - --------- (.)
	15. 07JUL2010 (172) - 26JUL2010 (191)
	16. 07JUL2010 (172) - 08JUL2010 (173)
	17. 27JUL2010 (192) - 08AUG2010 (204)
	18. 09AUG2010 (205) - 26AUG2010 (222)
	19. 09AUG2010 (205) - 12AUG2010 (208)
	20. 12AUG2010 (208) - 04JAN2011 (353)
Duration of AE	1. .
	2. 4
	3. .
	4. 5
	5. 44
	6. 43
	7. 72
	8. 12
	9. 13
	10. 4
	11. 4
	12. 2
	13. 6
	14. .
	15. 20
	16. 2

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053097

Parameter	Value
	17. 13
	18. 18
	19. 4
	20. 146
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
	18. .
	19. .
	20. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053097

Parameter	Value
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY,OTHER
	5. OTHER
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. OTHER
	9. NONE
	10. OTHER
	11. OTHER
	12. OTHER
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY,OTHER
	16. REMEDIAL DRUG THERAPY,OTHER
	17. STUDY DRUG DISCONTINUED AND RESTARTED
	18. REMEDIAL DRUG THERAPY,OTHER
	19. REMEDIAL DRUG THERAPY
	20. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. UNCHANGED
	15. RESOLVED
	16. RESOLVED
	17. UNCHANGED
	18. RESOLVED
	19. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053097

Parameter	Value
	20. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053106

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053106/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/69/BLACK/SOUTH AFRICA/YES
Medical history	Acute myocardial infarction, Anaemia, Angina pectoris, Cardiac failure congestive, Diabetes mellitus, Blood cholesterol increased, Hypertension, Hypotension, Myocardial ischaemia, Lower respiratory tract infection, Pleural effusion, Pulmonary oedema, Coronary arterial stent insertion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTIVAN, ADRENALINE, ALBUMIN, ASPAVOR, ASPIRIN, BENYLIN ["DIPHENHYDRAMINE HCI, PARACETAMOL, PSEUDOEPHEDR.HCI"], BISOCOR, CORALAN, DIAGLUCIDE, DOBUTREX, DORMICUM, DORMONOCT, DUOLIN NEBULIZERS, DUPHALAC [LACTOSE ALONE], ECOTRIN, ENOXAPARIN, ETOMINE, FRESH FROZEN PLASMA, GLUCOPHAGE, HAEMOFER, IMODIUM, IMOVANE, ISMO, KAYEXALATE, KLACID XL, LASIX, MAXALON, METFORMIN, MORPHINE, NITROCINE, NOVORAPID, PANTOCID, PERFALGAN, PHOLTEX, PLAVIX, PLAVIX (CLOPIDOGREL), POTASSIUM CHLORIDE, PROPOFOL, RAPIFEN, REUTERI, ROCEPHIN, SIMVASTATIN, SLOW K, SYNAP FORTE, TOPZOLE, TREPILINE, ULSANIC, VIT BCO, VITAMIN K, WARFARIN, ZOFRAN
Adverse Events (AE) Preferred term	1. Gastritis 2. Haemorrhoidal haemorrhage 3. Cardiac failure congestive 4. Renal impairment 5. Coagulation time prolonged 6. Liver function test abnormal 7. Thrombocytopenia 8. Gastritis haemorrhagic 9. Constipation 10. Weight decreased 11. Coagulation time prolonged 12. Cardiac failure congestive 13. Hypotension 14. Pleural effusion 15. Coagulation time prolonged 16. Diarrhoea 17. Nausea 18. Hyperkalaemia 19. Cardiac failure congestive 20. Insomnia 21. Hypotension 22. Cardiac failure congestive 23. Hypoalbuminaemia 24. Diarrhoea 25. Pleural effusion 26. Hypotension 27. Cardiac failure congestive 28. Cardiac failure congestive 29. Dyspnoea 30. Oedema peripheral

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053106

Parameter	Value
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MODERATE/YES/YES/YES
	3. MODERATE/NO/YES/YES
	4. MODERATE/NO/YES/YES
	5. MODERATE/YES/YES/YES
	6. MODERATE/YES/NO/YES
	7. MODERATE/YES/NO/YES
	8. MILD/YES/YES/YES
	9. MILD/NO/NO/YES
	10. MILD/NO/NO/YES
	11. MODERATE/YES/NO/YES
	12. MODERATE/NO/YES/YES
	13. MODERATE/NO/YES/YES
	14. MODERATE/NO/YES/YES
	15. MILD/YES/NO/YES
	16. MILD/NO/NO/YES
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MILD/NO/NO/YES
	20. MILD/NO/NO/YES
	21. MILD/NO/NO/YES
	22. MILD/NO/YES/YES
	23. MILD/NO/YES/YES
	24. MILD/NO/NO/YES
	25. MODERATE/NO/NO/YES
	26. MILD/NO/NO/YES
	27. MILD/NO/NO/YES
	28. MODERATE/NO/YES/NO
	29. MILD/NO/NO/NO
	30. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 25MAY2010 (4) - 18JUN2010 (28)
	2. 06JUN2010 (16) - 08JUN2010 (18)
	3. 07JUN2010 (17) - 18JUN2010 (28)
	4. 07JUN2010 (17) - 18JUN2010 (28)
	5. 07JUN2010 (17) - 08JUN2010 (18)
	6. 07JUN2010 (17) - 22JUN2010 (32)
	7. 07JUN2010 (17) - 19JUL2010 (59)
	8. 09JUN2010 (19) - 18JUN2010 (28)
	9. 12JUN2010 (22) - 13JUN2010 (23)
	10. 18JUN2010 (28) - --------- (.)
	11. 25JUN2010 (35) - 30JUN2010 (40)
	12. 18JUL2010 (58) - 05AUG2010 (76)
	13. 18JUL2010 (58) - 20JUL2010 (60)
	14. 19JUL2010 (59) - 05AUG2010 (76)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053106

Parameter	Value
	15. 22JUL2010 (62) - 22JUL2010 (62)
	16. 24JUL2010 (64) - 27JUL2010 (67)
	17. 24JUL2010 (64) - 27JUL2010 (67)
	18. 01AUG2010 (72) - 05AUG2010 (76)
	19. 24AUG2010 (95) - 25AUG2010 (96)
	20. 24AUG2010 (95) - --------- (.)
	21. 24AUG2010 (95) - 25AUG2010 (96)
	22. 16SEP2010 (118) - 06OCT2010 (138)
	23. 16SEP2010 (118) - 04OCT2010 (136)
	24. 17SEP2010 (119) - 13OCT2010 (145)
	25. 21SEP2010 (123) - 06OCT2010 (138)
	26. 24SEP2010 (126) - 27SEP2010 (129)
	27. 22NOV2010 (185) - 23NOV2010 (186)
	28. 25NOV2010 (188) - 27NOV2010 (190)
	29. 25JAN2011 (249) - --------- (.)
	30. 25JAN2011 (249) - --------- (.)
Duration of AE	1. 25
	2. 3
	3. 12
	4. 12
	5. 2
	6. 16
	7. 43
	8. 10
	9. 2
	10. .
	11. 6
	12. 19
	13. 3
	14. 18
	15. 1
	16. 4
	17. 4
	18. 5
	19. 2
	20. .
	21. 2
	22. 21
	23. 19
	24. 27
	25. 16
	26. 4
	27. 2
	28. 3

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053106

Parameter	Value
	29. .
	30. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
	27.
	28.
	29.
	30.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053106

Parameter	Value
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
	27.
	28.
	29.
	30.
Action taken	1. OTHER
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. STUDY DRUG DISCONTINUED AND RESTARTED
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. REMEDIAL DRUG THERAPY
	19. REMEDIAL DRUG THERAPY
	20. REMEDIAL DRUG THERAPY
	21. OTHER
	22. REMEDIAL DRUG THERAPY
	23. REMEDIAL DRUG THERAPY
	24. REMEDIAL DRUG THERAPY
	25. OTHER
	26. OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053106

Parameter	Value
	27. REMEDIAL DRUG THERAPY,OTHER
	28. REMEDIAL DRUG THERAPY
	29. NONE
	30. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. IMPROVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. IMPROVED
	20. UNCHANGED
	21. RESOLVED
	22. RESOLVED
	23. RESOLVED
	24. RESOLVED
	25. RESOLVED
	26. RESOLVED
	27. IMPROVED
	28. RESOLVED
	29. UNCHANGED
	30. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053108

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053108/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/68/WHITE/SOUTH AFRICA/YES
Medical history	Anxiety, Cardiac failure chronic, Cholecystectomy, Back pain, Depression, Diabetes mellitus, Oesophagogastric fundoplasty, Gout, Hypercholesterolaemia, Hypertension, Myocardial ischaemia, Myocardial infarction, Nausea, Obesity, Angina unstable, Spinal fusion surgery, Foot operation, Prostatectomy, Cough, Coronary artery bypass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACCUPRIL, ADCO-GLUCOMED GLICAZIDE, ADRENALINE, ALZAM, ASPAVOR, ASPIRIN, BISOCOR, BISOLVON, CARDICOR, CILIFT, CIPLA PIOGLITAZONE, COLCHICINE, CRESTOR, DIAMACRON MR, DORMICUM, DULCOLAX [BISACODYL.], DUOLIN NEBULIZERS, ELANTAN, GLUCOPHAGE, IMDUR, KLACID XL, LANOXIN, LASIX, NITROCINE INFUSION, NOVORAPID, NOVORAPID SLIDING SCALE, PLAVIX, PROPOFOL, PULMISON, PURATA, PURESIS, PURICOS, QUINASPEN, RAPIFEN, SIMVASTATIN, SLOW K, SPIRACTIN, TAVANIC, TRAMACET, VOLUVEN, X-PREP, XYLOCAINE SPRAY, ZOFRAN
Adverse Events (AE) Preferred term	1. Bronchitis 2. Cardiac failure congestive 3. Hypotension 4. Contusion 5. Contusion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 06JUL2010 (12) - 20JUL2010 (26) 2. 28FEB2011 (249) - 06MAR2011 (255) 3. 02MAR2011 (251) - 03MAR2011 (252) 4. 14MAR2011 (263) - 26APR2011 (306) 5. 14MAR2011 (263) - 26APR2011 (306)
Duration of AE	1. 15 2. 7 3. 2 4. 44 5. 44
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. I 3. I 4. . 5. .
Action taken	1. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053108

Parameter	Value
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053110

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053110/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/76/BLACK/SOUTH AFRICA/YES
Medical history	Cardiac pacemaker insertion, Cardiomyopathy, Chronic obstructive pulmonary disease, Diarrhoea, Hepatitis, Hypercholesterolaemia, Hypertension, Insomnia, Pleural effusion, Pleuritic pain, Escherichia sepsis, Tracheostomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACYCLOVIR CREAM, ADCO SIMVISTATIN, ALLOPURINOL, ALLUPURINOL, CEFUROXIME, CLARITHROMYCIN, ECOTRIN, ENOXAPARIN, FUROSEMIDE, IPRATROPIUM SALBUTAMOL, LOPERAMIDE HCl, LOPRAZOLAM, MOXIFLOXACIN, MOXIFLOXACIN HCl, PARACETAMOL,DEXTROPROPOXYPHENE NAPSYLATE,DIPHENHYDRAM HCl,CAFFEINE, POTASSIUM CHLORIDE, TELITHROMYCIN, THEOPHYLLINE, WARFARIN
Adverse Events (AE) Preferred term	1. Cough 2. Oral herpes 3. Gout 4. Bronchospasm 5. Bronchopneumonia 6. Gout 7. Bronchospasm 8. Cardiac failure congestive
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 16JUL2010 (4) - 21JUL2010 (9) 2. 16JUL2010 (4) - 21JUL2010 (9) 3. 16JUL2010 (4) - 21JUL2010 (9) 4. 16JUL2010 (4) - 19JUL2010 (7) 5. 30AUG2010 (49) - 07SEP2010 (57) 6. 17SEP2010 (67) - 16OCT2010 (96) 7. 17SEP2010 (67) - --------- (.) 8. 15NOV2010 (126) - --------- (.)
Duration of AE	1. 6 2. 6 3. 6 4. 4 5. 9 6. 30 7. . 8. .
Dose on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053110

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. IMPROVED
	8. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053117

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053117/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/57/WHITE/SOUTH AFRICA/YES
Medical history	Arthralgia, Bone pain, Femur fracture, Clavicle fracture, Hand fracture, Hand fracture, Rib fracture, Hand fracture, Pain in extremity, Pain in extremity, Insomnia, Pain in extremity, Nerve compression, Pain, Pain in extremity, Pelvic pain, Wound infection, Lower limb fracture, Pelvic fracture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATERAX, CEFAZOLINE, CELEBREX, COXFLAM, DECASONE, DECAZONE, DIPRIVAN, DORMICUM, ENOXAPARIN, FLAGYL, FOLIC ACID, GENTAMYCIN, IMMOVANE, INTERFLORA, KEFZOL, KYTRIL, LENTOGESIC(DEXTROPROPOXYPHENE'PARACETAMOL'L-GLUTAMINE), LIGNOCAINE, LIGNOCAINE 2%, LOXIFLAM, MORPHINE, PARACETAMOL,DEXTROPROPOXYPHENE,DIPHENHYDRAMINE,CAFFEINE, PERFALGAN, RAPIFEN, RAYZON, RIFAMPICIN, SLOW MAG, STILNOX, SUFENTA, TAVANIC, TRAMAL, VITAMIN A, VITAMIN D, WARFARIN, XERALTO, ZINACEF, ZINC
Adverse Events (AE) Preferred term	1. Cellulitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 26NOV2010 (70) - 02DEC2010 (76)
Duration of AE	1. 7
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053122

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053122/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/64/WHITE/SOUTH AFRICA/YES
Medical history	Anaemia, Contusion, Chronic obstructive pulmonary disease, Colonoscopy, Diabetes mellitus, Diverticulum, Endoscopy upper gastrointestinal tract, Hypertension, Hysterectomy, Obesity, Peptic ulcer, Skin cancer, Hyperlipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALTOSEC, BUSCOPAN, DORMICUM, DORMONOCT, DULCOLAX [BISACODYL], DUOLIN, HAEMOFER, KLEEN PREP, LISORETIC, METFORMIN, NEXIAM, NOVORAPID, PROPOFOL, PULMISON, RAPIFEN, SIMVASTATIN, SYNAP FORTE, TRANSACT, VERAHEXAL SR, WARFARIN
Adverse Events (AE) Preferred term	1. Haematoma 2. Diverticulum 3. Anaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/YES/YES 3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 25NOV2010 (3) - --JAN2011 (.) 2. 16MAR2011 (114) - 18MAR2011 (116) 3. 16MAR2011 (114) - 17MAR2011 (115)
Duration of AE	1. . 2. 3 3. 2
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY,OTHER 3. OTHER
Outcome of event	1. UNCHANGED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-370053122[4)]	ANEMIA（PT：貧血） 治験担当医は、合併症（憩室症）及び既往症（貧血）によるものであり、否定できると判断した。弊社は、ワルファリンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053132

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370053132/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/42/WHITE/SOUTH AFRICA/YES
Medical history	Abdominal pain, Pancreatitis acute, Anaemia, Decreased appetite, Anxiety, Gastric cancer, Hypercholesterolaemia, Hyperglycaemia, Hypertension, Pruritus, Pneumonia, Pleural effusion, Pyrexia, Pyrexia, Nephrolithiasis, Splenectomy, Gastrectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	5 FU (5-FLUOROURACIL), ADALAT, ARCOXIA, ATROPINE, CAMPTO, CILIFT, CIPRAMIL, CLEXANE, CLOPAMON, CORDARONE, DECASONE, DIFLUCAN, DORMONOCT, DULCOLAX [BISACODAY], DUOLIN NEBS, DUPHALAC [LACTULOSE], DUROGAESIC PATCHES, DUROGESIC, KLEEN PREP, KYTRIL, LASIX, MAXALON, MERONEM, MINAMINO SYRUP, MORPHINE, MORPHINE TITRATION, MOVICOL, NEUROBION, NOVORAPID, PANADO, PANTOCID, PERFALGAN, PETHEDINE, PETHIDINE, PURBAC, RAYZON, SOLUCORTEF, STOPAYNE [CAFFEINE,CODEINE PHOSPHATE,MEPROBAMATE,PARACETAMOL], TARGOCID, TAZOCIN, TIENAM, TPN, TRAMAL, TREPELINE, ULSANIC, VALIUM, VITAMIN BCO, VOLTAREN SUPPOSITRY, VOLUVEN, XPREP, ZOFRAN
Adverse Events (AE) Preferred term	1. Abdominal pain 2. Agitation 3. Vomiting 4. Constipation 5. Gastritis 6. Respiratory distress 7. Anxiety 8. Hypertension 9. Gastric cancer 10. Chest pain 11. Tachycardia 12. Hypotension 13. Sepsis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. SEVERE/NO/YES/YES 10. MODERATE/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MODERATE/NO/NO/YES 13. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 13MAR2011 (6) - --------- (.) 2. 13MAR2011 (6) - 27MAR2011 (20) 3. 13MAR2011 (6) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053132

Parameter	Value
	4. 14MAR2011 (7) - --------- (.)
	5. 15MAR2011 (8) - --------- (.)
	6. 21MAR2011 (14) - 27MAR2011 (20)
	7. 21MAR2011 (14) - --------- (.)
	8. 21MAR2011 (14) - 26MAR2011 (19)
	9. 21MAR2011 (14) - 27MAR2011 (20)
	10. 26MAR2011 (19) - --------- (.)
	11. 26MAR2011 (19) - 27MAR2011 (20)
	12. 27MAR2011 (20) - 27MAR2011 (20)
	13. 27MAR2011 (20) - 27MAR2011 (20)
Duration of AE	1. .
	2. 15
	3. .
	4. .
	5. .
	6. 7
	7. .
	8. 6
	9. 7
	10. .
	11. 2
	12. 1
	13. 1
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 15 mg
	12. 15 mg
	13. 15 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370053132

Parameter	Value
	9. .
	10. .
	11. .
	12. .
	13. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED
	7. UNCHANGED
	8. RESOLVED
	9. DEATH
	10. UNCHANGED
	11. UNCHANGED
	12. UNCHANGED
	13. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370063018

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370063018/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/45/BLACK/SOUTH AFRICA/YES
Medical history	Constipation, Cardiac failure, Hypertension, Cerebrovascular accident, Alcohol use, Congestive cardiomyopathy, Retroviral infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTONE [SPIRONOLACTONE], AUGMENTIN, BACTRIM, CARVEDILOL, DOBUTREX, LACTULAX, LASIX, PREXUM, PYNDOXINE, RIFAFOUR, SLOW K, THIAMINE
Adverse Events (AE) Preferred term	1. Pulmonary oedema 2. Cardiac failure 3. Lower respiratory tract infection 4. Liver function test abnormal 5. Congestive cardiomyopathy 6. Cardiac failure congestive
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. SEVERE/YES/YES/YES 6. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 10APR2009 (43) - --------- (.) 2. 10APR2009 (43) - --------- (.) 3. 10APR2009 (43) - 14APR2009 (47) 4. 02JUN2009 (96) - --------- (.) 5. 24JUN2009 (118) - 25JUN2009 (119) 6. 24JUN2009 (118) - 25JUN2009 (119)
Duration of AE	1. . 2. . 3. 5 4. . 5. 2 6. 2
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. .
Action taken	1. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370063018

Parameter	Value
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
Outcome of event	1. IMPROVED
	2. IMPROVED
	3. IMPROVED
	4. UNCHANGED
	5. DEATH
	6. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-370063018[2),2)]	DEATH DUE TO DILATED CARDIOMYOPATHY（PT：うっ血性心筋症） 治験担当医はリバーロキサバンと報告事象との関連性はあると判断した。弊社は、合併症(HIV 感染)に起因したと考えられることから、リバーロキサバンとの因果関係は否定できると考える。 FATAL CONGESTIVE CARDIAC FAILURE（PT：うっ血性心不全） 治験担当医はリバーロキサバンと報告事象との関連性はあると判断した。弊社は、合併症（HIV 感染）に続発した心不全が誘因となったと考え、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

被験者番号：11702-370063018

死亡に至るまでの経過

被験者は 45 歳、黒人女性。2009 年 2 月 27 日に肺塞栓症と診断され、同日リバーロキサバン（30mg）の投与を開始した。

2009 年 4 月 10 日、肺水腫（肺水腫）、心不全（心不全の悪化）、下気道感染（下気道感染）を発現した。これらの事象により被験者が入院に至ったため、これら 3 事象は重篤とされた。また、肺水腫（肺水腫）及び心不全（心不全の悪化）については重大な医学的事象と考えられた。治験責任（分担）医師は、いずれの事象も重症度は中等度で、治験薬との因果関係は「なし」と判断した。被験者は拡張型心筋症及びレトロウイルス感染（HIV）の病歴を有していた。しかし、抗レトロウイルス治療は受けておらず、長期のアルコール摂取歴があった。2009 年 2 月、事象の発現前に被験者は心臓症状のため入院した。腹部エコー検査を行ったところ、右側胸水の徴候が認められ、EF（駆出率）は 40%であった。追加検査を実施したところ index イベントが確認されたため、本試験に組み入れられた。2009 年 4 月 10 日、被験者は心臓症状の悪化により再入院した。同日、被験者は誤って治験薬を一時的に中断し、2009 年 4 月 16 日に再開した。2009 年 4 月 13 日、トロポニン I 0.03ng/mL 未満。2009 年 4 月 15 日、胸部 CT スキャンを実施したところ、肺塞栓症は認められず、心不全に続発したと考えられる肺水腫のみが認められた。2009 年 4 月 14 日、D ダイマーは 3.85μg/L に上昇、N 末端プロ脳性ナトリウム利尿ペプチド（NT-proBNP）は 12,915ng/L（基準値：0～300ng/L）。下気道感染に対する治療として酸素吸入を行い、心不全に対して行っていた carvedilol の投与は継続した。4 日後、症状が改善し安定したため退院した。肺水腫（肺水腫）及び心不全（心不全の悪化）の最終転帰は継続中及び改善と報告され、下気道感染（下気道感染）の転帰は 2009 年 4 月 14 日に改善と報告された。

2009 年 5 月、3 ヵ月目の来院時に被験者は息切れ、咳嗽及び両脚の腫脹を伴う心不全を発現していた。エコー検査の結果、EF は 13%で、心臓専門医は心不全専門外来で治療可能と判断した。

2009 年 6 月 24 日、被験者はうっ血性心不全（うっ血性心不全）及びうっ血性心筋症（拡張型心筋症）を発現した。いずれも生命を脅かす事象であり死亡に至ったため重篤な有害事象とされた。またうっ血性心不全は入院に至った事象、うっ血性心筋症は重大な医学的事象と考えられた。治験責任（分担）医師は、いずれの事象も重症度は高度で、治験薬との因果関係は「あり」と判断した。4 ヵ月目の来院時にこれらの事象の悪化が顕著であったため、同日、心臓集中治療室に入院した。入院時に撮影した胸部 X 線写真からは結核の徴候が認められ、症状からは肺塞栓症が疑われたが、被験者の容態が悪くそれ以上の検査は行われなかった。翌日実施した血液検査の結果、BNP は 7,454ng/L まで上昇した。いずれの事象に対しても治療は行われなかった。結核が疑われたため結核治療薬が投与された。2009 年 6 月 25 日、両事象により被験者は死亡に至った。剖検は実施されなかった。

CIAC は死亡原因をうっ血性心不全と判定した。

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
Alkaline Phosphatase	Central: 36-118 U/L	27 Feb 2009	76 U/L	02 Apr 2009	91 U/L	28 May 2009	105 U/L
		13 Mar 2009	64 U/L	24 Apr 2009	87 U/L		
Amylase	Central: 28-100 U/L	27 Feb 2009	44 U/L				

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
Bilirubin, Direct	Central: 0.10-0.32 mg/dL	27 Feb 2009	**0.35 mg/dL (H)**	02 Apr 2009	**0.34 mg/dL (H)**		
		13 Mar 2009	0.16 mg/dL	28 May 2009	**1.08 mg/dL (H)**		
Bilirubin, Total	Central: 0.22-1.28 mg/dL	27 Feb 2009	0.85 mg/dL	02 Apr 2009	0.82 mg/dL	28 May 2009	**3.15 mg/dL (H)**
		13 Mar 2009	0.44 mg/dL	24 Apr 2009	**1.30 mg/dL (H)**		
Creatinine	Local: 0.68-1.13 mg/dL	27 Feb 2009	**1.37 mg/dL (H)**				
SGOT/AST	Central: 11-37 U/L	27 Feb 2009	**54 U/L (H)**	02 Apr 2009	**38 U/L (H)**		
		13 Mar 2009	36 U/L	28 May 2009	37 U/L		
SGPT/ALT	Central: 8-43 U/L [a] Local: 5-40 U/L	27 Feb 2009	18 U/L	13 Mar 2009	16 U/L	28 May 2009	13 U/L
		27 Feb 2009	20 U/L [a]	02 Apr 2009	16 U/L		
PICT Seconds	Central: 24.80-36.40 S	27 Feb 2009	**62.90 S (H)**	24 Apr 2009	34.70 S		
Prothrombin Time (PT)	Central: 11.80-15.50 S	27 Feb 2009	**19.50 S (H)**	24 Apr 2009	**39.40 S (H)**		
PT Ratio	Central: 0.70-1.20 %	27 Feb 2009	**0.52 % (L)**	24 Apr 2009	**0.21 % (L)**		
PT, INR	Central: 0.9-1.2	27 Feb 2009	**1.6 (H)**	24 Apr 2009	**3.8 (H)**		

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370063019

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370063019/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/37/BLACK/SOUTH AFRICA/YES
Medical history	Asthma, Dyspepsia, HIV test positive, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	3TC (LAMIVUDINE), AMOXIL, AMOXYCILLIN, ASTHAVENT, AUGMENTIN, AZT, BUDEFLAM, CIPFLOXACIN, CO-AMOXYCLAV, DEPO PROVERA, EFAVIRENT, ENOXAPARIN, FORATEC HFA, MOXYPEN, PREDNISONE, SINGULAIR, TAGAMET, WARFARIN
Adverse Events (AE) Preferred term	1. Upper respiratory tract infection 2. Haemoptysis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 23MAR2009 (19) - 06OCT2009 (216) 2. 23MAR2009 (19) - 03APR2009 (30)
Duration of AE	1. 198 2. 12
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-370063019[4)]	HAEMOPTYSIS（PT：喀血） 治験担当医は、因果関係を否定できると判断した。弊社は、ワルファリンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。また、合併症（喘息及び上気道感染）による可能性も考えられる。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370073004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370073004/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/SOUTH AFRICA/YES
Medical history	Breast cancer, Cardiac failure, Hypertension, Mastectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLOC, ARIMIDEX, BISOCOR, CONCOR, ENOXAPARIN, TORASEMIDE, TORASSEMIDE, WARFARIN
Adverse Events (AE) Preferred term	1. Lung cancer metastatic
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 20NOV2008 (165) - --------- (.)
Duration of AE	1. .
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370073006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370073006/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/77/WHITE/SOUTH AFRICA/YES
Medical history	Appendicectomy, Basal cell carcinoma, Hypertension, Insomnia, Peptic ulcer, Type 2 diabetes mellitus, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DILATREND, ECOTRIN, ENOXAPARIN, GLUCOMED, GLUCOPHAGE, IMOVANE, KLACID, PREXUM, ROCEPHIN, SIMVASTATIN, SPIRECTIN, UNAT, WARFARIN
Adverse Events (AE) Preferred term	1. Cholecystitis acute
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 10JUL2008 (3) - 15JUL2008 (8)
Duration of AE	1. 6
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370073015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370073015/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/SOUTH AFRICA/YES
Medical history	Constipation, Gout, Lung neoplasm malignant
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARCOXIA, CHEMOTHERAPY(SPECIFICS UNKNOWN), MOVICOL, PERFALGAN
Adverse Events (AE) Preferred term	1. Laceration 2. Sepsis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 23FEB2009 (24) - 23FEB2009 (24) 2. 22MAY2009 (112) - 27MAY2009 (117)
Duration of AE	1. 1 2. 6
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. F
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370073022

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370073022/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/87/WHITE/SOUTH AFRICA/YES
Medical history	Anxiety, Asthma, Cardiac failure chronic, Renal impairment, Depression, Gout, Hip arthroplasty, Hip arthroplasty, Hypertension, Hypothyroidism, Osteoarthritis, Restless legs syndrome, Supraventricular tachycardia, Varicose vein operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATERAX, BACTOBAN CREAM, BATEDINE CREAM, CALCIUM GLUCONATE, CELEBREX, CLAMENTIN, DUOVENT, ELTROXIN, ENOXAPARIN, KEXELATE, PEXOLA, PROBIFLORA, PURESIS, PURICOS, SPIRACTIN, WARFARIN, ZARTAN [ZARTAN / LOSARTAN. HYPERTENSION], ZITHROMAX
Adverse Events (AE) Preferred term	1. Gout 2. Upper respiratory tract infection 3. Blister 4. Hyperkalaemia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 19OCT2009 (7) - 24OCT2009 (12) 2. 29JAN2010 (109) - 06FEB2010 (117) 3. 05FEB2010 (116) - --------- (.) 4. 02MAR2010 (141) - 29MAR2010 (168)
Duration of AE	1. 6 2. 9 3. . 4. 28
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370073022

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370073023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370073023/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/65/WHITE/SOUTH AFRICA/YES
Medical history	Insomnia, Postmenopause, Glucose tolerance impaired
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATERAX, ATIVAN, BROMAZEPAM, DOLOROL, LORAZEPAM, METFORMIN, MOVICOL, REMERON, RIVOTRIL, SEROQUEL, XANOR SR
Adverse Events (AE) Preferred term	1. Anxiety 2. Anxiety
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 14APR2010 (115) - 19APR2010 (120) 2. 20APR2010 (121) - --------- (.)
Duration of AE	1. 6 2. .
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED 2. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370093004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370093004/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/60/WHITE/SOUTH AFRICA/YES
Medical history	Anxiety, Back pain, Bronchospasm, Chronic obstructive pulmonary disease, Hypokalaemia, Hypomagnesaemia, Osteoporosis, Spinal fusion surgery, Postmenopause, Elbow operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATERAX, AUGMENTIN, COMBIVENT, COXFLAM, DF 118, IMOVANE, PERFALGAN, RAYZON, REUTERI, SERETIDE, SLOW K, SOLU -MEDROL, STILNOX, SYNAP FORTE, TEMGESIC, TORADOL, TRAMACET, VOLTAREN, XANOR
Adverse Events (AE) Preferred term	1. Pain in extremity
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 04MAY2009 (90) - 14MAY2009 (100)
Duration of AE	1. 11
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370093008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370093008/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/53/ASIAN/SOUTH AFRICA/YES
Medical history	Anxiety, Back pain, Bronchitis, Depression, Drug hypersensitivity, Haemorrhoid operation, Hypertension, Hysterectomy, Neuropathy peripheral, Pain in extremity, Tachycardia, Weight decreased, Spinal fusion surgery, Abdominal hernia repair, Oral fungal infection, Breast lump removal, Intervertebral disc degeneration
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATERAX, BUSCOPAN, CLOXIN, CONCOR, CYMBALTA, DF 118, IMMOVANE, LANTANON, LOSEC, LYRICA, MYCOSTATIN, NEXIAM, PERFALGAN, RANMOXY, STILNOX, STILPANE ["""PARACETAMOL. COD PHOS, CAFF. ANHYDR, MEPROBAM"""], SYNAPFORTE, TORADOL, TRAMAL, ULSANIC, XANOR, ZOFRAN
Adverse Events (AE) Preferred term	1. Nausea 2. Vomiting 3. Spinal disorder 4. Nervous system disorder 5. Dyspepsia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 25MAY2009 (20) - 29MAY2009 (24) 2. 25MAY2009 (20) - 29MAY2009 (24) 3. 25MAY2009 (20) - 02JUN2009 (28) 4. 25MAY2009 (20) - 02JUN2009 (28) 5. 11SEP2009 (129) - 14SEP2009 (132)
Duration of AE	1. 5 2. 5 3. 9 4. 9 5. 4
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370093008

Parameter	Value
Outcome of event	5. REMEDIAL DRUG THERAPY,OTHER
	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370093009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370093009/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/77/WHITE/SOUTH AFRICA/YES
Medical history	Asthma, Intestinal obstruction, Urinary tract infection, Constipation, Diverticulitis, Drug hypersensitivity, Colectomy, Hernia hiatus repair, Humerus fracture, Hypertension, Hysterectomy, Migraine, Nausea, Osteoporosis, Drug hypersensitivity, Varicose vein operation, Contusion, Contusion, Drug hypersensitivity, Cystocele repair
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALTOSEC, AMIKACIN, BUSCOPAN, CALCICARD, CEPODEM, CIPLOXX, CLAFORAN, COMBIVENT, FACTIVE, IMOVANE, KETEK, KLEAN-PREP, MAXOLON, MOVICOL, NEXIAM, PANAFCORT, PANTOLOC, PERFALGAN, QUADRIDERM ["""BETAMETHASONE, GENTAMICIN,TOLNAFTATE, CLIOQUINOL"""], SANDOZ CALCIUM, SOLU-CORTEF, STILPANE ["""PARACETAMOL, COD.PHOS, CAFF.ANHYD, MEPROBAM"""], SYMBICORT, SYNAP FORTE, ZOFRAN
Adverse Events (AE) Preferred term	1. Disorientation 2. Diverticulitis 3. Constipation 4. Drug hypersensitivity 5. Impetigo
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 09MAY2009 (3) - 09MAY2009 (3) 2. 27MAY2009 (21) - 29MAY2009 (23) 3. 10AUG2009 (96) - 12AUG2009 (98) 4. 27AUG2009 (113) - 27AUG2009 (113) 5. 10NOV2009 (188) - 04DEC2009 (212)
Duration of AE	1. 1 2. 3 3. 3 4. 1 5. 25
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370093009

Parameter	Value
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370093015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370093015/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/46/BLACK/SOUTH AFRICA/YES
Medical history	Spinal osteoarthritis, Cholecystectomy, Constipation, Haemorrhoid operation, Hypertension, Pleural effusion, Pneumonia, Splenic rupture, Procedural pain, Subdiaphragmatic abscess, Headache, Benign pancreatic neoplasm
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC 200, ARCOXIA, ARTHREXIN, ATERAX, AUGMENTIN, AVELON, CATAFLAM, CLEXANE, DF 118, DULCOLAX SUPP [BISACODYL], FLEET ENEMA, IMMOVANE, KLACID, MAXALON, MOVICOL, MYPAID, PANTALOC, PERFALGAN, PETHIDINE, PREXUM, RAYZON, SINGULAIR, SYNAP FORTE, TARGOCID, TEMGESIC, TIENAM, TRAMAL, TREPILINE, XYZOL
Adverse Events (AE) Preferred term	1. Blood alkaline phosphatase increased 2. Blood amylase increased 3. Subdiaphragmatic abscess 4. Subdiaphragmatic abscess 5. Spinal osteoarthritis 6. Bronchitis 7. Influenza
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 10DEC2009 (1) - 06JAN2010 (28) 2. 10DEC2009 (1) - 10DEC2009 (1) 3. 11DEC2009 (2) - 11DEC2009 (2) 4. 18DEC2009 (9) - 26DEC2009 (17) 5. 14APR2010 (126) - --------- (.) 6. 06JUL2010 (209) - 17JUL2010 (220) 7. 11AUG2010 (245) - 18AUG2010 (252)
Duration of AE	1. 28 2. 1 3. 1 4. 9 5. . 6. 12 7. 8
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 20 mg 6. 20 mg 7. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370093015

Parameter	Value
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. . 7. .
Action taken	1. NONE 2. NONE 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 5. REMEDIAL DRUG THERAPY 6. REMEDIAL DRUG THERAPY 7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED 4. RESOLVED 5. UNCHANGED 6. RESOLVED 7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370093017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370093017/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/SOUTH AFRICA/YES
Medical history	Abdominal pain, Iron deficiency anaemia, Back pain, Cardiac failure chronic, Colon cancer, Constipation, Coronary artery bypass, Coronary artery disease, Dementia, Hypercholesterolaemia, Hypertension, Hypokalaemia, Hypothyroidism, Hysterectomy, Neuropathy peripheral, Osteoarthritis, Oedema peripheral, Spinal laminectomy, Urinary incontinence, Asthenia, Escherichia urinary tract infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC 200, ASPAVOR, AUTRIN, CARDICOR, CELEBREX, CEROXIM, CIPROBAY, DISPRIN CV, DULCOLAX SUPP [BISACODYL], DUPHALAC SYRUP [LACTULOSE], ELANTAN, ELTROXIN, FIBRE PLUS ["""HERBAL PREP FOR CONSTIPATION. PSYLLIUM,FRUCTOSE,HIBISCUS FLOWER,B, FLUZOL HEXAL, FRESH FROZEN PLASMA, LANOXIN, LASIX, LIBRAX, LOMOTIL ["""DIPHENOXYLATE HCL,ATROPINE SULP."""], LYRICA, MOVICOL, NEXIAM, RINGERS LACTATE, RISPERDIL, SERENACE, SLOW K, SYNAP FORTE, TEMGESIC, TRAMACET, URISPAS, ZOFRAN
Adverse Events (AE) Preferred term	1. Influenza 2. Diarrhoea 3. Urinary tract infection 4. Anaemia 5. Cystitis 6. Diarrhoea 7. Colon cancer
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/NO 7. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 26JUN2010 (137) - 02JUL2010 (143) 2. 30JUL2010 (171) - 15AUG2010 (187) 3. 07SEP2010 (210) - 13SEP2010 (216) 4. 14SEP2010 (217) - 17SEP2010 (220) 5. 22SEP2010 (225) - 27SEP2010 (230) 6. 16FEB2011 (372) - --------- (.) 7. 17FEB2011 (373) - 17FEB2011 (373)
Duration of AE	1. 7 2. 17 3. 7 4. 4 5. 6 6. . 7. 1
Dose on AE onset	1. 20 mg 2. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370093017

Parameter	Value
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. F
	7. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. INSUFFICIENT FOLLOW-UP
	7. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-370093017[4)]	ANEMIA（PT：貧血） 治験担当医は、否定できると判断した。弊社は、リバーロキサバンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370113005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/SOUTH AFRICA/YES
Medical history	Haemorrhoid operation, Headache, Insomnia, Iron deficiency anaemia, Menopause, Radical hysterectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADVANTAN CREAM, AGIOLAX, AMIKACIN, AMITRIPTYLINE, BISACODYL/DULCOLAX, BROMAZEPAM, CEFEPIME/MAXIPIME, CLONIDINEHCI, DOLOROL, DULCOLAX/BISACODYL SUPP, ENOXAPARIN, FERRIMED DS, FLEET ENEMA, FLUTICASONE PROPIONATE, GENTAMYCIN, LEVOCETIRIZINE DIHYDROCHLORIDE, LEVOFLOXACIN/TAVANIC, LORAZEPAM/ATIVAN, METOCLOPROMIDE/MAXALON, MIDAZOLAM, MORPHINE, NORMACOL/STERCULIA, PANADOL, PANTOPRAZOLE, PIPERCILLIN/TAZOCIN, SCORBEX, SYNAP FORTE, TEICOPLANIN/TARGOCID, TRAMADOL/TRAMACET ["""""""""TRAMACET INGREDIENTS=TRAMADOL ,PARACETAMOL"""""""""], WARFARIN, ZOLPIDEM/STILNOX, ZOPIVANE
Adverse Events (AE) Preferred term	1. Pruritus generalised 2. Insomnia 3. Pneumonia 4. Sepsis 5. Pleural effusion 6. Constipation 7. Chronic sinusitis 8. Anxiety
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. SEVERE/NO/YES/YES 5. SEVERE/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 18MAY2008 (1) - 10JUN2008 (24) 2. 18MAY2008 (1) - --------- (.) 3. 19MAY2008 (2) - 30MAY2008 (13) 4. 19MAY2008 (2) - 30MAY2008 (13) 5. 19MAY2008 (2) - 30MAY2008 (13) 6. 02JUN2008 (16) - 13JUN2008 (27) 7. 07JUN2008 (21) - --------- (.) 8. 17JUN2008 (31) - --------- (.)
Duration of AE	1. 24 2. . 3. 12 4. 12 5. 12 6. 12 7. . 8. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113005

Parameter	Value
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	5. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. IMPROVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. IMPROVED
	8. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370113006/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/76/WHITE/SOUTH AFRICA/YES
Medical history	Chronic obstructive pulmonary disease, Insomnia, Parkinson's disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, CLOPAMON, CLOXACILLIN, COMBIVENT INH, CORDARONE X, DIGOXIN/LANOXIN, DOLOROL FORTE, FUROSEMIDE/LASIX, GEODON/ZIPRASIDONE, HYDRO-CORTISONE, INFLAMMIDE NOVOLIOZER, MADOPOR, MAGNESIUM SULPHATE, MIDAZOLAM, PANTOPRAZOLE, PEVARYL POWDER/ECONAZOLE BASE, PRAMIPEXOLE/PEXOLA, PREXUM/PERINDOPRIL, RIFAMPICIN/RIMACTANE, RIVOTRIL/CLONAZEPAM, ROCEPHINE/CEFTRIAXONE, SERETIDE INH, TARGOCID/TEICOPLANIN, TAZOCIN/PIPERACILLIN4GRAM+TAZOBACTAM0.50GRAM, TRAMACET, WARFARIN, ZOLPIDEM TARTRATE/IVEDAL
Adverse Events (AE) Preferred term	1. Sepsis 2. Atrial fibrillation 3. Delirium 4. Blood pressure increased 5. Intervertebral discitis 6. Intraspinal abscess 7. Gastrointestinal haemorrhage 8. Arthritis 9. Fungal skin infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/NO 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/YES/YES/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 20MAY2008 (1) - 31MAY2008 (12) 2. 21MAY2008 (2) - 21MAY2008 (2) 3. 21MAY2008 (2) - 09JUL2008 (51) 4. 22MAY2008 (3) - 25MAY2008 (6) 5. 23MAY2008 (4) - 30OCT2008 (164) 6. 23MAY2008 (4) - 30OCT2008 (164) 7. 25MAY2008 (6) - 26MAY2008 (7) 8. 02JUN2008 (14) - 30JUN2008 (42) 9. 19JUN2008 (31) - 05MAY2009 (351)
Duration of AE	1. 12 2. 1 3. 50 4. 4 5. 161

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113006

Parameter	Value
	6. 161
	7. 2
	8. 29
	9. 321
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113006

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370113014/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/66/WHITE/SOUTH AFRICA/YES
Medical history	Diabetes mellitus, Hypercholesterolaemia, Hypertension, Insomnia, Anaemia postoperative, Prostatectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ECOTRIN, GLUCOPHAGE/METFORMIN, HEXAZIDE, SIMVASTATIN, SINOPREN/LISINOPRIL, STILNOX, STILPANE [""""""""""PARACETAMOL, CODEINE PHOSPHATE, CAFFEINE ANHYDR., MEPROBAMATE""
Adverse Events (AE) Preferred term	1. Haematuria
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 05SEP2008 (3) - 09SEP2008 (7)
Duration of AE	1. 5
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113026

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370113026/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/SOUTH AFRICA/YES
Medical history	Cellulitis, Constipation, Depression, Hypercholesterolaemia, Hypertension, Insomnia, Hemiplegia, Osteoarthritis, Cerebrovascular accident
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPAVOR/ATORVASTATIN, AUGMENTIN SR/AMOXYCILLIN 1000MG,CLAVULANIC ACID 62.5MG, AUGMENTIN/AMOXYCILLIN 1000MG,CLAVULANIC ACID 200MG/20ML, BAYER ASPIRIN, COMBIVENT UDV, COZAAR COMP/LOSARTAN POTASSIUM 50MG,HYDROCHLOROTHIAZIDE 12.5MG, DORMONOCT/LOPRAZOLAM, LASIX RETARD/FUROSEMIDE, LASIX/FUROSEMIDE, LILLY FLUAXETINE, MAXIPIME/CEFEPIME, PERFALGAN, SENNOSIDE A,B 7.5MG/TAB, TRAMACET/TRAMADOL HCI 37.5MG,PARACETAMOL 325MG
Adverse Events (AE) Preferred term	1. Epistaxis 2. Bronchopneumonia 3. Diabetes mellitus
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. SEVERE/NO/YES/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 06JUN2009 (4) - 06JUN2009 (4) 2. 25JUN2009 (23) - 02JUL2009 (30) 3. 25JUN2009 (23) - --------- (.)
Duration of AE	1. 1 2. 8 3. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg
Dose status on AE onset	1. . 2. I 3. I
Action taken	1. OTHER 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 3. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113027

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370113027/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/37/WHITE/SOUTH AFRICA/YES
Medical history	Gout, Idiopathic thrombocytopenic purpura, Gastrooesophageal reflux disease, Splenectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, ENOXAPARIN, HIBERIX VACCINE, MENCEVAC VACCINE, PANTOLOC, PNEUMOVAC VACCINE, PREDNISONE, PULMISON(PREDNISONE), WARFARIN
Adverse Events (AE) Preferred term	1. Contusion 2. Soft tissue injury 3. Idiopathic thrombocytopenic purpura
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 20FEB2010 (236) - 09MAR2010 (253) 2. 07APR2010 (282) - 17APR2010 (292) 3. 08MAY2010 (313) - 14MAY2010 (319)
Duration of AE	1. 18 2. 11 3. 7
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113028

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370113028/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/86/WHITE/SOUTH AFRICA/YES
Medical history	Anaemia, Dementia, Depression, Cardiac failure, Hypercholesterolaemia, Hypertension, Cerebrovascular accident, Urinary tract infection, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALZAM(APRAZOLAM), AMOXICILLIN 1000MG,CLAVULANIC ACID 200MG, ASPAVOR(ATORVASTATIN), CIPROFLOXIN, COMBIVENT NEBS, DISPRIN CV(ASPIRIN), LASIX(FUROSEMIDE), PREXUM PLUS (PERINDOPRIL) [""""""""""PERINDOPRIL TERTBUTYLAMINE SALT,INDAPAMIDE""""""", SERLIFE(SERTRALINE HCI), SPIRONOLACTONE, XANOR SR(ALPRAZOLAM)
Adverse Events (AE) Preferred term	1. Pneumonia 2. Dehydration 3. Renal failure 4. Cardiac failure acute 5. Hypokalaemia 6. Oedema peripheral
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/NO/YES 3. SEVERE/NO/NO/YES 4. SEVERE/NO/NO/YES 5. SEVERE/NO/NO/YES 6. SEVERE/NO/NO/YES
Start/stop date of event with relative date	1. 11AUG2009 (42) - 12AUG2009 (43) 2. 11AUG2009 (42) - --------- (.) 3. 11AUG2009 (42) - --------- (.) 4. 11AUG2009 (42) - --------- (.) 5. 11AUG2009 (42) - --------- (.) 6. 11AUG2009 (42) - --------- (.)
Duration of AE	1. 2 2. . 3. . 4. . 5. . 6. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113028

Parameter	Value
	5. .
	6. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
Outcome of event	1. DEATH
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113031

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370113031/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/63/WHITE/SOUTH AFRICA/YES
Medical history	Oophorectomy bilateral, Cellulitis, Hypertension, Hypothyroidism, Road traffic accident, Nephrectomy, Hysterectomy, Rib fracture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC200(N-ACETYLCYSTEINE), ATERAX(HYDROXYZINE 2 HCl), BENILYN CO(DIPHENHYDRAMINE HCl 12.5MG,COD.PHOS10MG,AMMON.CHLOR125MG), CEFEPIME, CEFUROXIME, COMBIVENT, ENOXAPARIN, ESOMEPRAZOLE, EXPIGEN(SORIMACROGOL LAURATE 36.33MG,AMMON.CHLO.34MG/10ML), LEVOFLOXACIN, LORNOXICAM, NIFEDIPINE, SINUCLEAR(PARACET.325MG,PHENYLPROPANOLAMINE HCl 18MG), SYNAP FORTE, TELITHROMYCIN, THYROXINE, WARFARIN
Adverse Events (AE) Preferred term	1. Bronchitis 2. Urinary tract infection 3. Cystitis 4. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 07SEP2009 (21) - 19SEP2009 (33) 2. 11NOV2009 (86) - 16NOV2009 (91) 3. 16NOV2009 (91) - 19NOV2009 (94) 4. 29NOV2009 (104) - 04DEC2009 (109)
Duration of AE	1. 13 2. 6 3. 4 4. 6
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113031

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113035

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370113035/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/42/WHITE/SOUTH AFRICA/YES
Medical history	Drug hypersensitivity, Rhinitis allergic, Depression, Hypercholesterolaemia, Hypertension, Hypothyroidism, Cough
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADRENALINE TARTRATE, ALPRAZOLAM, ATROVENT NEBS, BACTRIM, BACTRIM DS, BESTUM(ADVANCED MULTISUPPLEMENT) [""""PROBIOTICS,MINERALS,ANTI-OXIDANTS,VITAMENS,, CANCIDIS(CASOFUNGIN), CANCIDIS(CASPOFUNGIN), CEFEPIME, CLOPAMON, CLOXACILLIN, CRESTOR(ROSUVASTATIN), DIFLUCAN(FLUCONAZOLE), DOPAMINE HCI, DORMICUM(MIDAZOLAM), DUPHALAC [LACTULOSE], ELTROXIN(THYROXINE), ENOXAPARIN, FLUOXETINE, FUROSEMIDE, HYDROCORTISONE, INTERFLORA, KLACID XL, LOPERAMIDE, LOSARTEN, MAINTELYTE 5%, MEROPENEM, MORPHINE SULPHATE, NACHL 0.9%, NEXIAM(ESOMEPRAZOLE), NEXOMIST(MOMETASONE FUROATE_, NOVARAPID(INSULINASPART), PANTOPRAZOLE, PARACETAMOL, PROBIFLORA, PULMISON, PYRIDOXINE, RAMIPRIL, RIDAQ(HYDROCHLOROTHIAZIDE), RIFAFOUR E200, SIMVASTATIN, STOCRIN(EFAVIRENZ), TAVANIC(LEVOFLOXACIN), TAZOCIN(PIPERACILLIN 4GR,TAZOBACTAM0.5MG), TELITHROMYCIN, TRUVADA(EMITRICITABINE 200MG,TENOFOVIR 300MG), VIT K, WARFARIN, XYZAL(LEVOCETIRIZINE DIHYDROCHLORIDE), ZYVOXID(LINEZOLIDE)
Adverse Events (AE) Preferred term	1. Myalgia 2. Pneumonia 3. Pneumonia 4. Pneumonia primary atypical 5. HIV test positive 6. International normalised ratio increased 7. Depression 8. Rhinitis allergic 9. Generalised oedema
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. SEVERE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JUL2010 (.) - 25OCT2010 (230) 2. 16MAR2010 (7) - 28MAR2010 (19) 3. 29MAR2010 (20) - 02APR2010 (24) 4. 04MAY2010 (56) - 03JUN2010 (86) 5. 04MAY2010 (56) - --------- (.) 6. 12MAY2010 (64) - 12MAY2010 (64) 7. 22MAY2010 (74) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113035

Parameter	Value
	8. 26JUL2010 (139) - --------- (.)
	9. 04DEC2010 (270) - 22FEB2011 (350)
Duration of AE	1. .
	2. 13
	3. 5
	4. 31
	5. .
	6. 1
	7. .
	8. .
	9. 81
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
Outcome of event	1. RESOLVED
	2. WORSENED
	3. RESOLVED
	4. RESOLVED
	5. IMPROVED
	6. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113035

Parameter	Value
	7. IMPROVED
	8. IMPROVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113040

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370113040/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/48/WHITE/SOUTH AFRICA/YES
Medical history	Insomnia, Road traffic accident, Skin graft, Skin graft, Debridement, Debridement
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADCO-AMOCLAV(AMOXICILLIN 875MG,CLAVULANIC ACID 125MG), ARCOXIA, AUGMENTIN SR 2000, BISOLVIN LINCTUS, BISOLVON LINCTUS, BUPRENORPHINE(TEMGESIC), CEFOZOLIN, CORENZA PARA, CORENZA PARA C(PARACET.650MG,PHENYLEPHR.HCI 10MG,VIT C 250MG), INTERFLORA, LEVOFLOXACIN, NACHL 0.9%, NORMISON, PARACETAMOL, PROSPAN, RAYSON(PARECOXIB), ROCHEPINE, SYNAP FORTE, TAMIFLU(OSELTAMIVIR, TAVANIC(LEVOFLOXIN), TRAMACET, ZINNAT, ZINNAT(CEFUROXIME)
Adverse Events (AE) Preferred term	1. Bronchitis 2. Pleural effusion 3. Pleural effusion 4. Pleural effusion 5. Bronchitis 6. Influenza 7. Aphthous stomatitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 13OCT2010 (14) - 19OCT2010 (20) 2. 30OCT2010 (31) - 06NOV2010 (38) 3. 06NOV2010 (38) - 12DEC2010 (74) 4. 13DEC2010 (75) - 16DEC2010 (78) 5. 07MAR2011 (159) - 17MAR2011 (169) 6. 24JUN2011 (268) - 15JUL2011 (289) 7. 05SEP2011 (341) - --------- (.)
Duration of AE	1. 7 2. 8 3. 37 4. 4 5. 11 6. 22 7. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113040

Parameter	Value
	7. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. I
	5. .
	6. .
	7. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	3. STUDY DRUG DISCONTINUED AND RESTARTED
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
Outcome of event	1. RESOLVED
	2. IMPROVED
	3. WORSENED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113043

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370113043/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/70/WHITE/SOUTH AFRICA/YES
Medical history	Hypercholesterolaemia, Hypertension, Insomnia, Pyelonephritis, Iodine allergy, Myocardial ischaemia, Haemoglobin decreased, Urostomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CEFUROXIME, CIPROFLOXACIN XR, CIPROFLOXXACIN XR, CLEXANE, ENOXAPARIN, ETILEFRINE(EFFORTIL), FLUZOL, FUROSEMIDE, GENPAIN ["IBUBRUFEN, PARACETAMOL, COD PHOS"], GRANISETRON(KYTRIL), HYDROXYZINE(ATERAX), INTERFLORA, LORNOXICAM(XEFO), MACRODANTIN, MAINTELYTE 5%, MAXALON, MAXIPIME, NORMISON, ONDANSETRON, PERFALGEN, PETHIDINE, PROBIFLORA, PROMETHAZINE, SIMVASTATIN, TAMSULOSIN, TRAMACET, WARFARIN, ZOLPIDEM TARTRATE, ZOLPIDEM(STILNOX)
Adverse Events (AE) Preferred term	1. Insomnia 2. Urinary tract infection 3. Urinary tract infection 4. Urethral disorder 5. Urinary tract infection 6. Insomnia 7. Pruritus 8. Hypotension 9. Umbilical hernia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 26OCT2010 (3) - 27OCT2010 (4) 2. 15JAN2011 (84) - 20JAN2011 (89) 3. 30JAN2011 (99) - 10FEB2011 (110) 4. 22FEB2011 (122) - 22FEB2011 (122) 5. 04MAR2011 (132) - 09MAR2011 (137) 6. 04MAR2011 (132) - 06MAR2011 (134) 7. 05MAR2011 (133) - 06MAR2011 (134) 8. 07MAR2011 (135) - 07MAR2011 (135) 9. 09MAR2011 (137) - --------- (.)
Duration of AE	1. 2 2. 6 3. 12 4. 1 5. 6 6. 3

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113043

Parameter	Value
	7. 2
	8. 1
	9. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113043

Parameter	Value
	9. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113044

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370113044/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/79/WHITE/SOUTH AFRICA/YES
Medical history	Cerebrovascular accident, Haemoglobin decreased, Hypertension, Drug hypersensitivity, Knee arthroplasty
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMIKACIN SULPH., CIPLOX(CIPROFLOXACIN), COLCHICINE, ERTAPENEM, MYPRADOL, NA CHL 0.9%, PANTOPRAZOLE, PARACETAMOL, RINGERS LACTATE, SYNAP FORTE, URIZONE, VOLTAREN JEL
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Pyelonephritis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 15NOV2010 (23) - 24NOV2010 (32) 2. 01DEC2010 (39) - 05DEC2010 (43)
Duration of AE	1. 10 2. 5
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113045

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370113045/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/33/WHITE/SOUTH AFRICA/YES
Medical history	Drug hypersensitivity, Headache, Hypercholesterolaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMITRIPTYLINE, AMOXYCILLIN(ZOXIL), DF 118, ETORICOXIB, MYPRADOL, NORFLEX CO(ORPHENADRINE CITR.35MG,PARACET 450MG), ONDANSETRON, PERFALGAN, PROPAIN FORTE ["PARACET. COD.PHOS., DIPHENHYDR.HCI, CAFFANHYDR., PHENOBARB."], ROSUVASTIN(CRESTOR), TRAMACET
Adverse Events (AE) Preferred term	1. Headache 2. Dyspnoea 3. Liver function test abnormal 4. Toothache
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/YES/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. -----2011 (.) - 09SEP2011 (218) 2. 08FEB2011 (5) - 10FEB2011 (7) 3. 09FEB2011 (6) - 01MAR2011 (26) 4. 04AUG2011 (182) - 04AUG2011 (182)
Duration of AE	1. . 2. 3 3. 21 4. 1
Dose on AE onset	1. 2. 15 mg 3. 15 mg 4. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. .
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. OTHER 3. NONE 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370113045

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370153012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370153012/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/26/WHITE/SOUTH AFRICA/YES
Medical history	
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DEPO PROVERA, STOPAYNE [INGREDIENTS NOT KNOWN AS PAINSTOP WAS PURCHASED AT A PRIVATE PHARMACY
Adverse Events (AE) Preferred term	1. Haemoptysis 2. Headache 3. Tinnitus 4. Haemoptysis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 03FEB2009 (6) - 03FEB2009 (6) 2. 08FEB2009 (11) - 29APR2009 (91) 3. 08FEB2009 (11) - 29APR2009 (91) 4. 29APR2009 (91) - 29APR2009 (91)
Duration of AE	1. 1 2. 81 3. 81 4. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. NONE 2. NONE 3. NONE 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370153012

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-370153012[4)]	HAEMOPTYSIS（PT：喀血） 治験担当医は、因果関係は否定できると判断した。弊社は、リバーロキサバンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370153016

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370153016/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/68/ASIAN/SOUTH AFRICA/YES
Medical history	Anaemia, Asthma, Cholecystitis, Diabetes mellitus, Hiatus hernia, Lymphadenopathy, Rheumatoid arthritis, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASTHAVENT, AUGMENTIN, BEROTEC, BUDEFLAM, DIAMICRON, ENOXAPARIN, FOLATE, LOSEC, MAXOLON, METHOTREXATE, MORPHINE, PANADO, SPECTRAPAIN, WARFARIN
Adverse Events (AE) Preferred term	1. Cholelithiasis 2. Rectal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 12AUG2009 (35) - --------- (.) 2. 18AUG2009 (41) - 18AUG2009 (41)
Duration of AE	1. . 2. 1
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE
Outcome of event	1. UNCHANGED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-370153016[4)]	RECTAL BLEED（PT：直腸出血） 治験担当医は、ワルファリンとの因果関係を否定できると判断した。弊社は、ワルファリンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370153017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370153017/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/66/BLACK/SOUTH AFRICA/YES
Medical history	Cardiac failure chronic, Cor pulmonale, Cough, HIV test positive, Hypertension, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	3TC, ALDACTONE [SPIRONOLACTONE], BACTRIM, D4T, EFAVIRENZ, ENOXAPARIN, LASIX, WARFARIN
Adverse Events (AE) Preferred term	1. Epistaxis 2. Rectal haemorrhage 3. Sepsis 4. Blood alkaline phosphatase increased 5. Gamma-glutamyltransferase increased 6. Aspartate aminotransferase increased 7. Blood urea increased 8. Blood creatinine increased 9. Pericardial effusion 10. Lymphadenopathy 11. Hepatic encephalopathy 12. International normalised ratio increased 13. Lobar pneumonia 14. Tuberculosis
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. SEVERE/YES/YES/YES 3. SEVERE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/NO 10. MODERATE/NO/NO/NO 11. MODERATE/NO/NO/NO 12. MODERATE/YES/NO/NO 13. SEVERE/NO/YES/NO 14. SEVERE/NO/NO/NO
Start/stop date of event with relative date	1. 12NOV2009 (83) - 12NOV2009 (83) 2. 12NOV2009 (83) - 13NOV2009 (84) 3. 12NOV2009 (83) - --------- (.) 4. 12NOV2009 (83) - --------- (.) 5. 12NOV2009 (83) - --------- (.) 6. 12NOV2009 (83) - --------- (.) 7. 12NOV2009 (83) - --------- (.) 8. 12NOV2009 (83) - --------- (.) 9. 16NOV2009 (87) - --------- (.) 10. 16NOV2009 (87) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370153017

Parameter	Value
	11. 16NOV2009 (87) - --------- (.)
	12. 19NOV2009 (90) - 24NOV2009 (95)
	13. 20NOV2009 (91) - 30NOV2009 (101)
	14. 21NOV2009 (92) - --------- (.)
Duration of AE	1. 1
	2. 2
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. 6
	13. 11
	14. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370153017

Parameter	Value
	13.
	14.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED
	7. UNCHANGED
	8. UNCHANGED
	9. UNCHANGED
	10. UNCHANGED
	11. UNCHANGED
	12. RESOLVED
	13. DEATH
	14. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-370153017[1),1),1),1)]	EPISTAXIS（PT：鼻出血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、投与中止約 11 週間後の発現であり、時間的関連性がないため、エノキサパリンとの因果関係は否定できると考える。 LOBAR PNEUMONIA（PT：大葉性肺炎） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、投与中止約 12 週間後の発現であり、時間的関連性がないため、エノキサパリンとの因果関係は否定できると考える。 RECTAL BLEEDING（PT：直腸出血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、投与中止約 11 週間後の発現であり、時間的関連性がないため、エノキサパリンとの因果関係は否定できると考える。 SEPSIS（PT：敗血症） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、合併症（HIV 感染）及び免疫不全によるものであり、エノキサパリン及びワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370153018

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370153018/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/59/BLACK/SOUTH AFRICA/YES
Medical history	Hypertension, Lipoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, BRUFEN, CLEXANE, CLOXACILLIN, COVERSYL, DOXYFENE, HYDROCHLOROTHIAZIDE, PANADO, TRAMAL, WARFAIN
Adverse Events (AE) Preferred term	1. Hypertension 2. Liposarcoma 3. Sepsis 4. Anaemia 5. Platelet count increased
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 09JAN2010 (66) - 21JAN2010 (78) 2. 20JAN2010 (77) - 20JAN2010 (77) 3. 28JAN2010 (85) - 06MAY2010 (183) 4. 02FEB2010 (90) - 09FEB2010 (97) 5. 02FEB2010 (90) - --------- (.)
Duration of AE	1. 13 2. 1 3. 99 4. 8 5. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. I 3. I 4. . 5. .
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 3. REMEDIAL DRUG THERAPY,OTHER 4. OTHER 5. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370153018

Parameter	Value
	4. RESOLVED
	5. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370153019

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370153019/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/69/BLACK/SOUTH AFRICA/YES
Medical history	Fall, Haemorrhoids, Deafness, Obesity, Postmenopause, Chest injury
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXYL, AUGMENTIN, CODEINE PHOSPHATE, DOXYPHENE (DEXTROPROPOXYLENE HCL 65MG, PARACETAMOL 250MG), ENOXAPARIN, FACTOR IX, FLUCONAZOLE, LACTULOSE, LASIX, MAXALON, PANADO, SENEKOT(SENNOSIDES B), SPECTRAPAIN, TAZOCIN, WARFARIN
Adverse Events (AE) Preferred term	1. Vomiting 2. International normalised ratio increased 3. Urinary tract infection 4. Haemorrhoids 5. Gastrointestinal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 18NOV2009 (2) - 18NOV2009 (2) 2. 23NOV2009 (7) - 01DEC2009 (15) 3. 30NOV2009 (14) - 02DEC2009 (16) 4. 30NOV2009 (14) - --------- (.) 5. 16DEC2009 (30) - 26DEC2009 (40)
Duration of AE	1. 1 2. 9 3. 3 4. . 5. 11
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. NONE 4. NONE 5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370153019

Parameter	Value
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-370153019[3),1),1)]	DECREASED HAEMOGLOBIN 2.8 REQUIRING BLOOD TRANSFUSION（PT：ヘモグロビン減少） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、ワルファリンの過量投与による出血に起因したと考え、ワルファリンとの因果関係は否定できないと考える。 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリン投与終了約 3 週間後の発現であり、時間的関連がないため、エノキサパリンとの因果関係は否定できると考える。 GIT BLEEDING（PT：胃腸出血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリン投与終了約 3 週間後の発現であり、時間的関連性がないため、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370153022

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/370153022/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/54/UNCODABLE/SOUTH AFRICA/YES
Medical history	Alanine aminotransferase increased, Aspartate aminotransferase increased, Hypertension, Hypothyroidism, Hysterectomy, Oedema peripheral, Drug hypersensitivity, Intervertebral disc protrusion, Vulvovaginal dryness, Gamma-glutamyltransferase increased
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADALAL XL, ASPIRIN, CARVIDELOL, ELTROXIN, LASIX, LOSEC, PERINDOPRIL, PREMARIN, SLOW K, TRYPTANOL, WARFARIN, ZOCOR
Adverse Events (AE) Preferred term	1. Acute myocardial infarction 2. Acute myocardial infarction 3. Blood amylase increased 4. Cor pulmonale
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 21NOV2010 (32) - 02DEC2010 (43) 2. 03DEC2010 (44) - --------- (.) 3. 21APR2011 (183) - --------- (.) 4. 19JUL2011 (272) - 23JUL2011 (276)
Duration of AE	1. 12 2. . 3. . 4. 5
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. I 2. I 3. . 4. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. NONE 3. NONE 4. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED 2. IMPROVED 3. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 370153022

Parameter	Value
	4. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/26/WHITE/CZECH REPUBLIC/YES
Medical history	Asthenia, Bone pain, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BIOPAROX INH. SOL. PSS, BIOPAROX SOL., CELASKON TBL., CLEXANE, DEGAN, DORMICUM, ENOXAPARIN, GLYVENOL, MUCOSOLVAN, MUCOSOLVAN SOL, MUSCORIL AMP., OLYNTH 0,1% NAS. SPR. SOL., OXYTOCIN, PARALEN EXTRA 500/75MG, REGULON [DESOGESTREL 150 UG+ETHINYLESTRADIOL 30 UG], VOLTAREN EMULGEL DRM. GEL, WARFARIN, ZINNAT, ZODAC
Adverse Events (AE) Preferred term	1. Nasopharyngitis 2. Arthralgia 3. Nasopharyngitis 4. Back pain 5. Pregnancy 6. Musculoskeletal chest pain 7. Abortion induced 8. Back pain 9. Nasopharyngitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/YES/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 05FEB2008 (113) - 12FEB2008 (120) 2. 21MAR2008 (158) - 30MAR2008 (167) 3. 25MAR2008 (162) - 30MAR2008 (167) 4. 15APR2008 (183) - 15APR2008 (183) 5. 18APR2008 (186) - 17JUN2008 (246) 6. 20MAY2008 (218) - 05JUN2008 (234) 7. 17JUN2008 (246) - 17JUN2008 (246) 8. 20JUN2008 (249) - 20JUN2008 (249) 9. 11AUG2008 (301) - 12AUG2008 (302)
Duration of AE	1. 8 2. 10 3. 6 4. 1 5. 61 6. 17 7. 1 8. 1 9. 2

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043003

Parameter	Value
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. OTHER
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043003

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-380043003[1)]	THERAPEUTIC ABORTION（PT：人工流産） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、投与中の妊娠はエノキサパリン投与時の禁忌症であるため、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043004/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/74/WHITE/CZECH REPUBLIC/YES
Medical history	Back pain, Diverticulum intestinal, Hypertension, Menopause, Osteoporosis, Transient ischaemic attack, Renal failure chronic, Pneumonia, Bone fissure
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT SOL., CEFOTAXIME AMP., CLARITHROMYCIN, CLEXANE, ERDOMED, MUCOSOLVAN SOL., NEUROL TBL. [ALPRAZOLAM], PRESTARIUM, TRAMAL RET.
Adverse Events (AE) Preferred term	1. Hydronephrosis 2. Renal cyst 3. Chronic obstructive pulmonary disease 4. Urinary tract infection 5. Diarrhoea 6. Nasopharyngitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/NO 2. MILD/NO/NO/NO 3. MODERATE/NO/NO/NO 4. MODERATE/NO/YES/NO 5. MILD/NO/NO/NO 6. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 30OCT2007 (15) - --------- (.) 2. 30OCT2007 (15) - --------- (.) 3. 14NOV2007 (30) - --------- (.) 4. 19NOV2007 (35) - 05DEC2007 (51) 5. 21NOV2007 (37) - 22NOV2007 (38) 6. 24DEC2007 (70) - 12JAN2008 (89)
Duration of AE	1. . 2. . 3. . 4. 17 5. 2 6. 20
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 15 mg 6. 15 mg
Dose status on AE onset	1. F 2. F 3. F 4. F 5. F 6. F
Action taken	1. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043004

Parameter	Value
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043005/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/39/WHITE/CZECH REPUBLIC/YES
Medical history	Deep vein thrombosis, Limb injury
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANALERGIN, AUGMENTIN, BETASERC, DALACIN C, DETRALEX, DOLMINA CRM [DICLOFENAC SODIUM], DORSIFLEX, ECOBEC, ERDOMED, HYLAK FORTE SOL., LEXAURIN, LIOTON GEL, MAGNESIUM LACTICUM, NEUROL [NEUROL - ALPRAZOLAM], NOVALGIN, RIVOTRIL, STOPTUSSIN GTT [BUTAMIRATE + GUAIFENESIN], SYMBICORT 400/12
Adverse Events (AE) Preferred term	1. Abscess soft tissue 2. Somatoform disorder 3. Diarrhoea 4. Anxiety 5. Insomnia 6. Sympathetic posterior cervical syndrome 7. Hypoacusis 8. Latent tetany 9. Dermatitis 10. Asthma
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 22NOV2007 (29) - 26NOV2007 (33) 2. 27NOV2007 (34) - 27NOV2007 (34) 3. 27NOV2007 (34) - 31DEC2007 (68) 4. 27NOV2007 (34) - 27NOV2007 (34) 5. 27NOV2007 (34) - 27NOV2007 (34) 6. 30NOV2007 (37) - 18FEB2008 (117) 7. 06DEC2007 (43) - --------- (.) 8. 01FEB2008 (100) - --------- (.) 9. 17FEB2008 (116) - 05MAY2008 (194) 10. 20JUN2008 (240) - --------- (.)
Duration of AE	1. 5 2. 1 3. 35 4. 1 5. 1 6. 81

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043005

Parameter	Value
	7. .
	8. .
	9. 79
	10. .
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY,OTHER
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. OTHER
	10. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. IMPROVED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043005

Parameter	Value
	10. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043009/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/74/WHITE/CZECH REPUBLIC/YES
Medical history	Appendicectomy, Osteoarthritis, Cholecystectomy, Hypercholesterolaemia, Hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACCUZIDE 20, BERLIPRIL, CARBO MEDICINALIS, CAVAL FILTER IMPLANTED, CLEXANE, DEGAN, DICYNONE, DIPIDOLOR, DOLSIN, ENOXAPARIN, GLYVENOL, HYLAK FORTE SOL., HYPNOMIDATE, LANZUL, LUSOPRESS, NOVALGIN, OFLOXIN, OPHTHALMO-SEPTONEX GTT, PRESTARIUM NEO FORTE [PERINDOPRILUM ARGININUM 10MG, HYPERTENSION], SUCCINYLCHOLINJODID, SUFENTA, TENAXUM, TRACRIUM, VASOCARDIN, WARFARIN
Adverse Events (AE) Preferred term	1. Renal neoplasm 2. Nephrolithiasis 3. Ileus paralytic 4. Diarrhoea 5. Anaemia 6. Nausea 7. Nasopharyngitis 8. Back pain 9. Conjunctivitis 10. Gastroenteritis 11. Conjunctival haemorrhage 12. Vertigo
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/YES/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/YES/NO/YES 12. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 16NOV2007 (3) - 27DEC2007 (44) 2. 19NOV2007 (6) - --------- (.) 3. 06DEC2007 (23) - 06DEC2007 (23) 4. 06DEC2007 (23) - 10DEC2007 (27) 5. 07DEC2007 (24) - 10APR2008 (149) 6. 01JAN2008 (49) - 23JAN2008 (71) 7. 04JAN2008 (52) - 09JAN2008 (57) 8. 09JAN2008 (57) - 10JAN2008 (58) 9. 25JUN2008 (225) - 02JUL2008 (232) 10. 20JUL2008 (250) - 26JUL2008 (256) 11. 29AUG2008 (290) - 07SEP2008 (299)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043009

Parameter	Value
	12. 13SEP2008 (305) - 20SEP2008 (312)
Duration of AE	1. 42
	2. .
	3. 1
	4. 5
	5. 126
	6. 23
	7. 6
	8. 2
	9. 8
	10. 7
	11. 10
	12. 8
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. OTHER
	6. REMEDIAL DRUG THERAPY
	7. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043009

Parameter	Value
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043011/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/52/WHITE/CZECH REPUBLIC/YES
Medical history	Aortic aneurysm, Carotid endarterectomy, Bronchitis chronic, Coronary artery disease, Diabetes mellitus, Hypertension, Myocardial infarction, Nephrolithiasis, Transient ischaemic attack, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AGAPURIN RETARD, AGEN, AMBROBENE, ANOPYRIN, ATARALGIN, BISEPTOL, CODEIN, DALACIN [INGREDIENT IS CLINDAMYCIN], DEGAN, DOXYBENE, ERDOMED, EUPHYLLIN CR N, FRAXIPARINE, GLUCOSE, HUMULIN N, IBALGIN, KORYLAN TBL, NOVALGIN, PARALEN, PARALEN PLUS, PLAVIX, PREDNISON FORTE, QUAMATEL, RAMIL, SECTRAL, TULIP [ATORVASTATIN CALCIUM], ZODAC
Adverse Events (AE) Preferred term	1. Toothache 2. Nasopharyngitis 3. Aortic aneurysm 4. Angina unstable 5. Paraesthesia 6. Paraesthesia 7. Musculoskeletal pain 8. Alanine aminotransferase increased 9. Chronic obstructive pulmonary disease 10. Dental caries 11. Bone abscess 12. Gingivitis 13. Shock hypoglycaemic 14. Aortic aneurysm 15. Decubitus ulcer 16. Nasopharyngitis 17. Hypotension
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/YES/YES 14. SEVERE/NO/YES/YES 15. MODERATE/NO/NO/YES 16. MILD/NO/NO/YES 17. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043011

Parameter	Value
Start/stop date of event with relative date	1. 26NOV2007 (6) - 17JAN2008 (58) 2. 26DEC2007 (36) - 03JAN2008 (44) 3. 06FEB2008 (78) - 07SEP2008 (292) 4. 11FEB2008 (83) - 15FEB2008 (87) 5. 15FEB2008 (87) - --------- (.) 6. 01MAR2008 (102) - 10MAR2008 (111) 7. 16MAR2008 (117) - 18MAR2008 (119) 8. 21MAR2008 (122) - 01OCT2008 (316) 9. 14APR2008 (146) - 26MAY2008 (188) 10. 24JUN2008 (217) - 24JUN2008 (217) 11. 24JUN2008 (217) - 24JUN2008 (217) 12. 24JUN2008 (217) - --------- (.) 13. 12AUG2008 (266) - 13AUG2008 (267) 14. 08SEP2008 (293) - 24SEP2008 (309) 15. 10SEP2008 (295) - 20OCT2008 (335) 16. 10OCT2008 (325) - 14NOV2008 (360) 17. 28OCT2008 (343) - 28OCT2008 (343)
Duration of AE	1. 53 2. 9 3. 215 4. 5 5. . 6. 10 7. 3 8. 195 9. 43 10. 1 11. 1 12. . 13. 2 14. 17 15. 41 16. 36 17. 1
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg 8. 20 mg 9. 20 mg 10. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043011

Parameter	Value
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. I
	16. .
	17. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. OTHER
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. OTHER
	11. OTHER
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY,OTHER
	14. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	15. OTHER
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043011

Parameter	Value
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043030

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043030/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/45/WHITE/CZECH REPUBLIC/YES
Medical history	Cholecystectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, COLDREX DRINK [PARACETAMOLUM750MG,PHENYLEPHRINI HYDROCHLORIDUM10 MG,ACIDUM ASCOR, COLDREX TBL [INGREDIENTS: PARACETAMOLUM 750 MG, PHENYLEPHRINI HYDROCHLORIDUM 10, COLDREX [INGREDIENTS: PARACETAMOLUM 750 MG, PHENYLEPHRINI HYDROCHLORIDUM 10 MG,, DETRALEX, ENOXAPARIN, FORMANO, WARFARIN, ZODAC
Adverse Events (AE) Preferred term	1. Rash maculo-papular 2. Nasopharyngitis 3. Nasopharyngitis 4. Metrorrhagia 5. Nasopharyngitis 6. Nasopharyngitis 7. Uterine polyp 8. Uterine leiomyoma 9. Haemorrhagic anaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/YES/YES 8. MODERATE/NO/YES/YES 9. MODERATE/YES/NO/NO
Start/stop date of event with relative date	1. 01APR2008 (10) - 11APR2008 (20) 2. 14APR2008 (23) - 17APR2008 (26) 3. 12MAY2008 (51) - 16MAY2008 (55) 4. 21JUN2008 (91) - 27MAR2009 (370) 5. 16SEP2008 (178) - 24SEP2008 (186) 6. 03NOV2008 (226) - 06NOV2008 (229) 7. 11DEC2008 (264) - 17DEC2008 (270) 8. 04MAR2009 (347) - 02APR2009 (376) 9. 27MAR2009 (370) - 15APR2009 (389)
Duration of AE	1. 11 2. 4 3. 5 4. 280 5. 9 6. 4 7. 7 8. 30

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043030

Parameter	Value
	9. 20
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. DOSE OF STUDY DRUG REDUCED
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	8. OTHER
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043030

Parameter	Value
	9. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043061

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043061/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/CZECH REPUBLIC/YES
Medical history	Arthralgia, Back pain, Coronary artery disease, Dyspnoea, Hypertension, Obesity, Parkinsonism, Thrombophlebitis superficial, Syncope, Varicose vein, Postmenopause, Stress urinary incontinence
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	A-GEN [AMPLODIPINE], AKTIFERRIN, ALFUZOSIN, ATROVENT N, BISOPROLOL, BROMHEXIN 8 GTT., CARBOTOX, CLEXANE, CURAM, DETRALEX, ENOXAPARIN, EUPHYLLIN [THEOPHYLLINE], HELICID, HYLAK FORTE, LOPERON, LOZAP [LOSARTAN POTASSIUM], NOLICIN, PHOSPHATES SOLUTION, PRESTARIUM NEO, UBRETID, VINPOCETINE COVEX, WARFARIN
Adverse Events (AE) Preferred term	1. Diarrhoea 2. Intestinal haemorrhage 3. Disbacteriosis 4. Liver function test abnormal 5. Gastrointestinal tract adenoma 6. Intestinal haemorrhage 7. Anaemia 8. Ischaemic stroke 9. Hypoacusis 10. Vertigo 11. Bronchitis 12. Hypertension 13. Urinary tract infection 14. Bronchitis chronic 15. Pulmonary hypertension
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. SEVERE/YES/YES/YES 7. MODERATE/YES/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/YES/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/YES 14. MODERATE/NO/NO/YES 15. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 10SEP2008 (7) - 14SEP2008 (11) 2. 14SEP2008 (11) - 15SEP2008 (12) 3. 15SEP2008 (12) - 18SEP2008 (15) 4. 15SEP2008 (12) - 18OCT2008 (45) 5. 24OCT2008 (51) - 24OCT2008 (51)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043061

Parameter	Value
	6. 25OCT2008 (52) - 26OCT2008 (53)
	7. 26OCT2008 (53) - 19NOV2008 (77)
	8. 11NOV2008 (69) - --------- (.)
	9. 11NOV2008 (69) - --------- (.)
	10. 29NOV2008 (87) - 30NOV2008 (88)
	11. 06DEC2008 (94) - 12DEC2008 (100)
	12. 03MAR2009 (181) - --------- (.)
	13. 26MAY2009 (265) - 04JUN2009 (274)
	14. 19AUG2009 (350) - --------- (.)
	15. 19AUG2009 (350) - --------- (.)
Duration of AE	1. 5
	2. 2
	3. 4
	4. 34
	5. 1
	6. 2
	7. 25
	8. .
	9. .
	10. 2
	11. 7
	12. .
	13. 10
	14. .
	15. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Dose status on AE onset	1.
	2.
	3.
	4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043061

Parameter	Value
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	7. NONE
	8. OTHER
	9. NONE
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED
	13. RESOLVED
	14. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043061

Parameter	Value
	15. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043064

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043064/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/82/WHITE/CZECH REPUBLIC/YES
Medical history	Arteriosclerosis, Bronchopneumonia, Cholecystectomy, Back pain, Bronchitis chronic, Hip arthroplasty, Hypertension, Bundle branch block left, Mitral valve incompetence, Pancreatitis chronic, Polyarthritis, Rib fracture, Hypothyroidism, Left ventricular dysfunction, Renal failure chronic, Postmenopause, Biliary dilatation, Lipofibroma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT, BETASERC, CEFOTAXIME, DEGAN, DETRALEX, DIACORDIN RETARD, DICLOFENAC RETARD, ECOBEC, EUTHYROX, GLYCERIN SUPPOSITORY, HELICID, LACTULOSE, LORADUR, LOZAP [LOSARTAN], NO-SPA, OFLOXIN, PARALEN, PERITOL, PRESTARIUM NEO, PYRIDOXIN, QUAMATEL, TORECAN, TRALGIT RETARD, VENDAL, ZINNAT
Adverse Events (AE) Preferred term	1. Mobility decreased 2. Venous insufficiency 3. Nasopharyngitis 4. Biliary colic 5. Cholangitis 6. Constipation 7. Papilla of Vater stenosis 8. Diverticulum intestinal 9. Decreased appetite 10. Urinary tract infection 11. Hypotension 12. Dyspepsia 13. Constipation 14. Dyspepsia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MODERATE/NO/YES/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --AUG2009 (.) - --------- (.) 2. 15JAN2009 (101) - --------- (.) 3. 26JAN2009 (112) - 04FEB2009 (121) 4. 04MAR2009 (149) - 10MAR2009 (155) 5. 05MAR2009 (150) - 19MAR2009 (164)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043064

Parameter	Value
	6. 06MAR2009 (151) - 06MAR2009 (151)
	7. 10MAR2009 (155) - 10MAR2009 (155)
	8. 10MAR2009 (155) - 10MAR2009 (155)
	9. 13MAR2009 (158) - 11APR2009 (187)
	10. 03APR2009 (179) - 13APR2009 (189)
	11. 18MAY2009 (224) - 31MAY2009 (237)
	12. 01JUL2009 (268) - 09JUL2009 (276)
	13. 06JUL2009 (273) - --------- (.)
	14. 08AUG2009 (306) - 12AUG2009 (310)
Duration of AE	1. .
	2. .
	3. 10
	4. 7
	5. 15
	6. 1
	7. 1
	8. 1
	9. 30
	10. 11
	11. 14
	12. 9
	13. .
	14. 5
Dose on AE onset	1.
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. I
	6. I
	7. I

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043064

Parameter	Value
	8. I
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	8. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. REMEDIAL DRUG THERAPY,OTHER
	13. REMEDIAL DRUG THERAPY
	14. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. IMPROVED
	14. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043084

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043084/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/57/WHITE/CZECH REPUBLIC/YES
Medical history	Drug hypersensitivity, Multiple sclerosis, Hepatitis A, Hypertension, Obesity, Renal hypertrophy, Hyperthyroidism, Traumatic ulcer, Urinary tract infection, Postmenopause, Hypertonic bladder, Lipid metabolism disorder, Cystitis noninfective, Venous insufficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	APO-IBUPROFEN, CARBIMAZOL, CLEXANE, ESSENTIALE FORTE N, GLYVENOL, HELICID, KALIUM CHLORATUM, LOZAP H, LOZAP [LOSARTAN KALICUM], MAGNESII LACTICI, METHOTREXAT, NEUROBENE, NOVALGIN, PREDNISON
Adverse Events (AE) Preferred term	1. Liver function test abnormal 2. Autoimmune thyroiditis 3. Folate deficiency 4. Gene mutation 5. Vitamin B12 deficiency
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 09MAR2009 (35) - 06APR2009 (63) 2. 13MAR2009 (39) - --------- (.) 3. 12MAY2009 (99) - --------- (.) 4. 12MAY2009 (99) - --------- (.) 5. 24NOV2009 (295) - --------- (.)
Duration of AE	1. 29 2. . 3. . 4. . 5. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. NONE 3. NONE 4. NONE 5. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043084

Parameter	Value
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043099

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043099/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/53/WHITE/CZECH REPUBLIC/YES
Medical history	Hypercholesterolaemia, Hypertension, Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN TBL., DOXYBENE TBL., ENOXAPARIN, ESSENTIALE F CPS., GLYVENOL CPS., RAMIL TBL., TORVACARD TBL., WARFARIN
Adverse Events (AE) Preferred term	1. Iliac artery occlusion 2. Factor V Leiden mutation 3. Nasopharyngitis 4. Liver function test abnormal 5. Liver function test abnormal 6. Hepatic steatosis 7. Aortic aneurysm
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/YES/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 10JUN2009 (23) - --------- (.) 2. 14SEP2009 (119) - --------- (.) 3. 08MAR2010 (294) - 14MAR2010 (300) 4. 19MAR2010 (305) - 29MAR2010 (315) 5. 29MAR2010 (315) - 06APR2010 (323) 6. 29MAR2010 (315) - --------- (.) 7. 29MAR2010 (315) - --------- (.)
Duration of AE	1. . 2. . 3. 7 4. 11 5. 9 6. . 7. .
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043099

Parameter	Value
	4.
	5.
	6.
	7.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. UNCHANGED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043103

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043103/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/69/WHITE/CZECH REPUBLIC/YES
Medical history	Angina pectoris, Bronchitis, Atrial fibrillation, Femoral neck fracture, Hyperbilirubinaemia, Hypertension, Myocardial infarction, Syncope, Left ventricular hypertrophy, Myocardial infarction, Myocardial ischaemia, Ischaemic stroke, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ABACTAL TBL., ABAKTAL, ACC LONG, AFONILUM, AGAPURIN RET., ANOPYRIN, ATROVENT, AUGMENTIN, BETALOC ZOK, CLEXANE, DETRALEX, ENOXAPARIN, FURON, KALNORMIN, LACTULOSA, SERETIDE DISCUS, SUPPOSITORIA GLYCERINI, TORVACARD, VENTOLIN, VEROSPIRON, WARFARIN, ZINNAT
Adverse Events (AE) Preferred term	1. Constipation 2. Intestinal haemorrhage 3. Haemorrhoids 4. Cholelithiasis 5. Methylenetetrahydrofolate reductase polymorphism 6. Gene mutation 7. Plasminogen activator inhibitor polymorphism 8. Nasopharyngitis 9. Device breakage 10. Bronchopneumonia 11. Bronchitis 12. Atrial fibrillation 13. Gastrointestinal haemorrhage 14. Haemorrhagic anaemia 15. Overdose 16. Diverticulum intestinal 17. Hiatus hernia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/YES/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MODERATE/NO/YES/YES 11. MODERATE/NO/NO/YES 12. MILD/NO/NO/YES 13. SEVERE/YES/YES/YES 14. SEVERE/YES/YES/YES 15. SEVERE/YES/NO/YES 16. MILD/NO/NO/NO 17. MILD/NO/NO/NO

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043103

Parameter	Value
Start/stop date of event with relative date	1. 31MAY2009 (6) - 01JUN2009 (7) 2. 01JUN2009 (7) - 01JUN2009 (7) 3. 01JUN2009 (7) - --------- (.) 4. 01JUN2009 (7) - --------- (.) 5. 31AUG2009 (98) - --------- (.) 6. 31AUG2009 (98) - --------- (.) 7. 31AUG2009 (98) - --------- (.) 8. 01OCT2009 (129) - 27OCT2009 (155) 9. 06OCT2009 (134) - 11NOV2009 (170) 10. 12MAR2010 (291) - 24MAR2010 (303) 11. 12MAR2010 (291) - 24MAR2010 (303) 12. 12MAR2010 (291) - 15APR2010 (325) 13. 26MAR2010 (305) - 08APR2010 (318) 14. 26MAR2010 (305) - 02APR2010 (312) 15. 26MAR2010 (305) - 28MAR2010 (307) 16. 06APR2010 (316) - --------- (.) 17. 12APR2010 (322) - --------- (.)
Duration of AE	1. 2 2. 1 3. . 4. . 5. . 6. . 7. . 8. 27 9. 37 10. 13 11. 13 12. 35 13. 14 14. 8 15. 3 16. . 17. .
Dose on AE onset	1. 2. 3. 4. 5. 6. 7. 8. 9. 10.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043103

Parameter	Value
	11.
	12.
	13.
	14.
	15.
	16.
	17.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	14. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	15. STUDY DRUG DISCONTINUED PERMANENTLY
	16. NONE
	17. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043103

Parameter	Value
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. UNCHANGED
	17. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-380043103[1),2),2)]	ENTERORRHAGIA（PT：腸出血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリン投与終了約 4 週間後の発現であり、時間的関連性がないことから、エノキサパリンとの因果関係は否定できると考える。 GASTROINTESTINAL BLEEDING（PT：胃腸出血） 治験担当医はエノキサパリンと報告事象との関連性があると判断した。弊社は、エノキサパリン投与前の発現であるため、エノキサパリンとの因果関係は否定できると考える。 HAEMORRHAGIC ANAEMIA（PT：出血性貧血） 治験担当医はエノキサパリンと報告事象との関連性があると判断した。弊社は、エノキサパリン投与前の発現であるため、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043111

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043111/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/CZECH REPUBLIC/YES
Medical history	Anaemia, Coronary artery disease, Hypertension, Inguinal hernia repair, Myocardial infarction, Obesity, Peptic ulcer, Rheumatic fever, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DETRALEX, DILATREND, EUPHYLLIN CRN, FURON, HELICID, INHIBACE [CILAZAPRIL], SIMGAL
Adverse Events (AE) Preferred term	1. Cholecystitis chronic 2. Cholelithiasis 3. Benign prostatic hyperplasia 4. Abdominal pain upper 5. Insomnia 6. Nasopharyngitis 7. Nasopharyngitis 8. Factor V Leiden mutation 9. Nasopharyngitis 10. Back pain 11. Atrial fibrillation 12. Mitral valve incompetence 13. Bronchitis chronic
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/YES/YES 12. MODERATE/NO/NO/YES 13. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 01SEP2009 (5) - --------- (.) 2. 01SEP2009 (5) - --------- (.) 3. 01SEP2009 (5) - --------- (.) 4. 03SEP2009 (7) - 05SEP2009 (9) 5. 12OCT2009 (46) - --------- (.) 6. 20OCT2009 (54) - 10NOV2009 (75) 7. 08FEB2010 (165) - 17MAR2010 (202) 8. 09MAR2010 (194) - --------- (.) 9. 25MAR2010 (210) - 05APR2010 (221) 10. 05APR2010 (221) - 29APR2010 (245) 11. 21APR2010 (237) - 21MAY2010 (267) 12. 22APR2010 (238) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043111

Parameter	Value
	13. 28APR2010 (244) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. 3
	5. .
	6. 22
	7. 38
	8. .
	9. 12
	10. 25
	11. 31
	12. .
	13. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043111

Parameter	Value
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	12. NONE
	13. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED
	13. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043112

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043112/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/48/WHITE/CZECH REPUBLIC/YES
Medical history	Anaemia, Fibrous dysplasia of bone, Hypertension, Insomnia, Obesity, Varicose vein, Osteoarthritis, Osteoarthritis, Back pain, Spinal osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASCORUTIN TBL., AZALIA TBL., CEFAZOLINE INJ., CLEXANE INJ., CONDROSULF CPS., DEGAN INJ., DETRALEX TBL., DIPHROPHOS INJ., DORMICUM INJ., HYPNOGEN TBL., KLACID TBL., LORISTA TBL., MAGNESIOM LACTICUM TBL., MARCAIN INJ., MEZOKAIN INJ., MIRENA, PARALEN TBL., PROPOFOL INJ., SORBIFER DURULES TBL., TRAMADOLI HYDROCHLORIDUM, TRAMAL CPS., TRAMAL GTT.
Adverse Events (AE) Preferred term	1. Uterine leiomyoma 2. Metrorrhagia 3. Anaemia 4. Metrorrhagia 5. Metrorrhagia 6. Uterine leiomyoma 7. Tinnitus 8. Nasopharyngitis 9. Mitral valve incompetence 10. Tricuspid valve incompetence 11. Left atrial dilatation 12. Methylenetetrahydrofolate reductase polymorphism 13. Coagulation factor mutation 14. Plasminogen activator inhibitor polymorphism
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/YES/YES 3. MODERATE/YES/NO/YES 4. MODERATE/YES/YES/YES 5. MODERATE/YES/NO/YES 6. MODERATE/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 10SEP2009 (3) - 01FEB2010 (147) 2. 15OCT2009 (38) - 24OCT2009 (47) 3. 20OCT2009 (43) - --------- (.) 4. 22NOV2009 (76) - 02DEC2009 (86) 5. 19DEC2009 (103) - 01FEB2010 (147) 6. 31JAN2010 (146) - 06FEB2010 (152)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043112

Parameter	Value
	7. 19APR2010 (224) - 03JUN2010 (269)
	8. 29MAY2010 (264) - 08JUN2010 (274)
	9. 11AUG2010 (338) - --------- (.)
	10. 11AUG2010 (338) - --------- (.)
	11. 11AUG2010 (338) - --------- (.)
	12. 20AUG2010 (347) - --------- (.)
	13. 20AUG2010 (347) - --------- (.)
	14. 20AUG2010 (347) - --------- (.)
Duration of AE	1. 145
	2. 10
	3. .
	4. 11
	5. 45
	6. 7
	7. 46
	8. 11
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
Dose on AE onset	1. 15 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043112

Parameter	Value
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. OTHER
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. NONE
	12. NONE
	13. NONE
	14. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. UNCHANGED
	11. UNCHANGED
	12. UNCHANGED
	13. UNCHANGED
	14. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043116

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043116/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/52/WHITE/CZECH REPUBLIC/YES
Medical history	Atrial flutter, Osteoarthritis, Phlebitis superficial, Varicose vein, Venous insufficiency, Rib fracture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BETALOC SR, DIGOXIN, DITUSTAT, GLYVENOL, MUCOSOLVAN SOL.
Adverse Events (AE) Preferred term	1. Diverticulum intestinal 2. Arthralgia 3. Oedema peripheral 4. Nasopharyngitis 5. Varicophlebitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 08OCT2009 (3) - --------- (.) 2. 16FEB2010 (134) - --------- (.) 3. 20APR2010 (197) - --------- (.) 4. 26MAY2010 (233) - 05JUN2010 (243) 5. 26OCT2010 (386) - 15DEC2010 (436)
Duration of AE	1. . 2. . 3. . 4. 11 5. 51
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. F
Action taken	1. NONE 2. NONE 3. NONE 4. REMEDIAL DRUG THERAPY 5. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. UNCHANGED 3. UNCHANGED 4. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043116

Parameter	Value
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043117

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043117/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/55/WHITE/CZECH REPUBLIC/YES
Medical history	Glaucoma, Glaucoma traumatic, Hyperuricaemia, Back pain, Pulmonary infarction, Tibia fracture, Varicose vein
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AZOPT GTT OPTH, CAVINTON, CIPHIN, COMBIGAN GTT OPTH, DETRALEX, MILURIT, MORPHIN BIOTIKA 1%, NOVALGIN, PROCTO-GLYVENOL, TORVACARD, TRAMAL, TRAMAL RET., TRITACE, XALATAN GTT OPTH
Adverse Events (AE) Preferred term	1. Liver function test abnormal 2. Optic ischaemic neuropathy 3. Papilloedema 4. Hypercholesterolaemia 5. Hypertension 6. Rectal haemorrhage 7. Haemorrhoids 8. Gout
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/YES/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 26OCT2009 (4) - 06NOV2009 (15) 2. 12FEB2010 (113) - --------- (.) 3. 12FEB2010 (113) - 15APR2010 (175) 4. 17FEB2010 (118) - --------- (.) 5. 19FEB2010 (120) - --------- (.) 6. 09MAR2010 (138) - 16MAR2010 (145) 7. 11MAR2010 (140) - --------- (.) 8. 20MAR2010 (149) - 22MAR2010 (151)
Duration of AE	1. 12 2. . 3. 63 4. . 5. . 6. 8 7. . 8. 3
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043117

Parameter	Value
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY,OTHER
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. IMPROVED
	5. IMPROVED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043121

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043121/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/53/WHITE/CZECH REPUBLIC/YES
Medical history	Anaemia, Ankle fracture, Appendicectomy, Cervical polyp, Exomphalos, Hepatic steatosis, Hypertension, Hypothyroidism, Insomnia, Obesity, Osteoarthritis, Osteoarthritis, Foot deformity, Joint dislocation, Renal failure, Thrombophlebitis, Thrombophlebitis, Varicose vein, Cholelithiasis, Postmenopause, Liver disorder, Shoulder operation, Lipoedema, Venous insufficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACIDUM FOLICUM, AUGMENTIN, DETRALEX, ENOXAPARIN, EUTHYROX, FLAVOBION, HYPNOGEN, LAKEA, LOKREN, LORADUR MITE, LOZAP H, LOZAP [LOSARTAN], MAGNESII LACTICI, NEUROL [ALPRAZOLAM], NOLICIN, TENAXUM, TENSIOMIN, TRALGIT, WARFARIN
Adverse Events (AE) Preferred term	1. Venous insufficiency 2. Hypertension 3. Alcoholism 4. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --AUG2010 (.) - 09SEP2010 (294) 2. 20NOV2009 (1) - 20NOV2009 (1) 3. 06JAN2010 (48) - 06APR2010 (138) 4. 12JAN2010 (54) - 21FEB2010 (94)
Duration of AE	1. . 2. 1 3. 91 4. 41
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. OTHER 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043121

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043129

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043129/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/CZECH REPUBLIC/YES
Medical history	Benign prostatic hyperplasia, Carpal tunnel syndrome, Bronchitis chronic, Gastritis, Constipation, Renal cyst, Humoral immune defect, Gastrooesophageal reflux disease, Hepatic steatosis, Hiatus hernia, Hyperlipidaemia, Hypertension, Hypokalaemia, Hyponatraemia, Insomnia, Haemorrhoids, Iron deficiency, Mitral valve incompetence, Obesity, Oesophagitis, Blood osmolarity decreased, Osteoarthritis, Osteoarthritis, Osteoporosis, Pleural adhesion, Pleural effusion, Pneumonia, Tinnitus, Venous insufficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACYLPYRIN, APAURIN SOL, CINARIZIN TBL, CYNT TBL, DAPRIL TBL, DEPOMEDROL, DETRALEX TBL, DUPHALAC SIR [LACTOSE ONLY], ENTEROL CPS [SACCHAROMYCES BOULARDII], ESPRITAL TBL, FURON TBL, INDAP TBL, LEXAURIN TBL, MESOCAIN 1%, MESOCAIN 1% SOL, NOVALGIN, NOVALGIN TBL, ORTANOL TBL, PANOGASTIN TBL, PANTOPRAZOL MYLAN TBL, SALINE SOL, TAFLOSIN CPS, TRALGIT, TRALGIT TBL
Adverse Events (AE) Preferred term	1. Pleurisy 2. Pleuritic pain 3. Pleuritic pain 4. Asthenia 5. Nasopharyngitis 6. Dyspepsia 7. Back pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 26FEB2010 (3) - 31MAY2010 (97) 2. 08MAR2010 (13) - 09MAR2010 (14) 3. 09MAR2010 (14) - 31MAY2010 (97) 4. 15MAR2010 (20) - 11JUL2010 (138) 5. 01JUL2010 (128) - 10JUL2010 (137) 6. 01JUL2010 (128) - 10JUL2010 (137) 7. 07DEC2010 (287) - 03JAN2011 (314)
Duration of AE	1. 95 2. 2 3. 84 4. 119 5. 10 6. 10 7. 28
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043129

Parameter	Value
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. IMPROVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043145

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043145/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/50/WHITE/CZECH REPUBLIC/YES
Medical history	Foot fracture, Gamma-glutamyltransferase increased, Hypertension, Insomnia, Multiple allergies, Obesity, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BETALOC SR, CLEXANE, DETRALEX, DITHIADEN, HEPARIN GEL AL 30000, HYDROCORTISON, HYPNOGEN, INFUSION OF NACL, OPHTALMO HYDROCORTISON, PREDNISON, PRESTARIUM NEO FORTE, STILNOX, ZINNAT, ZODAC
Adverse Events (AE) Preferred term	1. Angioedema 2. Bone pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 16JAN2011 (47) - 26JAN2011 (57) 2. 25MAR2011 (115) - 01APR2011 (122)
Duration of AE	1. 11 2. 8
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043146

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043146/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/66/WHITE/CZECH REPUBLIC/YES
Medical history	Appendicectomy, Back pain, Chronic obstructive pulmonary disease, Coronary artery disease, Diabetes mellitus, Diverticulum intestinal, Hepatic steatosis, Hypertension, Hyperuricaemia, Maxillary antrum operation, Obesity, Osteoporosis, Peptic ulcer, Osteoarthritis, Meniscus operation, Peripheral artery angioplasty, Lipid metabolism disorder, Venous insufficiency, Peripheral arterial occlusive disease, Coronary artery bypass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BETALOC SR, CONTROLOC, DETRALEX, FRAXIPARINE FORTE, IBUHEPA, LIPANTHYL 267M, PENTOMER RETARD, PRESTARIUM NEO, PURINOL [ALLOPURINOL], SERETIDE DISCUS, SORTIS, TROMBEX [CLOPIDOGRELUM], XYZAL
Adverse Events (AE) Preferred term	1. Peripheral arterial occlusive disease 2. Peripheral arterial occlusive disease 3. Peripheral ischaemia 4. Haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 04FEB2011 (32) - 02MAR2011 (58) 2. 02MAR2011 (58) - 03MAR2011 (59) 3. 03MAR2011 (59) - 05MAR2011 (61) 4. 04MAR2011 (60) - 01APR2011 (88)
Duration of AE	1. 27 2. 2 3. 3 4. 29
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. I 4. I
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 3. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. WORSENED 2. WORSENED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043146

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043147

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380043147/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/48/WHITE/CZECH REPUBLIC/YES
Medical history	Anaemia, Headache, Uterine dilation and curettage, Polymenorrhoea
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AKTIFERRIN, CLEXANE, ENOXAPARIN, MAGNESII LACTICI, NITROFURANTOIN, NOVALGIN, PERINDOPRIL, WARFARIN
Adverse Events (AE) Preferred term	1. Carbohydrate antigen 125 increased 2. Haemangioma of liver 3. Nasopharyngitis 4. Pulmonary fibrosis 5. Dyspepsia 6. Dysgeusia 7. Urinary tract infection 8. Muscle spasms 9. Hypertension 10. Angioedema 11. Metrorrhagia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/YES/YES/NO
Start/stop date of event with relative date	1. 17JAN2011 (4) - 15FEB2011 (33) 2. 18JAN2011 (5) - --------- (.) 3. 21JAN2011 (8) - 01FEB2011 (19) 4. 24JAN2011 (11) - --------- (.) 5. 16MAR2011 (62) - 18MAR2011 (64) 6. 16MAR2011 (62) - --------- (.) 7. 30MAR2011 (76) - 07APR2011 (84) 8. 07APR2011 (84) - 15APR2011 (92) 9. 11MAY2011 (118) - --------- (.) 10. 24JUN2011 (162) - 15JUL2011 (183) 11. 01AUG2011 (200) - 10AUG2011 (209)
Duration of AE	1. 30 2. . 3. 12 4. . 5. 3

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043147

Parameter	Value
	6. .
	7. 9
	8. 9
	9. .
	10. 22
	11. 10
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. OTHER
	11. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380043147

Parameter	Value
	6. IMPROVED
	7. RESOLVED
	8. RESOLVED
	9. IMPROVED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-380043147[2)]	METRORRHAGIA IRREGULARIS GRAVIS（PT：不正子宮出血） 治験担当医は報告事象との関連性があると判断した。弊社は、ワルファリン投与中止 3 週間後の発現であり、時間的関連性がないため、ワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380053012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380053012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/CZECH REPUBLIC/YES
Medical history	Atrial fibrillation, Glaucoma, Hyperlipidaemia, Hypertension, Obesity, Osteoarthritis, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANOPYRIN, BETALOC ZOK, BETOPTIC, CARDILAN, CITALEC, ENOXAPARIN, HELICID, LOZAP H, TRALGIT, WARFARIN
Adverse Events (AE) Preferred term	1. Chest pain 2. Atrial fibrillation
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 14APR2009 (70) - 28APR2009 (84) 2. 20FEB2010 (382) - 24FEB2010 (386)
Duration of AE	1. 15 2. 5
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380073022

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380073022/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/CZECH REPUBLIC/YES
Medical history	Renal cyst, Depression, Glaucoma, Hip arthroplasty, Hyperlipidaemia, Hypertension, Hyperuricaemia, Hysterectomy, Osteoarthritis, Osteoporosis, Back pain, Salpingo-oophorectomy, Transient ischaemic attack, Renal failure chronic, Postmenopause, Osteochondrosis, Carotid arteriosclerosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CITALEC, ENOXAPARIN, LACTULOSA, MAGNESIUM SULFURICUM 10%, MILURIT, PRESTARIUM NEO, SORTIS, TIMO-COMOD 0,5%, TRAMAL, TRENTAL, WARFARIN, ZOCOR
Adverse Events (AE) Preferred term	1. Constipation 2. Ischaemic stroke 3. Hemiparesis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 28MAY2008 (9) - 30MAY2008 (11) 2. 15AUG2008 (88) - 20AUG2008 (93) 3. 15AUG2008 (88) - 20AUG2008 (93)
Duration of AE	1. 3 2. 6 3. 6
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380073049

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380073049/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/66/WHITE/CZECH REPUBLIC/YES
Medical history	Cervicobrachial syndrome, Colon polypectomy, Diverticulum intestinal, Depression, Epilepsy, Hypertension, Hyponatraemia, Haemorrhoids, Menopause, Multiple myeloma, Pleural effusion, Syncope, Tracheal plastic repair, Loss of consciousness, Venous insufficiency, Musculoskeletal pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BETALOC ZOK, CALCICHEW D3 500MG/200I.U., CILKANOL, DEGAN, DITHIADEN, FOSAVANCE, FURON, FUROSEMID, HELICID, ISOPTIN, MELFALAN, NEUROL [ALPRAZOLAM], PREDNISON, PRESTARIUM NEO, PRESTARIUM NEO COMBI, TORECAN, TRAMAL, TRANSTEC, VELCADE, VEROSPIRON, VIGANTOL, ZOMETA
Adverse Events (AE) Preferred term	1. Osteoporosis 2. Dyspnoea 3. Cardiac failure 4. Hypotension 5. Nausea
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 13MAY2009 (23) - --------- (.) 2. 04SEP2009 (137) - 17SEP2009 (150) 3. 18SEP2009 (151) - 21SEP2009 (154) 4. 19SEP2009 (152) - 21SEP2009 (154) 5. 20SEP2009 (153) - 21SEP2009 (154)
Duration of AE	1. . 2. 14 3. 4 4. 3 5. 2
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY 4. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380073049

Parameter	Value
Outcome of event	5. REMEDIAL DRUG THERAPY 1. UNCHANGED 2. WORSENED 3. RESOLVED 4. RESOLVED 5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380083003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380083003/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/66/WHITE/CZECH REPUBLIC/YES
Medical history	Cholecystectomy, Ganglioneuroma, Hyperuricaemia, Inguinal hernia repair, Renal failure, Rheumatic fever
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AKTIFERRIN, AMOKSIKLAV, APO-ALOPURINOL, BISEPTOL, FERRONAT RET, FORTUM, OFLOXIN, PARALEN
Adverse Events (AE) Preferred term	1. Viral infection 2. Urinary tract infection 3. Pyelonephritis 4. Angiolipoma 5. Hyperuricaemia 6. Anaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 05JAN2009 (62) - 19JAN2009 (76) 2. 19JAN2009 (76) - 01MAR2009 (117) 3. 01MAR2009 (117) - 10MAR2009 (126) 4. 01MAR2009 (117) - --------- (.) 5. 01MAR2009 (117) - --------- (.) 6. 03MAR2009 (119) - 10MAR2009 (126)
Duration of AE	1. 15 2. 42 3. 10 4. . 5. . 6. 8
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY,OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380083003

Parameter	Value
	3. REMEDIAL DRUG THERAPY,OTHER
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. WORSENED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380083036

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380083036/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/63/WHITE/CZECH REPUBLIC/YES
Medical history	Chronic obstructive pulmonary disease, Diabetes mellitus, Hypercholesterolaemia, Hypertension, Obesity, Postmenopause, Barotitis media, Venous insufficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, ANOPYRIN, DAPRIL, DETRALEX, DUASPIR DISKUS, GLUCOPHAGE, INDAP, INSULATARD, LIPANTHYL, NALGESIN, TORVACARD, TRAMAL GTT, XYZAL, ZOREM
Adverse Events (AE) Preferred term	1. Neck pain 2. Transaminases increased 3. Transaminases increased 4. Transaminases increased 5. Hepatic steatosis 6. Transaminases increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/YES/YES 3. MILD/YES/NO/YES 4. MODERATE/YES/YES/YES 5. MODERATE/NO/NO/YES 6. MILD/YES/NO/NO
Start/stop date of event with relative date	1. --OCT2010 (.) - --------- (.) 2. 06DEC2010 (208) - 27DEC2010 (229) 3. 28DEC2010 (230) - 31JAN2011 (264) 4. 01FEB2011 (265) - 25MAR2011 (317) 5. 24FEB2011 (288) - --------- (.) 6. 26MAR2011 (318) - --------- (.)
Duration of AE	1. . 2. 22 3. 35 4. 53 5. . 6. .
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. . 5. . 6. F
Action taken	1. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380083036

Parameter	Value
	2. STUDY DRUG DISCONTINUED AND RESTARTED
	3. NONE
	4. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. IMPROVED
	3. WORSENED
	4. IMPROVED
	5. UNCHANGED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380093009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380093009/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/70/WHITE/CZECH REPUBLIC/YES
Medical history	Colon cancer, Chronic obstructive pulmonary disease, Renal cyst, Aortic dissection, Emphysema, Hepatic cyst, Hypertension, Hyperuricaemia, Pulmonary infarction, Aortic aneurysm, Cholelithiasis, Anaemia, Hyperlipidaemia, Renal failure chronic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AKTIFERIN, AMBROBENE, BERODUAL, CITALEC, COAXIL, ESPUMISAN, EUPHYLLIN [THEOPHYLLINE], FERRLECIT, FORADIL, FUROSEMID, GOPTEN, MESOCAIN 1%, MILURIT, MISTABRON, MODURETIC, MUCOSOLVAN, RIVOTRIL, SALINE, SOLUMEDROL, SYNTOPHYLLIN, SYNTPOHYLLIN, VENTOLIN
Adverse Events (AE) Preferred term	1. Chronic obstructive pulmonary disease 2. Depression 3. Chronic obstructive pulmonary disease
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 08SEP2008 (6) - 10SEP2008 (8) 2. 12SEP2008 (10) - --------- (.) 3. 14SEP2008 (12) - 14SEP2008 (12)
Duration of AE	1. 3 2. . 3. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. IMPROVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380093035

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380093035/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/61/WHITE/CZECH REPUBLIC/YES
Medical history	Emphysema, Hypertension, Pulmonary hypertension, Scoliosis, Duodenal ulcer, Tricuspid valve incompetence, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBROBENE, APAURIN, AUGMENTIN, CARDILAN, CLEXANE, CLINOMEL N4, CONTROLOC, DIAZEPAM, DIPIDOLOR, FRAXIPARINE, FUROSEMID, GLUCOSE 5%, HALOPERIDOL, HELICID, HEPAROID UNG., KCL 7,5%, KLACID, LOKREN, LOMIR, LOZAP [LOSARTAN POTASSIUM], MESOCAIN 1%, NACL 10%, NOVALGIN, OFLOXACIN, QUAMATEL, SALINE, SYNTOPHYLLIN, SYNTOSTIGMIN, TRAMAL, UNASYN, VENTOLIN
Adverse Events (AE) Preferred term	1. Lower gastrointestinal haemorrhage 2. Confusional state 3. Gastric ulcer 4. Duodenal ulcer 5. Headache 6. Phlebitis superficial 7. Pleural effusion 8. Gastritis 9. Anaemia 10. Urinary tract infection 11. Diverticulum intestinal 12. Hepatic cyst 13. Rectal neoplasm
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 04FEB2009 (1) - 09FEB2009 (6) 2. 04FEB2009 (1) - 06FEB2009 (3) 3. 05FEB2009 (2) - 16FEB2009 (13) 4. 05FEB2009 (2) - 16FEB2009 (13) 5. 05FEB2009 (2) - 06FEB2009 (3) 6. 07FEB2009 (4) - 07FEB2009 (4) 7. 13FEB2009 (10) - --------- (.) 8. 16FEB2009 (13) - 30MAR2009 (55)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380093035

Parameter	Value
	9. 19FEB2009 (16) - --------- (.)
	10. 19FEB2009 (16) - 05MAR2009 (30)
	11. 20FEB2009 (17) - --------- (.)
	12. 20FEB2009 (17) - --------- (.)
	13. 23FEB2009 (20) - 03JUN2009 (120)
Duration of AE	1. 6
	2. 3
	3. 12
	4. 12
	5. 2
	6. 1
	7. .
	8. 43
	9. .
	10. 15
	11. .
	12. .
	13. 101
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 15 mg
	12. 15 mg
	13. 15 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. I
	7. I
	8. I
	9. I
	10. I
	11. I
	12. I
	13. I

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380093035

Parameter	Value
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY,OTHER
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. NONE
	13. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED
	9. UNCHANGED
	10. RESOLVED
	11. UNCHANGED
	12. UNCHANGED
	13. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-380093035[4)]	BLEEDING FROM LOWER PART OF INTESTINAL TRACT - ENTERORRHAGIA（PT：下部消化管出血） 治験担当医は、併発症（直腸新生物）によるものであり、否定できると判断した。弊社は、発現日前日に投与されたエノキサパリンによるものとも考えられるが、リバーロキサバンの抗凝固作用を考慮し、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380093046

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380093046/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/80/WHITE/CZECH REPUBLIC/YES
Medical history	Hypertension, Hypokalaemia, Pleural effusion, Pulmonary infarction, Inguinal hernia, Bullous lung disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	KALIUM CHLORATUM, RAMIL
Adverse Events (AE) Preferred term	1. Pulmonary embolism
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 05MAY2009 (29) - 05MAY2009 (29)
Duration of AE	1. 1
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. F
Action taken	1. NONE
Outcome of event	1. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380093079

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380093079/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/59/WHITE/CZECH REPUBLIC/YES
Medical history	Hyperlipidaemia, Hypertension, Menopause, Mitral valve incompetence, Ovarian cystectomy, Pulmonary arterial pressure increased, Calculus ureteric, Caesarean section, Adnexa uteri cyst, Diastolic dysfunction, Liver disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, ENOXAPARIN, FRAXIPARINE, NOVALGIN, TANATRIL, TRAMAL, WARFARIN
Adverse Events (AE) Preferred term	1. Factor V Leiden mutation 2. Cholelithiasis 3. Haemangioma of liver 4. Renal cyst 5. International normalised ratio increased 6. Biliary colic 7. Musculoskeletal chest pain 8. Hepatic steatosis 9. Pancreas lipomatosis 10. Application site erythema 11. Liver function test abnormal 12. Bile duct stone 13. Biliary colic
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/YES/NO/YES 11. MODERATE/NO/YES/YES 12. MODERATE/NO/YES/YES 13. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 12MAY2010 (7) - --------- (.) 2. 13MAY2010 (8) - --------- (.) 3. 13MAY2010 (8) - 26JUN2010 (52) 4. 13MAY2010 (8) - 26JUN2010 (52) 5. 20MAY2010 (15) - 26MAY2010 (21) 6. 19JUN2010 (45) - 28JUN2010 (54) 7. 25JUN2010 (51) - 25JUN2010 (51) 8. 26JUN2010 (52) - 15JUL2010 (71) 9. 26JUN2010 (52) - 15JUL2010 (71) 10. 26JUN2010 (52) - 27JUN2010 (53) 11. 26JUN2010 (52) - 05AUG2010 (92) 12. 07APR2011 (337) - 26APR2011 (356)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380093079

Parameter	Value
	13. 08APR2011 (338) - 14APR2011 (344)
Duration of AE	1. .
	2. .
	3. 45
	4. 45
	5. 7
	6. 10
	7. 1
	8. 20
	9. 20
	10. 2
	11. 41
	12. 20
	13. 7
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380093079

Parameter	Value
	5. STUDY DRUG DISCONTINUED AND RESTARTED
	6. STUDY DRUG DISCONTINUED AND RESTARTED
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. STUDY DRUG DISCONTINUED AND RESTARTED
	12. STUDY DRUG DISCONTINUED PERMANENTLY
	13. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380093091

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380093091/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/63/WHITE/CZECH REPUBLIC/YES
Medical history	Cardiac hypertrophy, Renal cyst, Rib fracture, Hepatic steatosis, Hypercholesterolaemia, Hypertension, Insomnia, Benign prostatic hyperplasia, Spinal osteoarthritis, Pancreas lipomatosis, Type 2 diabetes mellitus, Haemangioma of spleen
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	APO ACEBUTOL, CLEXANE, HELICID, PRESTARIUM COMBI, SORTIS, TENAXUM, TIAPRIDAL, WARFARIN, ZOREM
Adverse Events (AE) Preferred term	1. Hypertension 2. Alanine aminotransferase increased 3. Alanine aminotransferase increased 4. Cytomegalovirus test positive 5. Epstein-Barr virus test positive 6. Hepatitis A virus test positive
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 14JAN2011 (1) - 15JAN2011 (2) 2. 17MAR2011 (63) - 24MAR2011 (70) 3. 24MAR2011 (70) - 28APR2011 (105) 4. 28MAR2011 (74) - --------- (.) 5. 28MAR2011 (74) - --------- (.) 6. 28MAR2011 (74) - --------- (.)
Duration of AE	1. 2 2. 8 3. 36 4. . 5. . 6. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. I 5. I 6. I

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380093091

Parameter	Value
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. STUDY DRUG DISCONTINUED AND RESTARTED
	4. NONE
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. WORSENED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380113001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/380113001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/72/WHITE/CZECH REPUBLIC/YES
Medical history	Pleuritic pain, Cranial nerve disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AGAPURIN, AUGMENTIN, DIAZEPAM, ENOXAPARIN, ENTEROL [SACCHAROMYCES BOULARDII], FRAGMIN, HELICID, HEPAROID UNQ. [HEPARINOID], HYLAK, KALIUM CHLORATUM, MILURIT, NOVALGIN, PREDNISON, TORECAN, TRAMAL, WARFARIN
Adverse Events (AE) Preferred term	1. Pneumonia 2. Vomiting 3. Diarrhoea 4. Lymphadenopathy 5. Lymphoma 6. Post procedural haematoma 7. Dyspnoea 8. Mantle cell lymphoma 9. Post procedural haematoma 10. Dyspnoea 11. Febrile neutropenia 12. Haematuria 13. Agitation
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/YES/NO/YES 7. MODERATE/NO/NO/YES 8. SEVERE/NO/YES/NO 9. MILD/YES/NO/NO 10. MODERATE/NO/NO/NO 11. SEVERE/NO/YES/NO 12. MODERATE/NO/NO/NO 13. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 27JAN2010 (1) - 05FEB2010 (10) 2. 31JAN2010 (5) - 01FEB2010 (6) 3. 31JAN2010 (5) - 01FEB2010 (6) 4. 03FEB2010 (8) - 03FEB2010 (8) 5. 03FEB2010 (8) - 03FEB2010 (8) 6. 13FEB2010 (18) - --FEB2010 (.) 7. 24FEB2010 (29) - 24FEB2010 (29) 8. 25FEB2010 (30) - --------- (.) 9. 11MAR2010 (44) - --MAR2010 (.) 10. 12MAR2010 (45) - 13MAR2010 (46) 11. 13MAR2010 (46) - 16MAR2010 (49)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380113001

Parameter	Value
	12. 15MAR2010 (48) - 19MAR2010 (52)
	13. 16MAR2010 (49) - -----2010 (.)
Duration of AE	1. 10
	2. 2
	3. 2
	4. 1
	5. 1
	6. .
	7. 1
	8. .
	9. .
	10. 2
	11. 4
	12. 5
	13. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 380113001

Parameter	Value
	4. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. OTHER
	13. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED
	10. WORSENED
	11. RESOLVED
	12. RESOLVED
	13. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390013031

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390013031/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/90/WHITE/ISRAEL/YES
Medical history	Angina pectoris, Anxiety, Femur fracture, Ankle fracture, Hypercholesterolaemia, Hypertension, Nausea, Nephrolithiasis, Osteoporosis, Spinal column stenosis, Urinary tract infection, Postmenopause, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASSIVAL, BISPHOSPHONATE, DOMPERIDONE, ISOKET RETARD, MICROPIRIN, PERPHENAN, TRAMADEX, VASCACE PLUS, VITA CAL+VIT D
Adverse Events (AE) Preferred term	1. Cerebellar haemorrhage 2. Hypokalaemia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 16MAY2009 (284) - 16MAY2009 (284) 2. 16MAY2009 (284) - --------- (.)
Duration of AE	1. 1 2. .
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. F 2. F
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 2. NONE
Outcome of event	1. DEATH 2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号：11702-390013031

死亡に至るまでの経過

被験者は 90 歳、白人女性。2008 年 8 月 6 日に肺塞栓症と診断され、同日リバーロキサバン（30mg）の投与を開始した。

2009 年 5 月 16 日、被験者は小脳出血（出血：小脳内出血）を発現した。本事象により死亡に至ったため重篤とされた。本事象により被験者の治験は中止された。治験責任（分担）医師は、本事象の重症度は高度で、治験薬との因果関係は「あり」と判断した。被験者は 1978 年以降、虚血性心疾患及び高血圧の病歴を有していた。被験者は頭痛、浮動性めまい、高血圧及び意識消失の症状を訴えた。救急処置室での血圧は 200/90mmHg。2009 年 5 月 16 日に頭部 CT スキャンを実施し、両脳室に対する圧迫所見を伴う小脳出血、及び脳室内出血が認められた。同日のヘモグロビン値（13.5g/dL）及び血小板数（295,000/mm^3）は共に正常であった。新鮮凍結血漿 733mL が輸血されたが、同日本事象により死亡した。剖検は実施されなかった。

CIAC は、小脳出血（出血：小脳内出血）を致死的で「重大な出血事象」と判定した。

Laboratory Parameter	**Normal Range**	**Date**	**Result**	**Date**	**Result**	**Date**	**Result**
Hemoglobin	Local: 12.0-15.5 g/dL	06 Aug 2008	**11.7 g/dL (L)**	16 May 2009	13.5 g/dL		
Platelets	Local: 150-450 giga/L	06 Aug 2008	302 giga/L	16 May 2009	295 giga/L		
Alkaline Phosphatase	Central: 36-118 U/L	06 Aug 2008	59 U/L	10 Dec 2008	55 U/L	10 Apr 2009	53 U/L
		20 Aug 2008	59 U/L	09 Jan 2009	52 U/L	03 May 2009	52 U/L
		08 Oct 2008	49 U/L	03 Feb 2009	55 U/L		
		11 Nov 2008	54 U/L	10 Mar 2009	57 U/L		
Amylase	Central: 28-100 U/L	06 Aug 2008	54 U/L	03 Feb 2009	45 U/L		
Bilirubin, Direct	Central: 0.10-0.32 mg/dL	06 Aug 2008	0.16 mg/dL	11 Nov 2008	0.10 mg/dL	10 Mar 2009	0.10 mg/dL
		20 Aug 2008	**<0.10 mg/dL (L)**	10 Dec 2008	0.10 mg/dL	10 Apr 2009	0.13 mg/dL
		08 Oct 2008	0.17 mg/dL	09 Jan 2009	0.14 mg/dL	03 May 2009	0.14 mg/dL
Bilirubin, Total	Central: 0.22-1.28 mg/dL	06 Aug 2008	0.44 mg/dL	11 Nov 2008	0.34 mg/dL	10 Mar 2009	0.50 mg/dL
		20 Aug 2008	0.22 mg/dL	10 Dec 2008	0.37 mg/dL	10 Apr 2009	0.42 mg/dL
		08 Oct 2008	0.38 mg/dL	09 Jan 2009	0.41 mg/dL	03 May 2009	0.46 mg/dL
SGOT/AST	Central: 11-37 U/L	06 Aug 2008	16 U/L	11 Nov 2008	16 U/L	10 Mar 2009	18 U/L
		20 Aug 2008	19 U/L	10 Dec 2008	16 U/L	10 Apr 2009	14 U/L
		08 Oct 2008	17 U/L	09 Jan 2009	17 U/L	03 May 2009	15 U/L

Laboratory Parameter	Normal Range	Date	Result	Date	Result	Date	Result
SGPT/ALT	Central: 8-43 U/L [a] Local: 0-43 U/L	06 Aug 2008	18 U/L [a]	11 Nov 2008	11 U/L	10 Apr 2009	**6 U/L (L)**
		06 Aug 2008	13 U/L	10 Dec 2008	11 U/L	03 May 2009	10 U/L
		20 Aug 2008	11 U/L	09 Jan 2009	10 U/L		
		08 Oct 2008	11 U/L	10 Mar 2009	10 U/L		
PICT Seconds	Central: 24.80-36.40 S	06 Aug 2008	**70.60 S (H)**	08 Oct 2008	<33.60 S		
		20 Aug 2008	**60.10 S (H)**	03 Feb 2009	<33.20 S		
Prothrombin Time (PT)	Central: 11.80-15.50 S	06 Aug 2008	**18.30 S (H)**	08 Oct 2008	15.30 S		
		20 Aug 2008	**26.40 S (H)**	03 Feb 2009	**18.50 S (H)**		
PT Ratio	Central: 0.70-1.20 %	06 Aug 2008	**0.55 % (L)**	08 Oct 2008	0.76 %		
		20 Aug 2008	**0.33 % (L)**	03 Feb 2009	**0.57 % (L)**		
PT, INR	Central: 0.9-1.2	06 Aug 2008	**1.6 (H)**	08 Oct 2008	1.2		
		20 Aug 2008	**2.5 (H)**	03 Feb 2009	**1.5 (H)**		

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390013040

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390013040/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/74/WHITE/ISRAEL/YES
Medical history	Anaemia, Metastases to bone, Hypercholesterolaemia, Hypertension, Prostate cancer, Obesity, Benign prostatic hyperplasia, Transurethral prostatectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DISOTHIAZIDE, LUCRIN DEPOT KIT, NIFEDIPINE, NORMITEN, PAMIDRONATE, PRIMONIL, SIMVASTATIN, STUNARONE
Adverse Events (AE) Preferred term	1. Haematochezia 2. Colonic polyp 3. Diverticulum 4. Dizziness 5. Dizziness
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 01SEP2009 (141) - --SEP2009 (.) 2. 06NOV2009 (207) - 06NOV2009 (207) 3. 06NOV2009 (207) - --------- (.) 4. 31DEC2009 (262) - 02JAN2010 (264) 5. 03JAN2010 (265) - 06JAN2010 (268)
Duration of AE	1. . 2. 1 3. . 4. 3 5. 4
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. .
Action taken	1. OTHER 2. OTHER 3. NONE 4. NONE 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390013040

Parameter	Value
	3. UNCHANGED
	4. WORSENED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390013048

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390013048/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/97/WHITE/ISRAEL/YES
Medical history	Back pain, Bronchitis, Cataract operation, Chalazion, Dizziness, Spinal fracture, Gastritis erosive, Gastroenteritis, Headache, Deafness, Hiatus hernia, Nephrolithiasis, Osteoporosis, Otitis media acute, Pain, Acarodermatitis, Tinnitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AEROVENT, BONDORMIN, BRICALIN, CEFAMEZINE, DIPYRONE, DUO-SCABIL, ENOXAPARIN, EURAX CREAM, FERRU-GRADOMET, FUSID, LOSEC, OXYCONTIN, PARACETAMOL, REKOD
Adverse Events (AE) Preferred term	1. Pruritus 2. Hip fracture 3. Acarodermatitis 4. Cough 5. Dyspnoea 6. Oedema peripheral 7. Dyspnoea 8. Pyrexia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/YES/NO 8. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 07FEB2010 (27) - 17MAR2010 (65) 2. 06APR2010 (85) - 10APR2010 (89) 3. 01MAY2010 (110) - --------- (.) 4. 14MAY2010 (123) - --------- (.) 5. 14JUN2010 (154) - 23JUL2010 (193) 6. 14JUN2010 (154) - --------- (.) 7. 24JUL2010 (194) - 29JUL2010 (199) 8. 24JUL2010 (194) - 28JUL2010 (198)
Duration of AE	1. 39 2. 5 3. . 4. . 5. 40 6. . 7. 6 8. 5
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390013048

Parameter	Value
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1. .
	2. I
	3. I
	4. I
	5. .
	6. .
	7. F
	8. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. IMPROVED
	5. WORSENED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390013052

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390013052/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/56/WHITE/ISRAEL/YES
Medical history	Diabetes mellitus, Dyspnoea, Hyperlipidaemia, Hypertension, Varicose vein, Iodine allergy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AEROVENT, APIDRA INSULIN, AVILAC, BRICALIN, ENOXAPARIN, KAYEXALATE, LANTUS INSULIN, LOTAN, MICROPIRIN, MUCOLIT, NORVASC, SIMOVIL, WARFARIN
Adverse Events (AE) Preferred term	1. Hyperkalaemia 2. Constipation 3. Cough 4. Gingival bleeding 5. Chest pain 6. Dyspnoea 7. Oedema peripheral 8. Orthopnoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 07SEP2010 (5) - 08SEP2010 (6) 2. 07SEP2010 (5) - 07SEP2010 (5) 3. 11SEP2010 (9) - --------- (.) 4. 17SEP2010 (15) - --------- (.) 5. 03OCT2010 (31) - 04OCT2010 (32) 6. 26MAY2011 (266) - 27MAY2011 (267) 7. 30JUN2011 (301) - --------- (.) 8. 30JUN2011 (301) - --------- (.)
Duration of AE	1. 2 2. 1 3. . 4. . 5. 2 6. 2 7. . 8. .
Dose on AE onset	1. 2. 3. 4. 5. 6.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390013052

Parameter	Value
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. IMPROVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390013055

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390013055/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/78/WHITE/ISRAEL/YES
Medical history	Benign prostatic hyperplasia, Bladder cancer, Prostate cancer, Diabetes mellitus, Duodenal ulcer, Hypercholesterolaemia, Hypertension, Obesity, Osteoporosis, Psoriasis, Rectal haemorrhage, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALENDRONATE, CALCIMORE, DERMOVATE, ENALADEX, FAMO, FUCIDIN 2%, ISOKET RETARD, PROCTO OBLIPHICHA, SIMOVIL, XATRAL, ZINNAT
Adverse Events (AE) Preferred term	1. Liver function test abnormal 2. Vertigo 3. Urinary tract infection 4. Haematoma 5. Cough
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 24SEP2010 (3) - 07OCT2010 (16) 2. 26OCT2010 (35) - --------- (.) 3. 30NOV2010 (70) - 10DEC2010 (80) 4. 01DEC2010 (71) - --JAN2011 (.) 5. 10APR2011 (201) - --------- (.)
Duration of AE	1. 14 2. . 3. 11 4. . 5. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. F
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED 2. NONE 3. REMEDIAL DRUG THERAPY 4. NONE 5. NONE
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390013055

Parameter	Value
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390013060

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390013060/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/83/WHITE/ISRAEL/YES
Medical history	Anaemia, Cataract, Renal failure chronic, Diverticulum intestinal, Chronic obstructive pulmonary disease, Depression, Diabetes mellitus, Glaucoma, Hypertension, Osteoporosis, Tobacco user, Upper limb fracture, Hypercholesterolaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPHA D3, ALPHAGAN, AUGMENTIN, AZENIL, BRICALIN, CALCIUM, CARDURA, ENOXAPARIN, FLIXOTIDE, FUSID, HYDROCORTIZONE, LANTON, MICROPIRIN, NAROCIN, NORMITEN, NORVASC, OCSAAR, OPTALGIN, OXYCODONE, PRAMIN, PREDNISON, PROCOR, ROCEPHIN, SIRAN, TAZOCIN, TRAMADEX, VASODIP, VENTOLIN, WARAFRIN, WARFARIN, ZINNAT
Adverse Events (AE) Preferred term	1. Atrial fibrillation 2. Injection site haemorrhage 3. Back pain 4. Subcutaneous haematoma 5. Oedema peripheral 6. Pneumonia 7. Wound haemorrhage 8. Vomiting 9. Hyponatraemia 10. Hyponatraemia 11. Back pain 12. Chest pain 13. Dyspnoea 14. Haematoma 15. Hyponatraemia 16. Thyroxine free increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/YES/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/YES/YES 10. MILD/NO/YES/YES 11. MILD/NO/NO/NO 12. MILD/NO/NO/NO 13. MILD/NO/NO/NO 14. MILD/YES/NO/NO 15. MILD/NO/NO/NO 16. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --MAY2011 (.) - --------- (.) 2. 17MAR2011 (8) - 07APR2011 (29)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390013060

Parameter	Value
	3. 23MAR2011 (14) - 25MAR2011 (16)
	4. 03APR2011 (25) - --------- (.)
	5. 07APR2011 (29) - --------- (.)
	6. 09APR2011 (31) - 12APR2011 (34)
	7. 28APR2011 (50) - 28APR2011 (50)
	8. 28APR2011 (50) - 01MAY2011 (53)
	9. 28APR2011 (50) - 01MAY2011 (53)
	10. 26MAY2011 (78) - 03JUN2011 (86)
	11. 24SEP2011 (199) - --------- (.)
	12. 24SEP2011 (199) - --------- (.)
	13. 24SEP2011 (199) - --------- (.)
	14. 05OCT2011 (210) - --------- (.)
	15. 06OCT2011 (211) - --------- (.)
	16. 09OCT2011 (214) - --------- (.)
Duration of AE	1. .
	2. 22
	3. 3
	4. .
	5. .
	6. 4
	7. 1
	8. 4
	9. 4
	10. 9
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390013060

Parameter	Value
	15.
	16.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY,OTHER
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. NONE
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. NONE
Outcome of event	1. IMPROVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390013060

Parameter	Value
	11. IMPROVED
	12. IMPROVED
	13. IMPROVED
	14. UNCHANGED
	15. UNCHANGED
	16. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390023006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390023006/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/67/WHITE/ISRAEL/YES
Medical history	Duodenal ulcer, Hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AHISTON, ATARAX, BETACORTEN, ENOXAPARIN, LORASTINE, NORMITEN, OPTALGIN, TAGAMET, WARFARIN, XATRAL
Adverse Events (AE) Preferred term	1. Lipid metabolism disorder 2. Drug eruption 3. Benign prostatic hyperplasia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --OCT2007 (.) - --------- (.) 2. 23JAN2008 (116) - 25JAN2008 (118) 3. 14JUL2008 (289) - --------- (.)
Duration of AE	1. . 2. 3 3. .
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. RESOLVED 3. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390033001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/66/WHITE/ISRAEL/YES
Medical history	Acute sinusitis, Blindness unilateral, Bone pain, Breast cancer, Hypercholesterolaemia, Hypertension, Menopause, Type 2 diabetes mellitus, Retinal vein thrombosis, Tinnitus, Breast lump removal
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CADEX, DEXACORT, ENOXAPARIN, FEMARA, GLUCOMIN, MICROPIRIN, NORMITEN, NORVASC, OPTALGIN, PREDNISON, SIMVASTATIN, VASCASE [CILAZAPRIL], WARFARIN
Adverse Events (AE) Preferred term	1. Epistaxis 2. Deafness unilateral 3. Pain in extremity 4. Ligament sprain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. SEVERE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 15SEP2007 (15) - 15SEP2007 (15) 2. 24JAN2008 (146) - 14FEB2008 (167) 3. 27FEB2008 (180) - 12MAR2008 (194) 4. 27FEB2008 (180) - 27FEB2008 (180)
Duration of AE	1. 1 2. 22 3. 15 4. 1
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. NONE 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033001

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390033002/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/53/WHITE/ISRAEL/YES
Medical history	Road traffic accident, Burn debridement, Wrist fracture, Tobacco user, Road traffic accident, Road traffic accident, Muscle rupture, Burns second degree, Burns third degree, Upper limb fracture, Deep vein thrombosis, Pulmonary mass, Drug hypersensitivity, Abdominal injury, Skin graft
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BEATRYL, BONDORMIN, BUPIVACAINE 0.1%, BUPIVACAINE 0.25%, CEFAMEZIN [CEFAZOLIN SODIUM], DOLESTINE, ENOXAPARIN, FENTANYL, FUSID, KCL, LIDOCAINE 1%, LOSEC, MARCAINE, MARCAINE 0.25%, MIDAZOLAM, MORPHINE, NORCURON, OPTALGIN, OXYCOD, OXYCONTIN, PERCOCET, PETHIDIN, PRAMIN, PROPOFOL, TRAMADEX, TRAMAL, VALIUM [DIAZEPAM], VOLTAREN, WARFARIN, ZANTAC
Adverse Events (AE) Preferred term	1. Night sweats 2. Haemoptysis 3. Insomnia 4. Hepatic enzyme increased 5. Dyspnoea exertional 6. Asthenia 7. Fatigue 8. Dizziness 9. Lung adenocarcinoma 10. Biopsy lung 11. Procedural pain 12. Insomnia 13. Constipation
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/YES/YES 10. MODERATE/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/YES/NO/NO
Start/stop date of event with relative date	1. --DEC2007 (.) - --JAN2008 (.) 2. 13SEP2007 (3) - 13SEP2007 (3) 3. 13SEP2007 (3) - 17SEP2007 (7) 4. 18SEP2007 (8) - 24SEP2007 (14) 5. 20SEP2007 (10) - 08OCT2007 (28) 6. 01OCT2007 (21) - --OCT2007 (.) 7. 01OCT2007 (21) - --OCT2007 (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033002

Parameter	Value
	8. 03OCT2007 (23) - --OCT2007 (.)
	9. 29OCT2007 (49) - 11NOV2007 (62)
	10. 29OCT2007 (49) - 29OCT2007 (49)
	11. 01NOV2007 (52) - --APR2008 (.)
	12. 11MAR2008 (183) - --MAR2008 (.)
	13. 13MAR2008 (185) - --MAR2008 (.)
Duration of AE	1. .
	2. 1
	3. 5
	4. 7
	5. 19
	6. .
	7. .
	8. .
	9. 14
	10. 1
	11. .
	12. .
	13. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033002

Parameter	Value
	13.
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED AND RESTARTED
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	10. STUDY DRUG DISCONTINUED AND RESTARTED
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390033017/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/50/WHITE/ISRAEL/YES
Medical history	Anaemia, Angina unstable, Cholecystectomy, Coronary artery bypass, Depression, Hyperlipidaemia, Type 2 diabetes mellitus, Pulmonary congestion, Coronary angioplasty, Coronary angioplasty, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BONDORMIN, CARTIA, CIPRALEX, ENOXAPARIN, FUSID, GLIBETIC, GLUCOPHAGE, LOSEC, NEOBLOC, NITROGLYCERINE SPRAY, OPTALGIN, RIDAZIN, WARFARIN
Adverse Events (AE) Preferred term	1. Chest pain 2. Dyspnoea 3. Pulmonary congestion
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 30JUL2008 (31) - 02AUG2008 (34) 2. 31JUL2008 (32) - 02AUG2008 (34) 3. 31JUL2008 (32) - --------- (.)
Duration of AE	1. 4 2. 3 3. .
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033018

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390033018/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/ISRAEL/YES
Medical history	Bronchitis chronic, Colon cancer, Hypercholesterolaemia, Hypertension, Hypothyroidism, Incisional hernia repair, Depressed mood, Intervertebral disc disorder, Osteoporosis, Atrial fibrillation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPIN, CALCIUM CARBONATE, DISOTHIAZIDE, ELTROXIN, ENALADEX, ENOXAPARIN, MICROPIRIN, MOXYPEN, PAXXET, RYTHMEX, SERETIDE, SIMVACOR, WARFARIN
Adverse Events (AE) Preferred term	1. Traumatic haematoma 2. Erythema 3. Oedema peripheral 4. Oedema 5. Abdominal pain upper 6. Cough 7. Hypertension 8. Abdominal pain upper 9. Cataract
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. SEVERE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 23JUL2008 (21) - 28JUL2008 (26) 2. 22SEP2008 (82) - 06OCT2008 (96) 3. 22SEP2008 (82) - 06OCT2008 (96) 4. 29SEP2008 (89) - --------- (.) 5. 28OCT2008 (118) - 30OCT2008 (120) 6. 23NOV2008 (144) - --NOV2008 (.) 7. 14DEC2008 (165) - 15DEC2008 (166) 8. 21DEC2008 (172) - 23DEC2008 (174) 9. 26DEC2008 (177) - 26DEC2008 (177)
Duration of AE	1. 6 2. 15 3. 15 4. . 5. 3 6. . 7. 2 8. 3 9. 1
Dose on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033018

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED
	2. NONE
	3. NONE
	4. NONE
	5. OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-390033018[4)]	POST TRAUMATIC HEMATOMA (FOREHEAD) FALL INDUCED (PT：挫傷) 治験担当医は、ワルファリン投与中の偶発症と考え、否定できると判断した。弊社は、ワルファリン投与と報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1) 治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2) 治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3) 治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4) 治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5) 治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6) 治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390033029/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/26/WHITE/ISRAEL/YES
Medical history	
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, COUMADIN
Adverse Events (AE) Preferred term	1. Vaginal haemorrhage
	2. Abdominal pain upper
	3. Hyperhidrosis
	4. Headache
	5. Anxiety
	6. Urinary tract infection
	7. Haematoma
	8. Abdominal pain upper
	9. Nasopharyngitis
	10. Pain in extremity
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/NO/YES
	4. MODERATE/NO/NO/YES
	5. MODERATE/NO/YES/YES
	6. MILD/NO/NO/NO
	7. MILD/YES/NO/NO
	8. MILD/YES/NO/NO
	9. MILD/NO/NO/NO
	10. MILD/YES/NO/NO
Start/stop date of event with relative date	1. 17DEC2008 (2) - 21DEC2008 (6)
	2. 18DEC2008 (3) - 19DEC2008 (4)
	3. 18DEC2008 (3) - 18DEC2008 (3)
	4. 23DEC2008 (8) - 23DEC2008 (8)
	5. 26DEC2008 (11) - 28DEC2008 (13)
	6. 02FEB2009 (49) - 11FEB2009 (58)
	7. 04FEB2009 (51) - 18FEB2009 (65)
	8. 11MAR2009 (86) - 11MAR2009 (86)
	9. 06APR2009 (112) - 11APR2009 (117)
	10. 30APR2009 (136) - 06MAY2009 (142)
Duration of AE	1. 5
	2. 2
	3. 1
	4. 1
	5. 3
	6. 10
	7. 15
	8. 1
	9. 6

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033029

Parameter	Value
	10. 7
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. F
	7. F
	8. F
	9. F
	10. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. NONE
	10. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033029

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033044

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390033044/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/77/WHITE/ISRAEL/YES
Medical history	Cholecystectomy, Drug hypersensitivity, Drug hypersensitivity, Dry eye, Hypercholesterolaemia, Hyperlipidaemia, Hypertension, Obesity, Osteoarthritis, Drug hypersensitivity, Spinal column stenosis, Vitamin B12 deficiency, Thalassaemia beta, Tobacco user, Thyroidectomy, Depression
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACAMOL, CIPRALEX, CRESTOR, FUSID, LOPRESOR, LOSEC, LYTEERS, MICROPIRIN, NEOBLOCK, OCSAAR
Adverse Events (AE) Preferred term	1. Tachypnoea 2. Tachycardia 3. Haemoptysis 4. Cough 5. Asthenia 6. Pyrexia 7. Chest pain 8. Dyspnoea 9. Cardiac failure 10. Headache 11. Headache 12. Gingival bleeding 13. Cough 14. Vaginal haemorrhage 15. Haematuria
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/YES/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/YES/NO/YES 13. MILD/NO/NO/YES 14. MILD/YES/NO/YES 15. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 24APR2010 (12) - --MAY2010 (.) 2. 24APR2010 (12) - --MAY2010 (.) 3. 28APR2010 (16) - 28APR2010 (16) 4. 20MAY2010 (38) - --JUN2010 (.) 5. 27MAY2010 (45) - 06JUN2010 (55) 6. 31MAY2010 (49) - 31MAY2010 (49)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033044

Parameter	Value
	7. 02JUN2010 (51) - 06JUN2010 (55)
	8. 03JUN2010 (52) - 06JUN2010 (55)
	9. 15JUN2010 (64) - --------- (.)
	10. 26JUN2010 (75) - --JUN2010 (.)
	11. 06JUL2010 (85) - 06JUL2010 (85)
	12. 26JUL2010 (105) - 26JUL2010 (105)
	13. 07AUG2010 (117) - --------- (.)
	14. 12AUG2010 (122) - 12AUG2010 (122)
	15. 28SEP2010 (169) - 29SEP2010 (170)
Duration of AE	1. .
	2. .
	3. 1
	4. .
	5. 11
	6. 1
	7. 5
	8. 4
	9. .
	10. .
	11. 1
	12. 1
	13. .
	14. 1
	15. 2
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033044

Parameter	Value
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. NONE
	14. NONE
	15. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. UNCHANGED
	14. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033044

Parameter	Value
	15. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033045

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390033045/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/74/WHITE/ISRAEL/YES
Medical history	Cholecystectomy, Arteriogram coronary, Endoscopy upper gastrointestinal tract, Hyperlipidaemia, Hypertension, Iron deficiency anaemia, Menopause, Obesity, Osteoarthritis, Catheterisation cardiac, Coronary arterial stent insertion, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACAMOL, ALDACTONE [SPIRONOLACTONE], ASPIRIN, CARDILOC, CIPRALEX, DEXACORT, DIOVAN, DUROGESTIC, ENOXAPARIN, ETOPAN, FUSID, LIPITOR, LYRICA, NORVASC, OCSAAR, OPTALGIN, OXYCOD, PREDNISON, TELFAST, VABEN
Adverse Events (AE) Preferred term	1. Musculoskeletal pain 2. Depressed mood 3. Pleuritic pain 4. Insomnia 5. Decreased appetite 6. Productive cough 7. Hypertension 8. Insomnia 9. Headache 10. Back pain 11. Wheezing 12. Oedema 13. Pyrexia 14. Chills 15. Hyperhidrosis 16. Hypertension 17. Rash generalised 18. Musculoskeletal chest pain 19. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/YES/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES 15. MILD/NO/NO/YES 16. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033045

Parameter	Value
	17. MODERATE/YES/NO/YES
	18. MODERATE/NO/YES/NO
	19. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --AUG2010 (.) - --------- (.)
	2. --AUG2010 (.) - --------- (.)
	3. --JUL2010 (.) - --JUL2010 (.)
	4. --SEP2010 (.) - --------- (.)
	5. --AUG2010 (.) - --------- (.)
	6. --AUG2010 (.) - --SEP2010 (.)
	7. 18MAY2010 (0) - 24MAY2010 (6)
	8. 19MAY2010 (1) - 19MAY2010 (1)
	9. 21MAY2010 (3) - 21MAY2010 (3)
	10. 22MAY2010 (4) - 22MAY2010 (4)
	11. 23MAY2010 (5) - --SEP2010 (.)
	12. 25MAY2010 (7) - --AUG2010 (.)
	13. 04JUL2010 (47) - 05JUL2010 (48)
	14. 04JUL2010 (47) - 06JUL2010 (49)
	15. 04JUL2010 (47) - 06JUL2010 (49)
	16. 14JUL2010 (57) - -----2010 (.)
	17. 08NOV2010 (174) - 06DEC2010 (202)
	18. 25NOV2010 (191) - 28NOV2010 (194)
	19. 25NOV2010 (191) - 02DEC2010 (198)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. 7
	8. 1
	9. 1
	10. 1
	11. .
	12. .
	13. 2
	14. 3
	15. 3
	16. .
	17. 29
	18. 4
	19. 8
Dose on AE onset	1.
	2.
	3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033045

Parameter	Value
	4.
	5.
	6.
	7.
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 15 mg
	12. 15 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
	18. F
	19. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033045

Parameter	Value
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. NONE
	14. NONE
	15. NONE
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. NONE
	19. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033047

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390033047/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/65/WHITE/ISRAEL/YES
Medical history	Breast abscess, Breast reconstruction, Breast cancer, Mastectomy, Menopause, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, ENOXAPARIN, FERROCAL, IMODIUM, OXYCONTIN, TAMOXEN, WARFARIN
Adverse Events (AE) Preferred term	1. Diarrhoea
	2. Headache
	3. Gingival bleeding
	4. Procedural complication
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/YES/NO/YES
	4. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 31AUG2010 (27) - 02SEP2010 (29)
	2. 01SEP2010 (28) - 03SEP2010 (30)
	3. 14SEP2010 (41) - 14SEP2010 (41)
	4. 15FEB2011 (195) - 23FEB2011 (203)
Duration of AE	1. 3
	2. 3
	3. 1
	4. 9
Dose on AE onset	1.
	2.
	3.
	4.
Dose status on AE onset	1.
	2.
	3.
	4.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033047

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033048

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390033048/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/79/WHITE/ISRAEL/YES
Medical history	Cataract, Creatinine renal clearance abnormal, Depression, Diabetes mellitus, Gastrooesophageal reflux disease, Fall, Hiatus hernia, Hypercholesterolaemia, Hypertension, Hypothyroidism, Obesity, Osteoporosis, Vitamin B12 deficiency, Vitamin D deficiency, Normochromic normocytic anaemia, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CADEX, CALCIUM, CLONEX, CORDIL, ELTROXIN, FERROGRODUMEN, FUSID, GLUCOPHAGE, GLUCORITE, ISOKET, LANTON, LIPITOR, LOPRESOR, MICROPIRIN, MIRO, SEROXAT, STILNOX, TRITACE, VIT B12, VITAMIN D
Adverse Events (AE) Preferred term	1. Cough 2. Diabetes mellitus inadequate control 3. Dyspnoea 4. Blood bilirubin increased 5. Aspartate aminotransferase increased 6. Abdominal pain upper 7. Alanine aminotransferase increased 8. Haematoma 9. Haematoma 10. Abdominal pain 11. Ecchymosis 12. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/YES/NO/YES 9. MILD/YES/NO/YES 10. MILD/YES/NO/YES 11. MILD/YES/NO/YES 12. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --JAN2011 (.) - --------- (.) 2. --JAN2011 (.) - --------- (.) 3. --FEB2011 (.) - --------- (.) 4. 10SEP2010 (5) - 15SEP2010 (10) 5. 10SEP2010 (5) - 15SEP2010 (10) 6. 11SEP2010 (6) - 14SEP2010 (9) 7. 12SEP2010 (7) - 20SEP2010 (15) 8. 06DEC2010 (92) - --DEC2010 (.) 9. 30DEC2010 (116) - --JAN2011 (.) 10. 30DEC2010 (116) - --JAN2011 (.) 11. 02JAN2011 (119) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033048

Parameter	Value
	12. 11JAN2011 (128) - 19JAN2011 (136)
Duration of AE	1. .
	2. .
	3. .
	4. 6
	5. 6
	6. 4
	7. 9
	8. .
	9. .
	10. .
	11. .
	12. 9
Dose on AE onset	1.
	2.
	3.
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. OTHER
	7. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390033048

Parameter	Value
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. IMPROVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. IMPROVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390043009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390043009/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/85/WHITE/ISRAEL/YES
Medical history	Liver function test abnormal, Microcytic anaemia, Appendicectomy, Atrial fibrillation, Cerebrovascular accident, Chest X-ray abnormal, Cardiac failure chronic, Renal failure chronic, Constipation, Fall, Gastroenteritis, Head injury, Hyperbilirubinaemia, Hyperlipidaemia, Hypertension, Hyponatraemia, Iron deficiency, Loss of consciousness, Myocardial infarction, Myocardial infarction, Obesity, Type 2 diabetes mellitus, Vitamin B12 deficiency, Coronary angioplasty, Face injury, Postmenopause, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDOSPIRONE, CLEXAN, DERALIN, FUSID, GLUCOMINE, LAEVOLAC, MICROPIRIN, NEOBLOC, NORVASC, RAMITENS, SIMVASTATIN, SLOW K, VITAMIN B12
Adverse Events (AE) Preferred term	1. Ischaemic hepatitis 2. Brucella test positive
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 04SEP2009 (4) - 08SEP2009 (8) 2. 07SEP2009 (7) - --------- (.)
Duration of AE	1. 5 2. .
Dose on AE onset	1. 15 mg 2. 15 mg
Dose status on AE onset	1. . 2. F
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 2. NONE
Outcome of event	1. DEATH 2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390043010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390043010/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/62/WHITE/ISRAEL/YES
Medical history	Acute myocardial infarction, Atrioventricular block complete, Breast cancer, Cardiac pacemaker insertion, Cholelithiasis, Cardiac failure chronic, Intervertebral disc disorder, Oesophagitis, Hyperlipidaemia, Hypertension, Hysterectomy, Pneumothorax traumatic, Intervertebral disc disorder, Mastectomy, Obesity, Pleural effusion, Pulmonary hypertension, Ejection fraction decreased, Coronary arterial stent insertion, Coronary arterial stent insertion, Breast cancer metastatic, Mass excision, Chemotherapy, Acute myocardial infarction
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTONE [SPIRONOLACTONE], ASPIRIN, DIMITONE, FUSID, KONAKION, LIPITOR, LOSEC, LYRICA, MAALOX, OPTALGIN, OXYCOD, PAPAVERIN, PLAVIX, PRAMIN, RESPRIM FORTE, SEDURAL, SIMVACOR, TARGIN, TAXOTERE, TRAMADEX, TRAMAL, TRITACE, VOLTAREN, ZANTAC
Adverse Events (AE) Preferred term	1. Abdominal pain 2. Dyspnoea 3. Cholelithiasis 4. Urinary tract infection 5. Flank pain 6. Radicular pain 7. Radicular pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 18JUN2010 (4) - 18JUN2010 (4) 2. 25JUL2010 (41) - 27JUL2010 (43) 3. 26JUL2010 (42) - --------- (.) 4. 18SEP2010 (96) - 30SEP2010 (108) 5. 09OCT2010 (117) - 11OCT2010 (119) 6. 21OCT2010 (129) - 25OCT2010 (133) 7. 26OCT2010 (134) - --------- (.)
Duration of AE	1. 1 2. 3 3. . 4. 13 5. 3 6. 5 7. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390043010

Parameter	Value
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. IMPROVED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390053011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390053011/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/29/WHITE/ISRAEL/YES
Medical history	Back pain, Headache
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN
Adverse Events (AE) Preferred term	1. Pregnancy 2. Abortion induced 3. Chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 05APR2008 (62) - 09APR2008 (66) 2. 09APR2008 (66) - 09APR2008 (66) 3. 15JUL2008 (163) - 16JUL2008 (164)
Duration of AE	1. 5 2. 1 3. 2
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. I 3. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 2. STUDY DRUG DISCONTINUED AND RESTARTED 3. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390063004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390063004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/85/WHITE/ISRAEL/YES
Medical history	Pancreatitis acute, Anaemia, Atrial fibrillation, Benign prostatic hyperplasia, Benign prostatic hyperplasia, Cerebrovascular accident, Cholecystostomy, Constipation, Hypertension, Hypothyroidism, Pleural effusion, Cholecystitis, Post procedural sepsis, Mechanical ventilation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLSALICYLIC ACID, ALFUZOSIN, AMIODARON, CEFTRIAXONE, CIPROFLOXACIN, DUPHALAC [ALL 3 INGREDIENTS], FUROSEMIDE, HYDROXYUREA, LAXATIVE, LEVOFLOXACIN, OMEPRAZOL, SODIUM VALPROATE, THYROXINE
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Tongue haemorrhage 3. Urinary retention 4. Urinary tract infection 5. Urinary tract infection 6. Creatinine renal clearance decreased 7. Urinary retention 8. Haematuria 9. Urinary retention
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 28APR2008 (42) - 19JUN2008 (94) 2. 05JUN2008 (80) - 06JUN2008 (81) 3. 18SEP2008 (185) - 19SEP2008 (186) 4. 18SEP2008 (185) - 26SEP2008 (193) 5. 26SEP2008 (193) - 06OCT2008 (203) 6. 07OCT2008 (204) - --------- (.) 7. 31OCT2008 (228) - 31OCT2008 (228) 8. 09NOV2008 (237) - 10NOV2008 (238) 9. 09NOV2008 (237) - 09NOV2008 (237)
Duration of AE	1. 53 2. 2 3. 2 4. 9 5. 11 6. . 7. 1 8. 2

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390063004

Parameter	Value
	9. 1
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. OTHER
	8. NONE
	9. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390063004

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390063005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390063005/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/85/WHITE/ISRAEL/YES
Medical history	Actinomycotic pulmonary infection, Atrial fibrillation, Atrial fibrillation, Diabetes mellitus, Sleep disorder, Blood bilirubin increased, Tobacco user
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXYCILLIN TRIHYDRATE, BROTIZOLAM, CIPROFLOXACIN, FUROSEMIDE, LACROMYCIN, METFORMIN
Adverse Events (AE) Preferred term	1. Conjunctival haemorrhage 2. Dry eye 3. Dyspnoea 4. Pulmonary congestion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 28APR2008 (39) - 15MAY2008 (56) 2. 14SEP2008 (178) - 05OCT2008 (199) 3. 22NOV2008 (247) - 24NOV2008 (249) 4. 24NOV2008 (249) - 26NOV2008 (251)
Duration of AE	1. 18 2. 22 3. 3 4. 3
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. I
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. NONE 4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. WORSENED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390063005

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390063011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390063011/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/62/WHITE/ISRAEL/YES
Medical history	Hyperlipidaemia, Hypertension, Menopause, Varicose vein, Phlebectomy, Postoperative thrombosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLSALICYLIC ACID, AMLODIPINE, AUGMENTIN, AUGMENTINE, ENOXAPARIN, HYDROCHLORTHIAZIDE, OMEPRASOLE, OXAZEPAM, WARFARIN
Adverse Events (AE) Preferred term	1. Supraventricular tachycardia 2. Dysuria
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 30JUN2009 (19) - 02JUL2009 (21) 2. 23MAY2010 (346) - 26MAY2010 (349)
Duration of AE	1. 3 2. 4
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390063012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390063012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/ISRAEL/YES
Medical history	Cerebrovascular accident, Pyrexia, Hyperlipidaemia, Obesity, Varicose vein operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETTYLSALICYLIC ACID, CEFIRIAXONE, CIPROFLOXACIN, DEPALEPT CHRONO, DICLOFENAC, ENOXAPARIN, PAPAVERINE, SIMVASTATIN, WARFARIN
Adverse Events (AE) Preferred term	1. Haematuria 2. Renal colic
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 21JUL2009 (24) - 25JUL2009 (28) 2. 23JUL2009 (26) - 27JUL2009 (30)
Duration of AE	1. 5 2. 5
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390063014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390063014/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/69/WHITE/ISRAEL/YES
Medical history	Anxiety, Breast cancer, Cataract, Diabetic neuropathy, Hyperlipidaemia, Hypertension, Knee arthroplasty, Obesity, Osteoarthritis, Pneumonia, Diabetic retinopathy, Varicose vein, Postmenopause, Myocardial ischaemia, Spondylolisthesis, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLSALICILIC ACID, ACETYLSALICYLIC ACID, ATENALOL, CITALOPRAM, CLOPIDOGREL, ENALAPRIL, HYDROCHLORTHIASIDE, INSULIN ASPARAT, IPRATROPIUM, METFORMIN, NITRODERM NITROGLYCERINE, OMEPRAZOLE, PARACETAMOL, ROXITHROMYCIN, SIMVASTATIN
Adverse Events (AE) Preferred term	1. Cholelithiasis 2. Hepatic steatosis 3. Chest pain 4. Blood alkaline phosphatase increased 5. Gamma-glutamyltransferase increased 6. Dyspnoea 7. Chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 19JUL2010 (12) - --------- (.) 2. 19JUL2010 (12) - --------- (.) 3. 03AUG2010 (27) - 04AUG2010 (28) 4. 06SEP2010 (61) - --------- (.) 5. 11NOV2010 (127) - --------- (.) 6. 25NOV2010 (141) - 27NOV2010 (143) 7. 27NOV2010 (143) - 29NOV2010 (145)
Duration of AE	1. . 2. . 3. 2 4. . 5. . 6. 3 7. 3
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390063014

Parameter	Value
	7. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390063015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390063015/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/55/WHITE/ISRAEL/YES
Medical history	Hyperlipidaemia, Myocardial infarction, Myocardial ischaemia, Coronary arterial stent insertion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLSALICYLIC ACID, ATORVASTATIN, ATROPINE SULFATE, BISOPROLOL, BROTIZOLAM, CLOPIDOGREL, DEXAMOL, DIPYRONE, EFFIENT, KCL, METOCLOPRAMIDE, MIDAZOLAM, OXAZEPAM, OXYCODONE
Adverse Events (AE) Preferred term	1. Back pain 2. Acute myocardial infarction
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 04FEB2011 (146) - 08FEB2011 (150) 2. 20APR2011 (221) - 26APR2011 (227)
Duration of AE	1. 5 2. 7
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390083004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390083004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/51/WHITE/ISRAEL/YES
Medical history	Acute promyelocytic leukaemia, Pancreatic cyst, Pulmonary embolism, Splenectomy, Benign neoplasm, Hernia repair
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACYCLOVIR, ALL TRANS RETINOIC ACID, ALLOPURINOL, ATRA, CEPORAL, CIPROXIN, CYTOSAR, CYTRABIN [CYTARABINE IS AN ACTIVE COMPONENT OF CHEMOTHERAPY CYTOSAR], DAUNORUBICIN, DEXAMETHASONE, ENOXAPARIN, FLUCONAZOLE, FUSID, IDARUBICIN, INSULIN MIXTARD, KITRIL, KYTRIL, LORIVAN, LOSEC, METOTREXATE, MITOXANTRON, MORFIUM, PLATELETS, PLATLETS, PRAMIN, PURINETOL, SIRAN, STERODEX, TAZOCIN, VANCOMYCIN, VOLTAREN, ZOVIRAX
Adverse Events (AE) Preferred term	1. Epistaxis 2. Impetigo 3. Oral herpes 4. Febrile neutropenia 5. Herpes simplex 6. Mucosal inflammation 7. Acute promyelocytic leukaemia 8. Folliculitis 9. Alanine aminotransferase increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/YES/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 20JAN2010 (5) - 20JAN2010 (5) 2. 29JAN2010 (14) - 07FEB2010 (23) 3. 29JAN2010 (14) - 07FEB2010 (23) 4. 30JAN2010 (15) - --------- (.) 5. 31JAN2010 (16) - --------- (.) 6. 01FEB2010 (17) - --------- (.) 7. 17MAR2010 (61) - 11APR2010 (86) 8. 11JUN2010 (147) - 17JUN2010 (153) 9. 18OCT2010 (276) - 20DEC2010 (339)
Duration of AE	1. 1 2. 10 3. 10 4. . 5. . 6. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390083004

Parameter	Value
	7. 26
	8. 7
	9. 64
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
Action taken	1. OTHER
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY,OTHER
	8. REMEDIAL DRUG THERAPY
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. IMPROVED
	6. IMPROVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390083004

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390083005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390083005/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/51/WHITE/ISRAEL/YES
Medical history	Goitre, Drug hypersensitivity, Uterine leiomyoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AKTIFERRIN, DECAPEPTYL [TRIPTORELIN]
Adverse Events (AE) Preferred term	1. Menorrhagia 2. Haemorrhagic cyst 3. Gastroenteritis viral 4. Mass
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MODERATE/YES/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 04FEB2011 (2) - 06FEB2011 (4) 2. 20FEB2011 (18) - 20FEB2011 (18) 3. 27APR2011 (84) - 28APR2011 (85) 4. 16MAY2011 (103) - 17MAY2011 (104)
Duration of AE	1. 3 2. 1 3. 2 4. 2
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. I 4. .
Action taken	1. NONE 2. NONE 3. STUDY DRUG DISCONTINUED AND RESTARTED 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390083005

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/36/WHITE/ISRAEL/YES
Medical history	
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Pleuritic pain
	2. Dyspnoea
	3. Headache
	4. Subdural haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/YES/YES
	4. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 22JUN2007 (2) - 24JUN2007 (4)
	2. 22JUN2007 (2) - 22JUN2007 (2)
	3. 06MAR2008 (260) - 10MAR2008 (264)
	4. 17MAY2008 (332) - 19MAY2008 (334)
Duration of AE	1. 3
	2. 1
	3. 5
	4. 3
Dose on AE onset	1.
	2.
	3.
	4.
Dose status on AE onset	1.
	2.
	3.
	4.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103001

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-390103001[4)]	CHRONIC SUBDURAL HEMATOMA（PT：硬膜下血腫） 治験担当医は、ワルファリンとの因果関係を否定できると判断した。弊社は、ワルファリンの抗凝固作用及び報告事象との時間的関連性を考慮し、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103014/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/66/WHITE/ISRAEL/YES
Medical history	Appendicectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, DELACIN [CLINDAMYCIN], LOSEC, RIFAMPICIN
Adverse Events (AE) Preferred term	1. Basal cell carcinoma 2. Basal cell carcinoma 3. Dyspepsia 4. Lymphadenopathy
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 08DEC2007 (61) - 08DEC2007 (61) 2. 27APR2008 (202) - 27APR2008 (202) 3. 13JUL2008 (279) - 20JUL2008 (286) 4. 14AUG2008 (311) - 11AUG2009 (673)
Duration of AE	1. 1 2. 1 3. 8 4. 363
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. I 2. I 3. . 4. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103014

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103027

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103027/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/75/WHITE/ISRAEL/YES
Medical history	Hyperlipidaemia, Hypertension, Obesity, Osteoarthritis, Hip arthroplasty, Hip arthroplasty, Umbilical hernia, Uterine leiomyoma, Postmenopause, Malignant melanoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, DISOTHIAZIDE, ENOXAPARIN, LOSEC, ROCEPHIN, SIMVACOR, TRITACE, VASODIP, WARFARIN
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Haematuria 3. Dizziness
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 08MAR2008 (20) - 20MAR2008 (32) 2. 15MAR2008 (27) - 20MAR2008 (32) 3. 15MAR2008 (27) - 16MAR2008 (28)
Duration of AE	1. 13 2. 6 3. 2
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED 3. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-390103027[4)]	HEMATURIA（PT：血尿） 治験担当医は、合併症（尿路感染）によるものであり、否定できると判断した。弊社は、エノキサパリン及びワルファリンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。また、合併症（尿路感染）による可能性も考えられる。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103037

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103037/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/65/WHITE/ISRAEL/YES
Medical history	Blood creatinine increased, Cholelithiasis, Hypertension, Leukocytosis, Peptic ulcer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	COLCHICINE, LOPRESSOR, LOSEC, NORMITEN, OCSAAR PLUS, ROCEPHIN, ROXIMYCIN, ROXO
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Upper respiratory tract infection 3. Gout 4. Influenza
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 19MAY2008 (7) - 20MAY2008 (8) 2. 15SEP2008 (126) - 21SEP2008 (132) 3. 22SEP2008 (133) - 04OCT2008 (145) 4. 14JAN2009 (247) - 21JAN2009 (254)
Duration of AE	1. 2 2. 7 3. 13 4. 8
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103037

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103039

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103039/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/73/WHITE/ISRAEL/YES
Medical history	Asthma, Gastrooesophageal reflux disease, Glaucoma, Haematuria, Hernia, Hypertension, Back pain, Obesity, Urinary incontinence, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CATAFLAM, OCSAAR, OMEPRADEX, OPTALGIN, OSMO ADALAT, VENTOLIN
Adverse Events (AE) Preferred term	1. Haematemesis 2. Hiatus hernia 3. Periodontitis 4. Periodontitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 17JUN2008 (15) - 23JUN2008 (21) 2. 18JUN2008 (16) - --------- (.) 3. 01SEP2008 (91) - 01SEP2008 (91) 4. 02DEC2008 (183) - 02DEC2008 (183)
Duration of AE	1. 7 2. . 3. 1 4. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. I 3. . 4. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED 2. NONE 3. OTHER 4. OTHER
Outcome of event	1. RESOLVED 2. UNCHANGED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103039

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103040

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103040/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/29/WHITE/ISRAEL/YES
Medical history	Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, HEPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Pleural effusion
	2. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
	2. MILD/YES/NO/NO
Start/stop date of event with relative date	1. 24JUL2008 (4) - 12AUG2008 (23)
	2. 01SEP2008 (43) - -----2009 (.)
Duration of AE	1. 20
	2. .
Dose on AE onset	1.
	2.
Dose status on AE onset	1.
	2.
Action taken	1. OTHER
	2. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103044

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103044/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/41/WHITE/ISRAEL/YES
Medical history	Anaemia, Ankle fracture, Thrombocytosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACAMOL, FERROUS FUMARATE, OMEPRADEX, ROCEPHIN, RULID, SOL. OPTALGIN, TAVANIC, VITAMIN C
Adverse Events (AE) Preferred term	1. Pyrexia 2. Cough 3. Dyspnoea 4. Coeliac disease 5. Iron deficiency
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 14OCT2008 (2) - 20OCT2008 (8) 2. 14OCT2008 (2) - 20OCT2008 (8) 3. 14OCT2008 (2) - 20OCT2008 (8) 4. 05APR2009 (175) - --------- (.) 5. 06JUL2009 (267) - --------- (.)
Duration of AE	1. 7 2. 7 3. 7 4. . 5. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. I 5. .
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. NONE 4. STUDY DRUG DISCONTINUED AND RESTARTED 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103044

Parameter	Value
	4. UNCHANGED
	5. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103056

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103056/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/73/WHITE/ISRAEL/YES
Medical history	Essential hypertension, Obesity, Lipid metabolism disorder, Renal cell carcinoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, RAMITENS, SIMVACOR, WARFARIN
Adverse Events (AE) Preferred term	1. Renal mass
	2. Pneumonia
	3. Haematoma
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/NO
	2. SEVERE/NO/YES/NO
	3. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 05JUL2009 (161) - 07JUL2009 (163)
	2. 07JUL2009 (163) - 14JUL2009 (170)
	3. 26JUL2009 (182) - 06AUG2009 (193)
Duration of AE	1. 3
	2. 8
	3. 12
Dose on AE onset	1.
	2.
	3.
Dose status on AE onset	1.
	2.
	3.
Action taken	1. OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103065

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103065/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/84/WHITE/ISRAEL/YES
Medical history	Benign prostatic hyperplasia, Creatinine renal clearance decreased, Myocardial infarction, Myocardial ischaemia, Coronary artery bypass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AHISTON, ASPIRIN, BETACORTEN, DILATAM, ENOXAPARIN, LIPITOR, LOSEC, PROLOL, VASCACE PLUS, WARFARIN, XATRAL XL
Adverse Events (AE) Preferred term	1. Prostatic mass 2. Dermatitis contact
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 04FEB2010 (7) - 06MAY2010 (98) 2. 08FEB2010 (11) - 14FEB2010 (17)
Duration of AE	1. 92 2. 7
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103069

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103069/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/38/WHITE/ISRAEL/YES
Medical history	Appendicectomy, Benign prostatic hyperplasia, Varicella, Pneumonia, Hernia repair
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, LOSEC, ROCEPHIN, RULID, WARFARIN, XATRAL, ZINNAT
Adverse Events (AE) Preferred term	1. Pleuritic pain
	2. Dental caries
	3. Subcutaneous haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
	2. MILD/NO/NO/YES
	3. MILD/YES/NO/NO
Start/stop date of event with relative date	1. 22APR2010 (43) - 23APR2010 (44)
	2. 04JUL2010 (116) - 04JUL2010 (116)
	3. 20MAR2011 (375) - 30MAR2011 (385)
Duration of AE	1. 2
	2. 1
	3. 11
Dose on AE onset	1.
	2.
	3.
Dose status on AE onset	1.
	2.
	3.
Action taken	1. OTHER
	2. INFUSION RATE OF STUDY DRUG REDUCED,OTHER
	3. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103072

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103072/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/91/WHITE/ISRAEL/YES
Medical history	Benign prostatic hyperplasia, Bronchitis chronic, Diverticulum intestinal, Diaphragmatic hernia, Fatigue, Hypertension, Acute myocardial infarction, Peripheral vascular disorder, Varicose vein, Carotid artery occlusion, Impaired fasting glucose, Venous insufficiency, Mesenteric panniculitis, Inguinal hernia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, AVODART, CALCIUM +D3, CIPROFLOXACIN, LOSARTAN, LOSEC, METFORMIN, PROCTOGLYCERINE, SEDURAL, SIMVAXON, TAMSULOSIN HCL
Adverse Events (AE) Preferred term	1. Haematuria 2. Urinary tract infection 3. Rectal haemorrhage 4. Haemorrhoids
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/YES/YES 4. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 09APR2010 (2) - 09APR2010 (2) 2. 21APR2010 (14) - 28APR2010 (21) 3. 13MAY2010 (36) - 14MAY2010 (37) 4. 16MAY2010 (39) - --------- (.)
Duration of AE	1. 1 2. 8 3. 2 4. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. I 4. .
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED AND RESTARTED 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103072

Parameter	Value
	4. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103076

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103076/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/75/WHITE/ISRAEL/YES
Medical history	Blood creatinine increased, Diverticulitis, Atrial fibrillation, Hypercholesterolaemia, Hypertension, Hypothyroidism, Back pain, Spinal osteoarthritis, Menopause, Musculoskeletal pain, Polymyalgia rheumatica, Intracardiac thrombus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATACAND PLUS, AVILAC, CADEX, CLEXAN, DEPO MEDROL, ELTROXIN, FUSID, LOSEC, PRENDINZON, PROCOR, SIMOVIL, VERACOR, ZINNAT
Adverse Events (AE) Preferred term	1. Alopecia 2. Pyrexia 3. Gastrointestinal haemorrhage 4. Atrial fibrillation 5. Rotator cuff syndrome 6. Osteoarthritis 7. Operative haemorrhage 8. Spinal laminectomy 9. Thyroid cyst 10. Thyroid neoplasm 11. Traumatic haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/YES/YES/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/YES/NO/NO
Start/stop date of event with relative date	1. --OCT2010 (.) - --------- (.) 2. 31AUG2010 (5) - 31AUG2010 (5) 3. 16SEP2010 (21) - 18SEP2010 (23) 4. 20SEP2010 (25) - 28SEP2010 (33) 5. 30JAN2011 (157) - --------- (.) 6. 30JAN2011 (157) - --------- (.) 7. 01MAY2011 (248) - 01MAY2011 (248) 8. 01MAY2011 (248) - 01MAY2011 (248) 9. 29MAY2011 (276) - --------- (.) 10. 29MAY2011 (276) - --------- (.) 11. 11SEP2011 (381) - 14SEP2011 (384)
Duration of AE	1. . 2. 1 3. 3

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103076

Parameter	Value
	4. 9
	5. .
	6. .
	7. 1
	8. 1
	9. .
	10. .
	11. 4
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. I
	5. .
	6. .
	7. I
	8. I
	9. .
	10. .
	11. F
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	5. NONE
	6. STUDY DRUG DISCONTINUED AND RESTARTED
	7. OTHER
	8. STUDY DRUG DISCONTINUED AND RESTARTED
	9. NONE
	10. NONE
	11. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103076

Parameter	Value
	4. RESOLVED
	5. UNCHANGED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. UNCHANGED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103077

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103077/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/ISRAEL/YES
Medical history	Hyperlipidaemia, Hypertension, Obesity, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACAMOL, ENOXAPARIN, HERPCLAIR, LOSEC, PRAVASTATIN, TORCHE [ORLATEN, CLOTRIMAZOLE 10 MG], VASODIP, WARFARIN, ZOVIRAX
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Diarrhoea 3. Vertigo 4. Herpes virus infection 5. Nasopharyngitis 6. Varicose vein 7. Rash 8. Blood thyroid stimulating hormone increased 9. Diarrhoea 10. Vomiting 11. Musculoskeletal stiffness 12. Stomatitis 13. Oral herpes 14. Oral candidiasis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/YES/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 06OCT2010 (30) - 06OCT2010 (30) 2. 03NOV2010 (58) - 14NOV2010 (69) 3. 06NOV2010 (61) - 07NOV2010 (62) 4. 09NOV2010 (64) - 15NOV2010 (70) 5. 31DEC2010 (116) - 02JAN2011 (118) 6. 10JAN2011 (126) - --------- (.) 7. 03MAR2011 (178) - 04MAR2011 (179) 8. 16MAY2011 (252) - --------- (.) 9. 25MAY2011 (261) - 25MAY2011 (261) 10. 25MAY2011 (261) - 25MAY2011 (261)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103077

Parameter	Value
	11. 12JUL2011 (309) - 26JUL2011 (323)
	12. 19AUG2011 (347) - --------- (.)
	13. 26AUG2011 (354) - 29AUG2011 (357)
	14. 29AUG2011 (357) - --------- (.)
Duration of AE	1. 1
	2. 12
	3. 2
	4. 7
	5. 3
	6. .
	7. 2
	8. .
	9. 1
	10. 1
	11. 15
	12. .
	13. 4
	14. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103077

Parameter	Value
	13.
	14.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. IMPROVED
	13. RESOLVED
	14. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103080

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103080/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/75/WHITE/ISRAEL/YES
Medical history	Diabetes mellitus, Hip arthroplasty, Hyperlipidaemia, Hypertension, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CO-DIOVAN, GLUCOPHAGE, LIPITOR, LOPRESSOR, VASODIP
Adverse Events (AE) Preferred term	1. Hepatic steatosis 2. Dyspnoea 3. Muscular weakness 4. Gait disturbance 5. Pulmonary congestion 6. Fatigue 7. Depression
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/NO 6. MODERATE/NO/YES/NO 7. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 18OCT2010 (7) - --------- (.) 2. 25OCT2010 (14) - 25OCT2010 (14) 3. 29APR2011 (200) - 30APR2011 (201) 4. 07MAY2011 (208) - --------- (.) 5. 31JUL2011 (293) - 04AUG2011 (297) 6. 02AUG2011 (295) - 07AUG2011 (300) 7. 03AUG2011 (296) - --------- (.)
Duration of AE	1. . 2. 1 3. 2 4. . 5. 5 6. 6 7. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103080

Parameter	Value
	5. F
	6. F
	7. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103091

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390103091/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/58/WHITE/ISRAEL/YES
Medical history	Crohn's disease, Goitre, Obesity, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CARDILOC, ENOXAPARIN, FENISTIL GEL, RAFASSAL, RAMIPRIL, RAMIPRIL PLUS, WARFARIN
Adverse Events (AE) Preferred term	1. Palpitations 2. Conjunctival haemorrhage 3. Hypertension 4. Palpitations 5. Rash
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 11FEB2011 (3) - 12FEB2011 (4) 2. 15APR2011 (66) - 15APR2011 (66) 3. 15APR2011 (66) - --------- (.) 4. 01JUN2011 (113) - 30JUN2011 (142) 5. 27JUL2011 (169) - --------- (.)
Duration of AE	1. 2 2. 1 3. . 4. 30 5. .
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. IMPROVED 4. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390103091

Parameter	Value
	5. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 390113008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/390113008/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/ISRAEL/YES
Medical history	Appendicectomy, Hyperlipidaemia, Melaena, Renal failure, Myocardial ischaemia, Coronary artery bypass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, CEFUROXINE, ENOXAPARIN, FOLIC ACID, FUSID, LOSEC, METRANIAZOLE, NORMITEN, SIMOVIL, SLOW FE, SLOW K, WARFARIN
Adverse Events (AE) Preferred term	1. Cholecystitis
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 09MAR2009 (4) - 10MAR2009 (5)
Duration of AE	1. 2
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. NONE
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400013002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400013002/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/90/WHITE/AUSTRALIA/YES
Medical history	Cataract, Glaucoma, Hypercholesterolaemia, Hypertension, Pleural effusion, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPINE, BETOPTIC, CALTRATE [CALCIUM CARBONATE WITH VIT D.], COLOXYL & SENNA, ENOXAPARIN, FRUSEMIDE, LACTULOSE, LASIX, MOXIFLOXACIN, PANADEINE FORTE, PANADOL, PRAVASTATIN, TRIMETHROPRIM
Adverse Events (AE) Preferred term	1. Chest pain 2. Pneumonia 3. Pleural effusion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/NO 2. MILD/NO/YES/NO 3. MILD/NO/YES/NO
Start/stop date of event with relative date	1. 29FEB2008 (198) - 06MAR2008 (204) 2. 29FEB2008 (198) - 06MAR2008 (204) 3. 29FEB2008 (198) - 06MAR2008 (204)
Duration of AE	1. 7 2. 7 3. 7
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. F 2. F 3. F
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. OTHER 3. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400013004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400013004/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/77/WHITE/AUSTRALIA/YES
Medical history	Breast cancer, Cardiac failure chronic, Depression, Hypercholesterolaemia, Hypertension, Pleural effusion, Rash, Respiratory disorder, Herpes zoster, Postmenopause, Congestive cardiomyopathy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMITRIPTYLINE, AUGMENTIN DUO FORTE, BISOPROLOL, BUMETANIDE, CALAMINE, CEFTRIAXONE, ENOXAPARIN, FRUSEMIDE, LORATADINE, METHYL PREDNISONE CREAM, PREGABALIN, SERETIDE, SPIRONOLACTONE, VENTOLIN
Adverse Events (AE) Preferred term	1. Rash 2. Congestive cardiomyopathy 3. Confusional state 4. International normalised ratio increased 5. Hepatic enzyme increased 6. Hepatic encephalopathy
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/YES/NO/YES 5. SEVERE/YES/YES/YES 6. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 21SEP2007 (3) - 06DEC2007 (79) 2. 29FEB2008 (164) - --------- (.) 3. 01MAR2008 (165) - --------- (.) 4. 02MAR2008 (166) - 07APR2008 (202) 5. 06MAR2008 (170) - --------- (.) 6. 06MAR2008 (170) - --------- (.)
Duration of AE	1. 77 2. . 3. . 4. 37 5. . 6. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. F 6. F

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400013004

Parameter	Value
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED PERMANENTLY
	4. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. UNCHANGED
	4. RESOLVED
	5. IMPROVED
	6. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400013004[2),2)]	ELEVATED LIVER ENZYMES（PT：肝酵素上昇） 治験担当医はリバーロキサバンとの関連性はあると判断した。弊社は、うっ血性心不全の悪化による心拍出量の低下から肝機能低下が引き起こされたと判断し、リバーロキサバンとの因果関係は否定できると考える。 HEPATIC ENCEPHALOPATHY（PT：肝性脳症） 治験担当医はリバーロキサバンとの関連性はあると判断した。弊社は、うっ血性心不全の悪化による心拍出量の低下から肝機能低下が引き起こされ、それに伴う脳症と考えられることから、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400013010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400013010/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/66/WHITE/AUSTRALIA/YES
Medical history	Benign prostatic hyperplasia, Hypercholesterolaemia, Hypertension, Sepsis, Lung cancer metastatic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, PARACETAMOL, SIMVASTATIN, TENORMIN
Adverse Events (AE) Preferred term	1. Gingival bleeding 2. Gingival bleeding 3. Contusion 4. Ischaemic stroke
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 01FEB2008 (1) - --------- (.) 2. 08FEB2008 (8) - 09FEB2008 (9) 3. 29FEB2008 (29) - 29FEB2008 (29) 4. 11MAR2008 (40) - 31MAR2008 (60)
Duration of AE	1. . 2. 2 3. 1 4. 21
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. NONE 2. NONE 3. NONE 4. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. INSUFFICIENT FOLLOW-UP 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400013010

Parameter	Value
	4. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400023009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400023009/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/70/WHITE/AUSTRALIA/YES
Medical history	Cardiomyopathy, Hypercholesterolaemia, Hypertension, Implantable defibrillator insertion, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DILATREND, FERROGRAD C, NEXIUM, PANTOPRAZOLE, SOMAC, ZESTRIL, ZOCOR
Adverse Events (AE) Preferred term	1. Oesophageal ulcer
	2. Anaemia
	3. Gastrointestinal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES
	2. MODERATE/NO/NO/YES
	3. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 27AUG2008 (91) - 29AUG2008 (93)
	2. 27AUG2008 (91) - 06NOV2008 (162)
	3. 27AUG2008 (91) - 06NOV2008 (162)
Duration of AE	1. 3
	2. 72
	3. 72
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
Dose status on AE onset	1. I
	2. I
	3. I
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400023022

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400023022/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/46/WHITE/AUSTRALIA/YES
Medical history	Breast cancer, Modified radical mastectomy, Insomnia, Transient ischaemic attack
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, PARACETAMOL, TEMAZEPAM, WARFARIN
Adverse Events (AE) Preferred term	1. Headache
	2. Vision blurred
	3. Muscular weakness
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
	2. SEVERE/NO/YES/YES
	3. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 01MAR2009 (17) - 03MAR2009 (19)
	2. 01MAR2009 (17) - 03MAR2009 (19)
	3. 01MAR2009 (17) - 03MAR2009 (19)
Duration of AE	1. 3
	2. 3
	3. 3
Dose on AE onset	1.
	2.
	3.
Dose status on AE onset	1.
	2.
	3.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400023026

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400023026/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/33/WHITE/AUSTRALIA/YES
Medical history	Asthma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Palpitations 3. Dyspnoea 4. Palpitations
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 26JUN2009 (72) - 27JUN2009 (73) 2. 26JUN2009 (72) - 27JUN2009 (73) 3. 28JUN2009 (74) - 10SEP2009 (148) 4. 28JUN2009 (74) - 16OCT2009 (184)
Duration of AE	1. 2 2. 2 3. 75 4. 111
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. I 2. I 3. . 4. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 3. NONE 4. NONE
Outcome of event	1. IMPROVED 2. IMPROVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400023026

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400023029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400023029/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/38/WHITE/AUSTRALIA/YES
Medical history	Hand fracture, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DIABEX, ENOXAPARIN, FLUCLOXACILLIN, NUROFEN PLUS, PARACETAMOL, TRAMADOL, WARFARIN
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Pain in extremity 3. Localised infection 4. Toothache 5. Weight decreased 6. Traumatic haemorrhage 7. Wound haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 19MAY2009 (20) - 20MAY2009 (21) 2. 19MAY2009 (20) - 03JUN2009 (35) 3. 19MAY2009 (20) - 03JUN2009 (35) 4. 02JUN2009 (34) - 03JUN2009 (35) 5. 23JUL2009 (85) - 20AUG2009 (113) 6. 09AUG2009 (102) - 10AUG2009 (103) 7. 01SEP2009 (125) - -------- (.)
Duration of AE	1. 2 2. 16 3. 16 4. 2 5. 29 6. 2 7. .
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400023029

Parameter	Value
	4.
	5.
	6.
	7.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400023035

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400023035/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/74/WHITE/AUSTRALIA/YES
Medical history	Coronary artery bypass, Gastrooesophageal reflux disease, Grand mal convulsion, Hypercholesterolaemia, Hypertension, Hypokalaemia, Hypomagnesaemia, Insomnia, Myocardial ischaemia, Skin neoplasm excision, Myelodysplastic syndrome, Pyrexia, Respiratory failure, Grand mal convulsion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPINE, ASPIRIN, ENOXAPARIN, FLUCLOXACILLIN, IMDUR, PANTOPRAZOLE, RAMIPRIL, SIMVASTATIN, TEMAZEPAM, VALPORATE EC, WARFARIN
Adverse Events (AE) Preferred term	1. Thrombophlebitis 2. Anticonvulsant drug level decreased 3. Glioblastoma multiforme 4. Post procedural haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/NO 4. SEVERE/NO/NO/NO
Start/stop date of event with relative date	1. 22FEB2010 (4) - 28FEB2010 (10) 2. 24FEB2010 (6) - --------- (.) 3. 31MAR2010 (41) - 08APR2010 (49) 4. 31MAR2010 (41) - 31MAR2010 (41)
Duration of AE	1. 7 2. . 3. 9 4. 1
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER 4. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. RESOLVED 2. UNCHANGED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400023035

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400023039

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400023039/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/64/WHITE/AUSTRALIA/YES
Medical history	Venous ligation, Varicose vein operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Haemoptysis
	2. Headache
	3. Hypoaesthesia
	4. Paraesthesia
	5. Headache
	6. Cough
	7. Haematuria
	8. Wound haemorrhage
	9. Wound haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/NO/YES
	4. MILD/NO/NO/YES
	5. MILD/NO/NO/YES
	6. MILD/NO/NO/YES
	7. MILD/YES/NO/YES
	8. MILD/NO/NO/YES
	9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 25MAR2010 (2) - 29MAR2010 (6)
	2. 26MAR2010 (3) - 26MAR2010 (3)
	3. 26MAR2010 (3) - 29MAR2010 (6)
	4. 26MAR2010 (3) - 29MAR2010 (6)
	5. 26MAR2010 (3) - 29MAR2010 (6)
	6. 30MAR2010 (7) - 30MAR2010 (7)
	7. 13APR2010 (21) - 13APR2010 (21)
	8. 21APR2010 (29) - 21APR2010 (29)
	9. 16SEP2010 (177) - 16SEP2010 (177)
Duration of AE	1. 5
	2. 1
	3. 4
	4. 4
	5. 4
	6. 1
	7. 1
	8. 1
	9. 1
Dose on AE onset	1.
	2.
	3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400023039

Parameter	Value
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033012/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/94/WHITE/AUSTRALIA/YES
Medical history	Atrial fibrillation, Dementia, Hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANGININE, ASPIRIN, ATROPINE, CANDESARTAN, CLOPIDOGREL, DIGOXIN, DONEPEZIL, ENDONE, ENOXAPARIN, ESOMEPRAZOLE, FRUSEMIDE, HALOPERIDOL, MAXALON, METOPROLOL, MORPHINE, NORMAL SALINE, PANADOL, SALBUTAMOL, TEMAZEPAM, TRIMETHOPRIM
Adverse Events (AE) Preferred term	1. Acute myocardial infarction 2. Acute pulmonary oedema 3. Cardiac failure congestive 4. Bradycardia 5. Agitation 6. Hypertension
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/YES/YES 3. SEVERE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 12JUN2008 (98) - 13JUN2008 (99) 2. 12JUN2008 (98) - 17JUN2008 (103) 3. 12JUN2008 (98) - --------- (.) 4. 12JUN2008 (98) - 12JUN2008 (98) 5. 13JUN2008 (99) - 16JUN2008 (102) 6. 13JUN2008 (99) - 16JUN2008 (102)
Duration of AE	1. 2 2. 6 3. . 4. 1 5. 4 6. 4
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033012

Parameter	Value
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. DEATH
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033013/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/69/WHITE/AUSTRALIA/YES
Medical history	Cholecystectomy, Renal impairment, Depression, Hyperlipidaemia, Hypertension, Myocardial ischaemia, Oedema peripheral, Gastrooesophageal reflux disease, Atrial fibrillation, Polymyalgia rheumatica, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPRIN, ATACAND [CANDESARTAN CILEXETIL; LACTOSE], ATENOLOL, BRUFEN, ENDONE, ENOXAPARIN, FLECATAB, FRUSEMIDE, GLYCERYL TRINITRATE, MAXOLON, MORPHINE, MYLANTA [SIMETHICONE; MG(OH)2; AL(OH)3 GEL DRIED; HYDROXYBENZOATES; NA SACCHARIN, NEXIUM, NITRO-DUR PATCH, PARACETAMOL, PREDNISONE, SIMVASTATIN, VENLAFAXINE, WARFARIN
Adverse Events (AE) Preferred term	1. Chest pain 2. Sciatica
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 14SEP2008 (172) - 18SEP2008 (176) 2. 16DEC2008 (265) - --------- (.)
Duration of AE	1. 5 2. .
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033017/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/53/WHITE/AUSTRALIA/YES
Medical history	Alcohol abuse, Epilepsy, Ankle fracture, Hypercholesterolaemia, Hypertension, Vitamin B12 deficiency, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPINE, ENOXAPARIN, LIPITOR, PANAMAX, PHENYTOIN, SPAN K, THIAMINE, WARFARIN
Adverse Events (AE) Preferred term	1. Hypercholesterolaemia 2. Hypokalaemia 3. Convulsion 4. Hepatic steatosis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/NO 4. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --NOV2008 (.) - --------- (.) 2. 04MAY2008 (3) - --------- (.) 3. 23NOV2008 (206) - 23NOV2008 (206) 4. 25NOV2008 (208) - --------- (.)
Duration of AE	1. . 2. . 3. 1 4. .
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY,OTHER 3. REMEDIAL DRUG THERAPY 4. NONE
Outcome of event	1. UNCHANGED 2. IMPROVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033017

Parameter	Value
	4. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033021/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/56/WHITE/AUSTRALIA/YES
Medical history	Anxiety, Breast cancer, Depression, Pain in extremity, Postmenopause, Brachial plexopathy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATENOLOL, CHLOROMYCETIN EYE DROPS, CHLOROMYCETIN EYE OINTMENT, CHOLECALCIFEROL, COLOXYL WITH SENNA, ENOXAPARIN, FENTANYL, FLUCLOX, GENTAMICIN, HEPARIN, HERCEPTIN, INTRATHECAL PHENOL, IVC FILTER, KAPANOL, LYRICA, MEXITIL, MIDAZOLAM, MOVICOL, OXYCODONE, OXYCONTIN, PARACETAMOL, TEMAZEPAM, TRAMADOL, VANCOMYCIN, VITAMIN K, WARFARIN, XELODA
Adverse Events (AE) Preferred term	1. Cellulitis 2. Hypertension 3. Headache 4. Palpitations 5. Musculoskeletal pain 6. Thrombosis 7. Musculoskeletal pain 8. Pleural effusion 9. Pleural effusion 10. Malignant pleural effusion 11. Cellulitis 12. Conjunctivitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. SEVERE/NO/YES/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. SEVERE/NO/YES/YES 9. SEVERE/NO/YES/YES 10. MODERATE/NO/YES/YES 11. MODERATE/NO/YES/YES 12. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --SEP2008 (.) - 26MAR2009 (269) 2. 21JUL2008 (21) - --------- (.) 3. 22JUL2008 (22) - 23JUL2008 (23) 4. 22JUL2008 (22) - 22JUL2008 (22) 5. 12SEP2008 (74) - 08OCT2008 (100) 6. 17SEP2008 (79) - 17SEP2008 (79) 7. 08OCT2008 (100) - --------- (.) 8. 05DEC2008 (158) - 12DEC2008 (165) 9. 28DEC2008 (181) - 31DEC2008 (184) 10. 11JAN2009 (195) - --------- (.) 11. 26MAR2009 (269) - 07APR2009 (281)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033021

Parameter	Value
	12. 31MAR2009 (274) - 07APR2009 (281)
Duration of AE	1. .
	2. .
	3. 2
	4. 1
	5. 27
	6. 1
	7. .
	8. 8
	9. 4
	10. .
	11. 13
	12. 8
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033021

Parameter	Value
	8. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	9. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	10. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
Outcome of event	1. WORSENED
	2. IMPROVED
	3. RESOLVED
	4. RESOLVED
	5. IMPROVED
	6. RESOLVED
	7. IMPROVED
	8. RESOLVED
	9. RESOLVED
	10. UNCHANGED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033024

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033024/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/76/WHITE/AUSTRALIA/YES
Medical history	Depression, Gastrooesophageal reflux disease, Hyperlipidaemia, Hypertension, Multiple myeloma, Osteoarthritis, Female sterilisation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BACTRIM, CALTRATE [CALCIUM CARBONATE], COVERSYL PLUS, DEXAMETHASONE, DIFLUCAN, FISH OIL, HYDROCORTISONE, INTRAGAM, LIPITOR, MAXALON, MAXOLON, MELPHALAN, MOTILIUM, MS CONTIN, NEXIUM, PACKED RED BLOOD CELLS, PANAFCORT, PROBITOR [OMEPRAZOLE], SEREPAX, SPAN K, VELCADE, ZOFRAN WAFERS, ZOLOFT, ZOMETA
Adverse Events (AE) Preferred term	1. Steroid withdrawal syndrome 2. Decreased appetite 3. Vomiting 4. Diarrhoea 5. Dehydration 6. Nasopharyngitis 7. Anaemia 8. Pathological fracture 9. Anaemia 10. Oropharyngeal candidiasis 11. Dysphagia 12. Vomiting 13. Hypokalaemia 14. Hypocalcaemia 15. Gastrooesophageal reflux disease 16. Anaemia 17. Anaemia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MODERATE/NO/YES/YES 12. MODERATE/NO/YES/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES 15. MODERATE/NO/NO/YES 16. MODERATE/NO/NO/YES 17. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 27JUL2008 (3) - 31JUL2008 (7)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033024

Parameter	Value
	2. 31JUL2008 (7) - 03AUG2008 (10)
	3. 05AUG2008 (12) - 05AUG2008 (12)
	4. 05AUG2008 (12) - 05AUG2008 (12)
	5. 06AUG2008 (13) - 06AUG2008 (13)
	6. 28AUG2008 (35) - 25SEP2008 (63)
	7. 30AUG2008 (37) - 04SEP2008 (42)
	8. 15SEP2008 (53) - --------- (.)
	9. 24SEP2008 (62) - 26SEP2008 (64)
	10. 20OCT2008 (88) - --------- (.)
	11. 24OCT2008 (92) - --------- (.)
	12. 24OCT2008 (92) - 29OCT2008 (97)
	13. 24OCT2008 (92) - 26OCT2008 (94)
	14. 24OCT2008 (92) - --------- (.)
	15. 24OCT2008 (92) - 24OCT2008 (92)
	16. 13NOV2008 (112) - 13NOV2008 (112)
	17. 18DEC2008 (147) - --------- (.)
Duration of AE	1. 5
	2. 4
	3. 1
	4. 1
	5. 1
	6. 29
	7. 6
	8. .
	9. 3
	10. .
	11. .
	12. 6
	13. 3
	14. .
	15. 1
	16. 1
	17. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033024

Parameter	Value
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY,OTHER
	8. OTHER
	9. REMEDIAL DRUG THERAPY,OTHER
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY,OTHER
	17. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033024

Parameter	Value
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED
	10. IMPROVED
	11. IMPROVED
	12. RESOLVED
	13. RESOLVED
	14. UNCHANGED
	15. RESOLVED
	16. RESOLVED
	17. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033035

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033035/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/70/WHITE/AUSTRALIA/YES
Medical history	Gastrooesophageal reflux disease, Hypercholesterolaemia, Hypertension, Thyroidectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AGAROL, ATORVASTATIN, CARTIA, CEFTRIAXONE, CITRACAL, COLOXYL [DOCUSATE SODIUM], COVERSYL PLUS, COVERSYL PLUS LD, ENOXAPARIN, ERYTHROMYCIN, HEPARIN, NEXIUM, OMEPRAZOLE, PARACETAMOL, ROXITHROMYCIN, TEMAZEPAM, THYROXINE, WARFARIN
Adverse Events (AE) Preferred term	1. Haemorrhoids 2. Palpitations 3. Pleural effusion 4. Mesothelioma malignant 5. Pleural effusion 6. Vomiting 7. Neutropenia 8. Haemoglobin decreased 9. Hypomagnesaemia 10. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/NO/NO 6. MODERATE/NO/NO/NO 7. MODERATE/NO/YES/NO 8. MODERATE/NO/NO/NO 9. MODERATE/NO/NO/NO 10. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --APR2009 (.) - --------- (.) 2. 19DEC2008 (22) - 19DEC2008 (22) 3. 28JAN2009 (62) - 30JAN2009 (64) 4. 22FEB2009 (87) - --------- (.) 5. 13MAR2009 (106) - --------- (.) 6. 24MAY2009 (178) - 24MAY2009 (178) 7. 20NOV2009 (358) - 03DEC2009 (371) 8. 21NOV2009 (359) - --------- (.) 9. 22NOV2009 (360) - 27NOV2009 (365) 10. 17DEC2009 (385) - --------- (.)
Duration of AE	1. . 2. 1 3. 3 4. . 5. . 6. 1

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033035

Parameter	Value
	7. 14
	8. .
	9. 6
	10. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY,OTHER
	4. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	5. OTHER
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. OTHER
	9. REMEDIAL DRUG THERAPY
	10. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033035

Parameter	Value
	10. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033042

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033042/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/AUSTRALIA/YES
Medical history	Coronary artery stenosis, Diverticulitis, Extrasystoles, Gastrooesophageal reflux disease, Hyperlipidaemia, Hypertension, Myocardial ischaemia, Musculoskeletal pain, Myocardial infarction, Coronary artery bypass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, ATENOLOL, CLOPIDOGREL, EZETROL, FISH OIL, GTN SPRAY, IBILEX, LIPITOR, NEXIUM, PANADOL, PARACETAMOL, RAMIPRIL
Adverse Events (AE) Preferred term	1. Abdominal discomfort 2. Dizziness 3. Musculoskeletal pain 4. Basal cell carcinoma 5. Lower extremity mass 6. Post procedural haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/YES/NO/YES
Start/stop date of event with relative date	1. -----2009 (.) - 09MAR2009 (18) 2. 28FEB2009 (9) - --------- (.) 3. 16APR2009 (56) - 18APR2009 (58) 4. 12JUN2009 (113) - 12JUN2009 (113) 5. 12AUG2009 (174) - 10SEP2009 (203) 6. 13AUG2009 (175) - 13AUG2009 (175)
Duration of AE	1. . 2. . 3. 3 4. 1 5. 30 6. 1
Dose on AE onset	1. 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. . 5. . 6. .
Action taken	1. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033042

Parameter	Value
	2. OTHER
	3. REMEDIAL DRUG THERAPY,OTHER
	4. OTHER
	5. REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033043

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033043/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/73/WHITE/AUSTRALIA/YES
Medical history	Abdominal pain, Constipation, Diverticulitis, Gastrooesophageal reflux disease, Gout, Hypertension, Mesothelioma malignant, Osteoarthritis, Dyspnoea, Vertigo positional
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPINE, AUGMENTIN DUO FORTE, BUSCOPAN, CEFTRIAXONE, DITROPAN, GLYCOPYRROLATE, GTN PATCH, IBUPROFEN, KEFLEX, LASIX, LORAZEPAM, MAXOLON, METOPROLOL, MIDAZOLAM, MORPHINE, MOVICOL, MS CONTIN, OMEPRAZOLE, PARACETAMOL, PHOLCODINE LINCTUS, ROXITHROMYCIN
Adverse Events (AE) Preferred term	1. Cardiac failure 2. Cough 3. Bladder spasm 4. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 12MAR2009 (3) - --------- (.) 2. 12MAR2009 (3) - 19MAR2009 (10) 3. 17MAR2009 (8) - 17MAR2009 (8) 4. 24MAR2009 (15) - 25MAR2009 (16)
Duration of AE	1. . 2. 8 3. 1 4. 2
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033043

Parameter	Value
	4. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033049

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033049/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/73/WHITE/AUSTRALIA/YES
Medical history	Depression, Hyperlipidaemia, Hypertension, Osteoporosis, Sciatica, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	COVERSYL, EFEXOR, ENDONE, FOSAMAX, FRUSEMIDE, GLUCOSAMINE, IVC FILTER, LIPITOR, NEXIUM, OMEGA-3 FISHOIL CAPSULES, PANADEINE FORTE, PANADOL
Adverse Events (AE) Preferred term	1. Fluid retention 2. Skin infection 3. Gastric ulcer haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. --AUG2009 (.) - --------- (.) 2. --NOV2009 (.) - --DEC2009 (.) 3. 11JUN2009 (9) - 23JUN2009 (21)
Duration of AE	1. . 2. . 3. 13
Dose on AE onset	1. 2. 3. 15 mg
Dose status on AE onset	1. 2. 3. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. IMPROVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033052

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033052/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/58/WHITE/AUSTRALIA/YES
Medical history	Urticaria, Hypertension, Obesity, Hyperlipidaemia, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMARYL, ASPIRIN, GLUCOSAMINE, PARACETAMOL, PERSANTIN SR, TEMAZE, ZYRTEC
Adverse Events (AE) Preferred term	1. Back pain 2. Non-small cell lung cancer 3. Ischaemic stroke 4. Haemorrhagic transformation stroke 5. Cough
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 29JUN2009 (7) - --JUL2009 (.) 2. 28JUL2009 (36) - --------- (.) 3. 31JUL2009 (39) - 03AUG2009 (42) 4. 03AUG2009 (42) - 23AUG2009 (62) 5. 12AUG2009 (51) - 17AUG2009 (56)
Duration of AE	1. . 2. . 3. 4 4. 21 5. 6
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. F 5. F
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY,OTHER 3. REMEDIAL DRUG THERAPY 4. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. UNCHANGED 3. WORSENED 4. DEATH

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033052

Parameter	Value
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033058

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033058/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/62/WHITE/AUSTRALIA/YES
Medical history	Diverticulum, Dupuytren's contracture, Gout, Irritable bowel syndrome, Gastrooesophageal reflux disease, Post-traumatic stress disorder, Spinal column stenosis, Pertussis, Seasonal allergy, Prostatomegaly, Dyslipidaemia, Spondylitis, Bladder hypertrophy, Renal failure chronic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CRESTOR, DIAZEPAM-DP, DICLOFENAC SODIUM, FLUVASTATIN, IMOVANE, INDOCID, LIPIDIL, MOVOX, NEXIUM, PENICILLIN/AMOXYCILLIN, PERIACTIN, PROGOUT, TRAMAL, WARFARIN
Adverse Events (AE) Preferred term	1. Cough 2. Coronary artery occlusion 3. Upper respiratory tract infection 4. Haemorrhoids 5. Pain in extremity 6. Diverticulum
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 29DEC2009 (133) - --------- (.) 2. 12JAN2010 (147) - --------- (.) 3. 03FEB2010 (169) - 10FEB2010 (176) 4. 17FEB2010 (183) - --------- (.) 5. 02JUL2010 (318) - --------- (.) 6. 28AUG2010 (375) - 03SEP2010 (381)
Duration of AE	1. . 2. . 3. 8 4. . 5. . 6. 7
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. I 3. . 4. . 5. . 6. F

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033058

Parameter	Value
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. UNCHANGED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033059

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033059/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/85/WHITE/AUSTRALIA/YES
Medical history	Aortic valve disease mixed, Atrial fibrillation, Cardiac failure chronic, Hypertension, Mitral valve incompetence, Non-Hodgkin's lymphoma, Pulmonary tuberculosis, Left atrial dilatation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATACAND [CANDESARTAN CILEXETIL; LACTOSE], AUGMENTIN DUO FORTE, BENPEN, BICOR, DILATREND, ENOXAPARIN, FRUSEMIDE, GASTROGEL, METOPROLOL, MOVICOL, RULIDE, WARFARIN
Adverse Events (AE) Preferred term	1. Dizziness postural 2. Haemoptysis 3. Lower respiratory tract infection 4. Cardiac failure 5. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 30OCT2009 (17) - --------- (.) 2. 01JAN2010 (80) - 04JAN2010 (83) 3. 30JAN2010 (109) - 05FEB2010 (115) 4. 30JAN2010 (109) - 05FEB2010 (115) 5. 30JAN2010 (109) - --------- (.)
Duration of AE	1. . 2. 4 3. 7 4. 7 5. .
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. NONE 2. NONE 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY 5. OTHER
Outcome of event	1. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033059

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033068

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033068/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/85/WHITE/AUSTRALIA/YES
Medical history	Aortic aneurysm, Atrial fibrillation, Chronic obstructive pulmonary disease, Constipation, Hip arthroplasty, Hip arthroplasty, Hypotension, Myocardial ischaemia, Meniere's disease, Menopause, Myocardial infarction, Osteoarthritis, Pernicious anaemia, Pneumonia, Renal cyst, Vertigo, Contusion, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, ATROVENT, CEFTRIAXONE, CENTRUM, COLOXYL WITH SENNA, DIGOXIN, ENDONE, GLUCOSAMINE, GLYCEROL SUPPOSITORIES, IVC FILTER, LACTULOSE, LIPEX, MAXALON, MAXOLON, MOVICOL, NEO-B12, PANADEINE FORTE, PANADOL OSTEO, PREDNISONE, ROXITHROMYCIN, SALBUTAMOL, SERETIDE, SPIRIVA, STEMETIL
Adverse Events (AE) Preferred term	1. Haemarthrosis 2. Genital ulceration 3. Nausea 4. Oropharyngeal pain 5. Alopecia 6. Aortic dissection 7. Nausea 8. Back pain 9. Pain in extremity 10. Vomiting
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. SEVERE/NO/YES/NO 7. MILD/NO/NO/NO 8. MILD/NO/NO/NO 9. MILD/NO/NO/NO 10. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 23DEC2009 (2) - 29DEC2009 (8) 2. 23DEC2009 (2) - 24DEC2009 (3) 3. 25DEC2009 (4) - 25DEC2009 (4) 4. 27DEC2009 (6) - 29DEC2009 (8) 5. 11MAR2010 (80) - --------- (.) 6. 22APR2010 (122) - --------- (.) 7. 23APR2010 (123) - 24APR2010 (124) 8. 23APR2010 (123) - --------- (.) 9. 24APR2010 (124) - --------- (.) 10. 25APR2010 (125) - 25APR2010 (125)
Duration of AE	1. 7 2. 2 3. 1 4. 3

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033068

Parameter	Value
	5. .
	6. .
	7. 2
	8. .
	9. .
	10. 1
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1. .
	2. .
	3. I
	4. I
	5. .
	6. F
	7. F
	8. F
	9. F
	10. F
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. OTHER
	5. STUDY DRUG DISCONTINUED PERMANENTLY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. NONE
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. UNCHANGED
	7. RESOLVED
	8. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033068

Parameter	Value
	9. UNCHANGED
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033072

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033072/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/46/WHITE/AUSTRALIA/YES
Medical history	Carpal tunnel syndrome, Migraine, Sciatica, Thrombophlebitis, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENDONE, GLYCERYL TRINITRATE, HYDROXYCHLOROQUINE, METOCLOPRAMIDE, MIRENA DEVICE, MORPHINE, NUROFEN, OMEPRAZOLE, PANADOL, PREMARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Cutaneous lupus erythematosus 2. Angiotensin converting enzyme increased 3. Oedema peripheral 4. Oedema peripheral 5. Muscle tightness 6. Chest pain 7. Presyncope 8. Nausea 9. Hyperhidrosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --APR2010 (.) - --------- (.) 2. 13APR2010 (19) - --------- (.) 3. 29APR2010 (35) - --------- (.) 4. 29APR2010 (35) - --------- (.) 5. 20MAY2010 (56) - 31MAY2010 (67) 6. 24JUL2010 (121) - 24JUL2010 (121) 7. 24JUL2010 (121) - 24JUL2010 (121) 8. 24JUL2010 (121) - 24JUL2010 (121) 9. 24JUL2010 (121) - 24JUL2010 (121)
Duration of AE	1. . 2. . 3. . 4. . 5. 12 6. 1 7. 1 8. 1 9. 1
Dose on AE onset	1. 2. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033072

Parameter	Value
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY,OTHER
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033077

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033077/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/52/WHITE/AUSTRALIA/YES
Medical history	Acute febrile neutrophilic dermatosis, Anxiety, Back pain, Chronic obstructive pulmonary disease, Depression, Hysterectomy, Nausea, Vomiting
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AQUEOUS CREAM [PARAFFIN;NA LAURYLSULPHATE;CETROSTEARYL ALCOHOL;CHLOROCRESOL], ATROVENT, CALTRATE [CALCIUM CARBONATE], CEFTRIZXONE, CHOLECALCIFEROL, CLOPIDOGREL, COLOXYL + SENNA, ENDONE, ENOXAPARIN, ERYTHROMYCIN, FLUVOXAMINE, GENTAMYCIN, METROCLOPRAMIDE, MORPHINE, OMEPRAZOLE, OXAZEPAM, OXYCODONE, OXYCONTIN, PARACETAMOL, PHENERGAN, PREDNISONE, RULIDE, SALBUTAMOL, TEMAZEPAM, WARFARIN
Adverse Events (AE) Preferred term	1. Influenza like illness 2. Productive cough 3. Dizziness 4. Headache 5. Abdominal pain 6. Lower respiratory tract infection 7. Chest pain 8. Dyspnoea 9. Nausea 10. Hyperhidrosis 11. Abscess neck 12. International normalised ratio increased
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. SEVERE/NO/YES/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MODERATE/NO/YES/NO 12. MODERATE/YES/NO/NO
Start/stop date of event with relative date	1. 08JUN2010 (12) - --------- (.) 2. 09JUN2010 (13) - --------- (.) 3. 10JUN2010 (14) - --------- (.) 4. 13JUN2010 (17) - --------- (.) 5. 15JUN2010 (19) - --------- (.) 6. 15JUN2010 (19) - 05JUL2010 (39) 7. 29JUN2010 (33) - 29JUN2010 (33) 8. 29JUN2010 (33) - 29JUN2010 (33) 9. 29JUN2010 (33) - 29JUN2010 (33)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033077

Parameter	Value
	10. 29JUN2010 (33) - 29JUN2010 (33)
	11. 18JUL2010 (52) - --------- (.)
	12. 25JUL2010 (59) - 25JUL2010 (59)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. 21
	7. 1
	8. 1
	9. 1
	10. 1
	11. .
	12. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033077

Parameter	Value
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. IMPROVED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. IMPROVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033085

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400033085/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/AUSTRALIA/YES
Medical history	Benign prostatic hyperplasia, Cerebrovascular accident, Depression, Dysarthria, Dysphagia, Faecal incontinence, Gastrooesophageal reflux disease, Hearing impaired, Hypertension, Myocardial ischaemia, Myocardial ischaemia, Leg amputation, Musculoskeletal pain, Myocardial infarction, Peripheral vascular disorder, Sleep apnoea syndrome, Transient ischaemic attack, Urinary incontinence, Malignant melanoma, Dyslipidaemia, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	50% GLUCOSE, AMLODIPINE, ASPIRIN, ATORVASTATIN, CLOPIDOGREL, ENOXAPARIN, FLUOXETINE, GLICLAZIDE MR, HUMULIN 30/70, INDAPAMIDE, LANTUS, METFORMIN, METOCLOPRAMIDE, METOPROLOL, OMEPRAZOLE, PERINDOPRIL, SALINE, SLOW K, WARFARIN, ZANIDIP
Adverse Events (AE) Preferred term	1. Nausea 2. Vomiting 3. Laceration 4. Dehydration 5. Hypokalaemia 6. Fall 7. Fall 8. Syncope 9. Nausea 10. Vomiting 11. Haematuria 12. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/NO 8. MODERATE/NO/YES/NO 9. MODERATE/NO/NO/NO 10. MILD/NO/NO/NO 11. MODERATE/NO/NO/NO 12. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 07DEC2010 (5) - 12DEC2010 (10) 2. 07DEC2010 (5) - 12DEC2010 (10) 3. 12DEC2010 (10) - --------- (.) 4. 14DEC2010 (12) - 13JAN2011 (42) 5. 17DEC2010 (15) - 17DEC2010 (15) 6. 21DEC2010 (19) - 21DEC2010 (19) 7. 22JUN2011 (202) - 22JUN2011 (202) 8. 22JUN2011 (202) - 30JUN2011 (210)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033085

Parameter	Value
	9. 22JUN2011 (202) - 22JUN2011 (202)
	10. 22JUN2011 (202) - 22JUN2011 (202)
	11. 26JUN2011 (206) - 28JUN2011 (208)
	12. 28JUN2011 (208) - 30JUN2011 (210)
Duration of AE	1. 6
	2. 6
	3. .
	4. 31
	5. 1
	6. 1
	7. 1
	8. 9
	9. 1
	10. 1
	11. 3
	12. 3
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400033085

Parameter	Value
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. OTHER
	12. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400033085[1)]	HAEMATURIA WITH CLOTS（PT：尿路出血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリン投与中止約 5 ヵ月半後の発現であり、時間的関連性がないため、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400053007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400053007/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/49/WHITE/AUSTRALIA/YES
Medical history	Alcoholism, Ankle fracture, Anxiety, Drug dependence, Depression, Ankle fracture, Gastrooesophageal reflux disease, Gout, Obesity, Sleep apnoea syndrome, Nicotine dependence, Shoulder operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CEPHAZOLIN, CLEXANE (ENOXAPARIN), COLGOUT (COLCHICINO), ENDONE, IBUPROFEN, INDOMETHACIN, MORPHINE, OXYCODONE, PARACETAMOL, SOMAC (PANTOPRAZOLE), ZOLOFT (SERTRALINE)
Adverse Events (AE) Preferred term	1. Ankle fracture 2. Joint injury 3. Excoriation 4. Skin fissures 5. Skin haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 19JUN2008 (44) - 20JUN2008 (45) 2. 22JUN2008 (47) - 27JUN2008 (52) 3. 24JUN2008 (49) - 24JUN2008 (49) 4. 24JUN2008 (49) - 24JUN2008 (49) 5. 24JUN2008 (49) - 24JUN2008 (49)
Duration of AE	1. 2 2. 6 3. 1 4. 1 5. 1
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. I 2. . 3. . 4. . 5. .
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY 3. NONE 4. NONE 5. NONE
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400053007

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400053013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400053013/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/AUSTRALIA/YES
Medical history	Bladder cancer, Chronic obstructive pulmonary disease, Erythema, Haemorrhoids, Pruritus, Pulmonary embolism, Urinary tract infection, Deep vein thrombosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLIN, AMPICILLIN, ARTIFICIAL TEARS, BACTRIM 800/160MG, CALAMINE LOTION, CELERY CAPSULES, CELESTANE M, CEPHALEXIN, CIPROFLOXACIN, DERMEZE, ELOCON CREAM, FLUCLOXACILLIN, FRUSEMIDE, GENTAMICIN, GENTAMYCIN, IBUPROFEN (BRUFEN), LINSEED/SUNFLOWER/ALMOND POWDER [DERMATITIS], LIQUID B [LIQUID B IS A B-COMPLEX VITAMIN AND THE PATIENT HEALTH BENEFITS.], LORATADINE, MAGNESIUM PHOSPHATE X6, NITROFURANTOIN, NORFLOXACIN, PARACETAMOL, PHENERGAN, PREDNISOLONE, ROXITHROMYCIN, SPIRIVA, TRAMADOL (TRAMAL)
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Haematuria 3. Urosepsis 4. Dermatitis 5. Hypotension 6. Oedema peripheral 7. Contusion 8. Urinary tract infection 9. Urinary tract infection 10. Dysuria 11. Oedema 12. Dermatitis exfoliative 13. Dermatitis exfoliative 14. Localised infection 15. Back pain 16. Urosepsis 17. Herpes simplex 18. Gastrointestinal haemorrhage 19. Sepsis 20. Hypotension 21. Urinary tract infection 22. Sepsis 23. Febrile neutropenia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/YES/NO/YES 8. MODERATE/NO/YES/YES 9. MILD/NO/YES/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400053013

Parameter	Value
	10. MILD/NO/YES/YES
	11. MILD/NO/NO/YES
	12. MODERATE/NO/YES/YES
	13. MODERATE/NO/NO/YES
	14. MILD/NO/NO/YES
	15. MILD/NO/NO/YES
	16. MILD/NO/YES/YES
	17. MODERATE/NO/YES/NO
	18. SEVERE/NO/YES/NO
	19. MODERATE/NO/NO/NO
	20. SEVERE/NO/NO/NO
	21. SEVERE/NO/NO/NO
	22. SEVERE/NO/YES/NO
	23. SEVERE/NO/NO/NO
Start/stop date of event with relative date	1. --DEC2008 (.) - 19JAN2009 (95)
	2. 05NOV2008 (20) - 19JAN2009 (95)
	3. 19JAN2009 (95) - 28JAN2009 (104)
	4. 19JAN2009 (95) - --------- (.)
	5. 19JAN2009 (95) - 22JAN2009 (98)
	6. 24JAN2009 (100) - 11MAR2009 (146)
	7. 30JAN2009 (106) - --------- (.)
	8. 26FEB2009 (133) - 06MAR2009 (141)
	9. 16MAR2009 (151) - 27MAR2009 (162)
	10. 30APR2009 (196) - 05MAY2009 (201)
	11. 13MAY2009 (209) - 17JUN2009 (244)
	12. 18MAY2009 (214) - 31MAY2009 (227)
	13. 01JUN2009 (228) - --------- (.)
	14. 07JUN2009 (234) - 13JUN2009 (240)
	15. 29JUN2009 (256) - --------- (.)
	16. 12JUL2009 (269) - 16JUL2009 (273)
	17. 22JUL2009 (279) - 10AUG2009 (298)
	18. 10AUG2009 (298) - 19AUG2009 (307)
	19. 12AUG2009 (300) - 17AUG2009 (305)
	20. 16AUG2009 (304) - --------- (.)
	21. 18AUG2009 (306) - --------- (.)
	22. 18AUG2009 (306) - 20AUG2009 (308)
	23. 18AUG2009 (306) - --------- (.)
Duration of AE	1. .
	2. 76
	3. 10
	4. .
	5. 4
	6. 47
	7. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400053013

Parameter	Value
	8. 9
	9. 12
	10. 6
	11. 36
	12. 14
	13. .
	14. 7
	15. .
	16. 5
	17. 20
	18. 10
	19. 6
	20. .
	21. .
	22. 3
	23. .
Dose on AE onset	1.
	2. 15 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
	22. 20 mg
	23. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400053013

Parameter	Value
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. I
	17. F
	18. F
	19. F
	20. F
	21. F
	22. F
	23. F
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. OTHER
	10. NONE
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. STUDY DRUG DISCONTINUED AND RESTARTED,STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. REMEDIAL DRUG THERAPY,OTHER
	19. NONE
	20. NONE
	21. REMEDIAL DRUG THERAPY
	22. REMEDIAL DRUG THERAPY
	23. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400053013

Parameter	Value
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. UNCHANGED
	14. RESOLVED
	15. IMPROVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. WORSENED
	20. UNCHANGED
	21. UNCHANGED
	22. DEATH
	23. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400063010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400063010/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/62/WHITE/AUSTRALIA/YES
Medical history	Appendicectomy, Asthma, Spinal osteoarthritis, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLIN, AMOXIL, ATROVENT NEBULISER, AUGMENTIN DUO FORTE, BUSCOPAN, ENOXAPARIN, FENTANYL, GRANISETRON, HEPARIN, MAXALON, MAXOLON, PARACETAMOL, PRODEINE, RANITIDINE, SALBUTAMOL NEBULISER, SALBUTAMOL SULFATE, SERETIDE, WARFARIN
Adverse Events (AE) Preferred term	1. Alopecia 2. Renal cyst 3. Pleuritic pain 4. Nausea 5. Adrenal neoplasm 6. Coagulation time shortened 7. Chest pain 8. Productive cough 9. Asthma 10. Lower respiratory tract infection 11. Upper respiratory tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/YES/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JUN2008 (.) - --------- (.) 2. 09DEC2007 (11) - 11DEC2007 (13) 3. 09DEC2007 (11) - 11DEC2007 (13) 4. 09DEC2007 (11) - 09DEC2007 (11) 5. 18DEC2007 (20) - 26MAR2008 (119) 6. 14MAR2008 (107) - 14MAR2008 (107) 7. 17MAR2008 (110) - 17MAR2008 (110) 8. 21MAR2008 (114) - 26MAR2008 (119) 9. 30MAY2008 (184) - --------- (.) 10. 30MAY2008 (184) - 09JUN2008 (194) 11. 29AUG2008 (275) - 07SEP2008 (284)
Duration of AE	1. . 2. 3 3. 3

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400063010

Parameter	Value
	4. 1
	5. 100
	6. 1
	7. 1
	8. 6
	9. .
	10. 11
	11. 10
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. NONE
	2. OTHER
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	6. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY,OTHER
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
Outcome of event	1. INSUFFICIENT FOLLOW-UP
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400063010

Parameter	Value
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. IMPROVED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400063010[1),1)]	ADRENAL TUMOUR（PT：副腎新生物） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症と判断し、エノキサパリンとの因果関係は否定できると考える。 REDUCED PERIOD OF ANTICOAGULATION（PT：凝固時間短縮） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症と判断し、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400063013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400063013/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/67/WHITE/AUSTRALIA/YES
Medical history	Hyperlipidaemia, Urethral stricture postoperative, Urethral stenosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, EZETROL, GENTAMYCIN, NORFLOXACIN, OXYCODONE, TEMAZEPAM, TRIMETHOPRIM, WARFARIN
Adverse Events (AE) Preferred term	1. Haematuria 2. Urinary tract infection 3. Urethral stenosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 22FEB2008 (18) - 22FEB2008 (18) 2. 22FEB2008 (18) - 28FEB2008 (24) 3. 21MAY2008 (107) - 23MAY2008 (109)
Duration of AE	1. 1 2. 7 3. 3
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400063025

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400063025/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/AUSTRALIA/YES
Medical history	Arthritis, Arthroscopy, Diverticulum, Synovial cyst, Hypertension, Obesity, Osteoporosis, Back pain, Arthralgia, Colitis ulcerative, Lung neoplasm, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMITRIPTYLINE, AMITRIPTYLLINE, CALTRATE [CALCIUM CARBONATE], DOMPERIDONE, ENDONE, ENOXAPARIN, FISH OIL, FOSAMAX, GASTROGEL, IMDUR, MORPHINE, PANADEINE, PARACETAMOL, WARFARIN
Adverse Events (AE) Preferred term	1. Diverticulitis 2. Liver function test abnormal 3. Headache 4. Pain in jaw 5. Synovial cyst 6. Musculoskeletal pain 7. Muscle spasms 8. Musculoskeletal pain 9. Abdominal pain upper 10. Colitis ulcerative
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 09AUG2008 (6) - 09AUG2008 (6) 2. 10AUG2008 (7) - 26AUG2008 (23) 3. 11AUG2008 (8) - 11AUG2008 (8) 4. 11AUG2008 (8) - 11AUG2008 (8) 5. 27OCT2008 (85) - --------- (.) 6. 07NOV2008 (96) - 02DEC2008 (121) 7. 07NOV2008 (96) - 07NOV2008 (96) 8. 03DEC2008 (122) - 03DEC2008 (122) 9. 07JAN2009 (157) - 07JAN2009 (157) 10. 12JAN2009 (162) - --------- (.)
Duration of AE	1. 1 2. 17 3. 1 4. 1 5. . 6. 26

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400063025

Parameter	Value
	7. 1
	8. 1
	9. 1
	10. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY,OTHER
	7. REMEDIAL DRUG THERAPY
	8. OTHER
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. INSUFFICIENT FOLLOW-UP
	6. IMPROVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400063025

Parameter	Value
	10. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400063025[2)]	ADVERSE REACTION TO CLEXANE ELEVATED LFT'S（PT：肝機能検査異常） 治験担当医はワルファリンと報告事象との関連性がある（associated）と判断した。弊社は、ワルファリン投与前の発現であることから、ワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400063027

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400063027/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/53/WHITE/AUSTRALIA/YES
Medical history	Colorectal cancer stage III, Constipation, Hypercholesterolaemia, Ileostomy, Rectal haemorrhage, Rhinorrhoea, Intestinal anastomosis, Post procedural complication, Ileostomy closure, Diarrhoea, Intestinal resection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN DUO FORTE, ENOXAPARIN, GASTROSTOP, GENTAMICIN, MAXOLON, MOVICOL, NORMAL SALINE, PANADOL, TIMENTIN, WARFARIN, XELODA
Adverse Events (AE) Preferred term	1. Faecaloma 2. Pyrexia 3. Fatigue 4. Lethargy 5. Decreased appetite
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 15AUG2008 (4) - 15AUG2008 (4) 2. 27AUG2008 (16) - 03SEP2008 (23) 3. 28AUG2008 (17) - 28AUG2008 (17) 4. 28AUG2008 (17) - 28AUG2008 (17) 5. 28AUG2008 (17) - 28AUG2008 (17)
Duration of AE	1. 1 2. 8 3. 1 4. 1 5. 1
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. NONE 4. NONE 5. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400063027

Parameter	Value
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400073008/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/76/WHITE/AUSTRALIA/YES
Medical history	Osteoporosis, Rheumatoid arthritis, Actinic keratosis, Temporal arteritis, Temporal arteritis, Knee arthroplasty, Knee arthroplasty, Biopsy artery
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANGININE, ASPIRIN, AUGMENTIN DUO, BENADRYL, BENADRYL ORIGINAL, CALCIUM OSTEOCAL, CODEINE, ELOCON OINTMENT, FISH OIL, FOSAMAX, LEUCOVORIN, LIPITOR, MACU-VISION, METHOTREXATE, METOPROLOL, NASONEX AQUEOUS NASAL SPRAY, PANADEINE, PANADOL, PANAMAX, PARIET, PREDNISONE, RULIDE, SIMVAR, SPIRIVA, SYMBICORT TURBUHALER
Adverse Events (AE) Preferred term	1. Cough 2. Bronchiectasis 3. Arthralgia 4. Wound haemorrhage 5. Occult blood positive 6. Hypoaesthesia oral 7. Ataxia 8. Vision blurred 9. Hypoaesthesia oral 10. Transient ischaemic attack 11. Blood cholesterol increased 12. Musculoskeletal pain 13. Diplopia 14. Heterophoria 15. Myalgia 16. Vertigo 17. Colonic polyp 18. Colonic polyp 19. Productive cough 20. Musculoskeletal chest pain 21. Influenza
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/YES/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/YES/YES 11. MILD/NO/NO/YES 12. MODERATE/NO/YES/YES 13. MODERATE/NO/YES/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073008

Parameter	Value
	14. MILD/NO/NO/YES
	15. MODERATE/NO/NO/YES
	16. MILD/NO/NO/YES
	17. MODERATE/NO/NO/YES
	18. MODERATE/NO/NO/YES
	19. MILD/NO/NO/YES
	20. MODERATE/NO/NO/YES
	21. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --NOV2007 (.) - 15APR2008 (231)
	2. --MAY2008 (.) - --------- (.)
	3. --MAY2008 (.) - --------- (.)
	4. 19SEP2007 (22) - 19SEP2007 (22)
	5. 10OCT2007 (43) - 10OCT2007 (43)
	6. 17OCT2007 (50) - 17OCT2007 (50)
	7. 17OCT2007 (50) - 17OCT2007 (50)
	8. 17OCT2007 (50) - 17OCT2007 (50)
	9. 18OCT2007 (51) - 18OCT2007 (51)
	10. 29OCT2007 (62) - 29OCT2007 (62)
	11. 31OCT2007 (64) - --------- (.)
	12. 06NOV2007 (70) - 12NOV2007 (76)
	13. 12NOV2007 (76) - 12NOV2007 (76)
	14. 21NOV2007 (85) - --------- (.)
	15. 23NOV2007 (87) - 25NOV2007 (89)
	16. 29NOV2007 (93) - 29NOV2007 (93)
	17. 15JAN2008 (140) - 15JAN2008 (140)
	18. 15JAN2008 (140) - 15JAN2008 (140)
	19. 16APR2008 (232) - 26SEP2008 (395)
	20. 29MAY2008 (275) - 30MAY2008 (276)
	21. 12SEP2008 (381) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. 1
	5. 1
	6. 1
	7. 1
	8. 1
	9. 1
	10. 1
	11. .
	12. 7
	13. 1
	14. .
	15. 3

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073008

Parameter	Value
	16. 1
	17. 1
	18. 1
	19. 164
	20. 2
	21. .
Dose on AE onset	1.
	2.
	3.
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
Dose status on AE onset	1.
	2.
	3.
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. I

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073008

Parameter	Value
	18. I
	19. .
	20. .
	21. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY,OTHER
	13. NONE
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. NONE
	17. OTHER
	18. OTHER
	19. REMEDIAL DRUG THERAPY
	20. NONE
	21. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. UNCHANGED
	12. RESOLVED
	13. RESOLVED
	14. UNCHANGED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073008

Parameter	Value
	20. RESOLVED
	21. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073032

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400073032/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/51/WHITE/AUSTRALIA/YES
Medical history	Asthma, Bronchitis, Back pain, Gout, Hypertension, Insomnia, Arthralgia, Sciatica, Upper respiratory tract infection, Upper respiratory tract infection, Upper respiratory tract infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AVAPRO, BENZYLPENICILLIN, CEPHALEXIN, CEPHAZOLIN, ELOCON CREAM 0.1 %, ENOXAPARIN, PROBENECID, WARFARIN
Adverse Events (AE) Preferred term	1. Muscle spasms 2. Blister 3. Vessel puncture site haematoma 4. Cellulitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --FEB2009 (.) - 16MAR2009 (60) 2. --FEB2009 (.) - 07APR2009 (82) 3. 23JAN2009 (8) - 05FEB2009 (21) 4. 15DEC2009 (334) - 05JAN2010 (355)
Duration of AE	1. . 2. . 3. 14 4. 22
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. NONE 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073032

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073037

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400073037/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/46/WHITE/AUSTRALIA/YES
Medical history	Appendicectomy, Depression, Fall, Pelvic fracture, Laceration, Musculoskeletal pain, Pain, Pain in extremity, Heterotaxia, Splenectomy, Debridement
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, CORTISONE, EFEXOR, ENDONE, PANADOL, PARACETAMOL, STEMETIL, WARFARIN
Adverse Events (AE) Preferred term	1. Pruritus 2. Headache 3. Lethargy 4. Dyspnoea 5. Pain in extremity 6. Chest discomfort 7. Cough 8. Catheter site haemorrhage 9. Chest pain 10. Wound haemorrhage 11. Vertigo 12. Tachycardia 13. Contusion 14. Pelvic pain 15. Contusion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/YES/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/YES/NO/YES 9. SEVERE/YES/NO/YES 10. MILD/YES/NO/YES 11. MODERATE/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/YES 14. MODERATE/NO/NO/YES 15. MILD/YES/NO/NO
Start/stop date of event with relative date	1. 06APR2009 (1) - --------- (.) 2. 07APR2009 (2) - --------- (.) 3. 08APR2009 (3) - --------- (.) 4. 17APR2009 (12) - --------- (.) 5. 01MAY2009 (26) - --------- (.) 6. 01MAY2009 (26) - --------- (.) 7. 01MAY2009 (26) - --------- (.) 8. 02MAY2009 (27) - 02MAY2009 (27)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073037

Parameter	Value
	9. 25MAY2009 (50) - --------- (.)
	10. 29MAY2009 (54) - 29MAY2009 (54)
	11. 08JUN2009 (64) - 13JUN2009 (69)
	12. 04AUG2009 (121) - --------- (.)
	13. 25SEP2009 (173) - --OCT2009 (.)
	14. 25SEP2009 (173) - --------- (.)
	15. 15OCT2009 (193) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. 1
	9. .
	10. 1
	11. 6
	12. .
	13. .
	14. .
	15. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073037

Parameter	Value
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. OTHER
	6. NONE
	7. NONE
	8. NONE
	9. OTHER
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED
	7. UNCHANGED
	8. RESOLVED
	9. IMPROVED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED
	13. RESOLVED
	14. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073037

Parameter	Value
	15. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073038

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400073038/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/57/WHITE/AUSTRALIA/YES
Medical history	Appendicectomy, Arthroscopy, Asthma, Oral herpes, Groin pain, Pain in extremity, Pilonidal sinus repair, Joint injury, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BENADRYL, CHEMIST'S OWN COLD AND FLU TABLETS, CLEXANE, DIFFLAM, DIGESIC, DIPRIVAN, DYNASTAT, FISH OIL, GLUCOSAMINE, HARTMANN'S IV INFUSION, HYPNOVEL, KEFLEX, KEFLIN, ONDASETRON, PANADEINE FORTE, PARACETAMOL, PETHIDINE
Adverse Events (AE) Preferred term	1. Malaise 2. Pleuritic pain 3. Dyspnoea exertional 4. Oedema peripheral 5. Epistaxis 6. Contusion 7. Fall 8. Oedema peripheral 9. Oedema peripheral 10. Rotator cuff syndrome 11. Back pain 12. Epistaxis 13. Nasopharyngitis 14. Vomiting 15. Diarrhoea 16. Epistaxis 17. Chest pain 18. Lip haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/YES/NO/YES 7. MODERATE/NO/NO/YES 8. SEVERE/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/YES/YES 11. MILD/NO/NO/YES 12. MILD/YES/NO/YES 13. MODERATE/NO/NO/YES 14. SEVERE/NO/NO/YES 15. SEVERE/NO/NO/YES 16. MILD/YES/NO/YES 17. MILD/NO/NO/YES 18. MILD/YES/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073038

Parameter	Value
Start/stop date of event with relative date	1. 26APR2009 (6) - 26APR2009 (6) 2. 11MAY2009 (21) - 02JUL2009 (73) 3. 17MAY2009 (27) - 17MAY2009 (27) 4. 27MAY2009 (37) - 04AUG2009 (106) 5. 30MAY2009 (40) - 30MAY2009 (40) 6. 06JUL2009 (77) - --AUG2009 (.) 7. 06JUL2009 (77) - 06JUL2009 (77) 8. 06JUL2009 (77) - 23JUL2009 (94) 9. 06JUL2009 (77) - 11JUL2009 (82) 10. 06JUL2009 (77) - 16NOV2009 (210) 11. 28AUG2009 (130) - 12NOV2009 (206) 12. 03SEP2009 (136) - 10SEP2009 (143) 13. 19OCT2009 (182) - 01NOV2009 (195) 14. 02NOV2009 (196) - 03NOV2009 (197) 15. 02NOV2009 (196) - 03NOV2009 (197) 16. 16NOV2009 (210) - 22NOV2009 (216) 17. 18FEB2010 (304) - --------- (.) 18. 04APR2010 (349) - 14APR2010 (359)
Duration of AE	1. 1 2. 53 3. 1 4. 70 5. 1 6. . 7. 1 8. 18 9. 6 10. 134 11. 77 12. 8 13. 14 14. 2 15. 2 16. 7 17. . 18. 11
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg 8. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073038

Parameter	Value
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. I
	17. .
	18. .
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	11. NONE
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. NONE
	16. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073038

Parameter	Value
	17. NONE
	18. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. UNCHANGED
	18. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073046

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400073046/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/37/WHITE/AUSTRALIA/YES
Medical history	Cervical vertebral fracture, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, AUGMENTIN DUO FORTE, CEFTRIAXONE, CLAMOXYL DUO FORTE, CLARITHROMYCIN, DENCORUB NOS, DIMETAPP COLD, COUGH & FLU - DAY & NIGHT LIQUID CAPS, ENOXAPARIN, PANADOL, SANDOZ PHOSPHATE, VOLTAREN, WARFARIN
Adverse Events (AE) Preferred term	1. Liver function test abnormal 2. Epistaxis 3. Pain in extremity 4. Arthralgia 5. Epistaxis 6. Headache 7. Headache 8. Sinusitis 9. Headache 10. Lethargy 11. Dyspnoea 12. Neck pain 13. Musculoskeletal pain 14. Arthralgia 15. Wound haemorrhage 16. Wound haemorrhage 17. Contusion 18. Headache 19. Blood blister 20. Cough
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/YES/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MODERATE/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MILD/NO/NO/YES 15. MILD/NO/NO/YES 16. MILD/NO/NO/YES 17. MILD/YES/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073046

Parameter	Value
	18. MODERATE/NO/NO/YES
	19. MILD/YES/NO/YES
	20. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 08SEP2009 (5) - 17SEP2009 (14)
	2. 13SEP2009 (10) - 13SEP2009 (10)
	3. 13SEP2009 (10) - 15SEP2009 (12)
	4. 15SEP2009 (12) - --------- (.)
	5. 17SEP2009 (14) - 17SEP2009 (14)
	6. 18SEP2009 (15) - 18SEP2009 (15)
	7. 26SEP2009 (23) - 26SEP2009 (23)
	8. 12OCT2009 (39) - 22OCT2009 (49)
	9. 29NOV2009 (87) - 29DEC2009 (117)
	10. 25DEC2009 (113) - 25DEC2009 (113)
	11. 25DEC2009 (113) - 25DEC2009 (113)
	12. 27DEC2009 (115) - 29DEC2009 (117)
	13. 27DEC2009 (115) - 29DEC2009 (117)
	14. 25JAN2010 (144) - 04FEB2010 (154)
	15. 28JAN2010 (147) - 04FEB2010 (154)
	16. 28JAN2010 (147) - 04FEB2010 (154)
	17. 25FEB2010 (175) - -----2010 (.)
	18. 25FEB2010 (175) - 25FEB2010 (175)
	19. 27FEB2010 (177) - -----2010 (.)
	20. 07MAR2010 (185) - --------- (.)
Duration of AE	1. 10
	2. 1
	3. 3
	4. .
	5. 1
	6. 1
	7. 1
	8. 11
	9. 31
	10. 1
	11. 1
	12. 3
	13. 3
	14. 11
	15. 8
	16. 8
	17. .
	18. 1
	19. .
	20. .
Dose on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073046

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073046

Parameter	Value
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. NONE
	12. NONE
	13. NONE
	14. NONE
	15. NONE
	16. NONE
	17. NONE
	18. REMEDIAL DRUG THERAPY
	19. NONE
	20. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED
	20. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073049

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400073049/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/72/WHITE/AUSTRALIA/YES
Medical history	Back pain, Multiple myeloma, Rhinorrhoea, Actinic keratosis, Upper respiratory tract infection, Vitamin B12 deficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXYCILLIN, ARTHREXIN, AUGMENTIN DUO FORTE, AZEP NASAL SPRAY, AZITHROMYCIN, CELESTONE CHRONODOSE, COLGOUT, DEXAMETHASONE, FLUTICASONE FUROATE, KLIOVANCE, LENALIDOMIDE, LYRICA, MELPHALAN, NEO-CYTAMEN, NEULASTA, PANADOL, SERETIDE, THALIDOMIDE, TRAMAL, VENTOLIN, VITAMIN D, WARFARIN, XYLOCAINE, ZEDD, ZOMETA
Adverse Events (AE) Preferred term	1. Neutropenia 2. Oedema peripheral 3. Asthma 4. Musculoskeletal pain 5. Pain in extremity 6. Nasopharyngitis 7. Neuropathy peripheral 8. Chest pain 9. Back pain 10. Pain in jaw 11. Gingival pain 12. Vitamin D deficiency 13. Upper respiratory tract infection 14. Musculoskeletal chest pain 15. Gout 16. Musculoskeletal chest pain 17. Musculoskeletal chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/YES/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MODERATE/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MODERATE/NO/NO/YES 15. MODERATE/NO/NO/YES 16. MODERATE/NO/NO/YES 17. MODERATE/NO/NO/NO

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073049

Parameter	Value
Start/stop date of event with relative date	1. --JUN2010 (.) - 15JUL2010 (112) 2. 08APR2010 (14) - 09APR2010 (15) 3. 17APR2010 (23) - --------- (.) 4. 29APR2010 (35) - --------- (.) 5. 29APR2010 (35) - 26AUG2010 (154) 6. 17JUN2010 (84) - 24JUN2010 (91) 7. 17JUN2010 (84) - --------- (.) 8. 01JUL2010 (98) - 12JUL2010 (109) 9. 05AUG2010 (133) - --NOV2010 (.) 10. 22AUG2010 (150) - 24AUG2010 (152) 11. 22AUG2010 (150) - 24AUG2010 (152) 12. 29SEP2010 (188) - 25NOV2010 (245) 13. 06NOV2010 (226) - 17NOV2010 (237) 14. 20NOV2010 (240) - 20JAN2011 (301) 15. 17DEC2010 (267) - 23DEC2010 (273) 16. 24FEB2011 (336) - 28FEB2011 (340) 17. 31MAR2011 (371) - 04APR2011 (375)
Duration of AE	1. . 2. 2 3. . 4. . 5. 120 6. 8 7. . 8. 12 9. . 10. 3 11. 3 12. 58 13. 12 14. 62 15. 7 16. 5 17. 5
Dose on AE onset	1. 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg 8. 20 mg 9. 20 mg 10. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073049

Parameter	Value
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073049

Parameter	Value
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. IMPROVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073050

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400073050/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/40/WHITE/AUSTRALIA/YES
Medical history	Atopy, Chronic sinusitis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLAMOXYL DUO FORTE, CLEXANE, ENOXAPARIN, PANADOL, PARACETAMOL, SALBUTAMOL, VITAMIN C, WARFARIN, ZYRTEC
Adverse Events (AE) Preferred term	1. Abdominal wall mass 2. Injection site haematoma 3. Epistaxis 4. Ocular hyperaemia 5. Back pain 6. Injection site haemorrhage 7. Arthralgia 8. Oedema peripheral 9. Onychomadesis 10. Contusion 11. Rash 12. Wound haemorrhage 13. Headache 14. Contusion 15. Wound haemorrhage 16. Pruritus 17. Upper respiratory tract infection 18. Haemoptysis 19. Pain in extremity 20. Skin haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/YES/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MILD/YES/NO/YES 15. MILD/NO/NO/YES 16. MILD/NO/NO/YES 17. MODERATE/NO/NO/YES 18. MILD/YES/YES/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073050

Parameter	Value
	19. MILD/NO/NO/YES
	20. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JUL2010 (.) - 24SEP2010 (159)
	2. 19APR2010 (1) - --MAY2010 (.)
	3. 19APR2010 (1) - --AUG2010 (.)
	4. 19APR2010 (1) - --------- (.)
	5. 29APR2010 (11) - 01MAY2010 (13)
	6. 30APR2010 (12) - 30APR2010 (12)
	7. 05MAY2010 (17) - --SEP2010 (.)
	8. 08MAY2010 (20) - --AUG2010 (.)
	9. 11MAY2010 (23) - 11MAY2010 (23)
	10. 15MAY2010 (27) - 25MAY2010 (37)
	11. 17MAY2010 (29) - --------- (.)
	12. 25MAY2010 (37) - 25MAY2010 (37)
	13. 04JUN2010 (47) - 04JUN2010 (47)
	14. 06JUN2010 (49) - 08JUN2010 (51)
	15. 06JUN2010 (49) - 08JUN2010 (51)
	16. 26JUL2010 (99) - --------- (.)
	17. 19AUG2010 (123) - 03SEP2010 (138)
	18. 23AUG2010 (127) - 25AUG2010 (129)
	19. 10SEP2010 (145) - --------- (.)
	20. 17SEP2010 (152) - 17SEP2010 (152)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. 3
	6. 1
	7. .
	8. .
	9. 1
	10. 11
	11. .
	12. 1
	13. 1
	14. 3
	15. 3
	16. .
	17. 16
	18. 3
	19. .
	20. 1
Dose on AE onset	1.
	2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073050

Parameter	Value
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073050

Parameter	Value
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. NONE
	16. NONE
	17. REMEDIAL DRUG THERAPY
	18. NONE
	19. NONE
	20. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. UNCHANGED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. UNCHANGED
	17. RESOLVED
	18. RESOLVED
	19. UNCHANGED
	20. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073052

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400073052/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/50/WHITE/AUSTRALIA/YES
Medical history	Crohn's disease, Thrombophlebitis superficial
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN DUO FORTE, DEEP HEAT CREAM [METHYL SALICYLATE, MENTHOL], ENOXAPARIN, PANADOL, WARFARIN
Adverse Events (AE) Preferred term	1. Contusion 2. Oedema peripheral 3. Lower gastrointestinal haemorrhage 4. Lower gastrointestinal haemorrhage 5. Muscle spasms 6. Cough 7. Haemoptysis 8. Thrombophlebitis superficial
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MODERATE/YES/YES/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 08JUN2010 (7) - 06JUL2010 (35) 2. 03JUL2010 (32) - 03JUL2010 (32) 3. 03JUL2010 (32) - 03JUL2010 (32) 4. 09SEP2010 (100) - 09SEP2010 (100) 5. 25SEP2010 (116) - 25OCT2010 (146) 6. 14NOV2010 (166) - 16NOV2010 (168) 7. 14NOV2010 (166) - 16NOV2010 (168) 8. 28DEC2010 (210) - --------- (.)
Duration of AE	1. 29 2. 1 3. 1 4. 1 5. 31 6. 3 7. 3 8. .
Dose on AE onset	1. 2. 3. 4. 5. 6.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400073052

Parameter	Value
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400083010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400083010/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/77/WHITE/AUSTRALIA/YES
Medical history	Cervix carcinoma, Gastritis, Haemorrhage, Haemorrhage, Osteoarthritis, Rheumatoid arthritis, Urinary incontinence
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARAVA, FOLIC ACID, METHOTREXATE, NATIVE B POLLEN (HERBAL), NORSPAN, OMEGA 3
Adverse Events (AE) Preferred term	1. Rectal haemorrhage 2. Anaemia 3. Sigmoiditis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 13JUN2008 (3) - --------- (.) 2. 25JUN2008 (15) - 03FEB2009 (238) 3. 24DEC2008 (197) - --------- (.)
Duration of AE	1. . 2. 224 3. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. F
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY,OTHER 3. NONE
Outcome of event	1. UNCHANGED 2. RESOLVED 3. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400083010[4)]	ANAEMIA（PT：貧血） 治験担当医は、因果関係は否定できると判断した。弊社は、リバーロキサバンの抗凝固作用によるＳ字結腸からの出血によるものと考えられ、リバーロキサバンとの因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400083013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400083013/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/62/WHITE/AUSTRALIA/YES
Medical history	Anaemia, Cough, Diffuse large B-cell lymphoma, Fatigue, Haematuria, Hypercholesterolaemia, Hypertension, Neutropenia, Dyspnoea, Hip arthroplasty, Type 2 diabetes mellitus, Ureteral stent insertion, Procedural pain, Lymphoproliferative disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACYCLOVIR, ALPRIM, AUGMENTIN DUO FORTE, CYCLOPHOSPHAMIDE, DEXAMETHASONE, DOXORUBICIN, ENOXAPARIN, LIPITOR, LORATIDINE, MERSYNDOL, NEUROFEN PLUS, OLMESARTAN, OXYNORM, PARACETAMOL, PEG FILGRASTIN, PREDNISOLONE, PREGABALIN, RITUXIMAB, TROPISETRON, VALACYCLOVIR, VINCRISTINE, WARFARIN
Adverse Events (AE) Preferred term	1. Neuropathy peripheral 2. Herpes zoster 3. Post herpetic neuralgia 4. Ataxia 5. Confusional state 6. Metastases to central nervous system
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/YES/YES 6. SEVERE/NO/NO/YES
Start/stop date of event with relative date	1. 21MAY2009 (34) - --------- (.) 2. 01JUN2009 (45) - 03AUG2009 (108) 3. 01JUN2009 (45) - --------- (.) 4. 03AUG2009 (108) - --------- (.) 5. 03AUG2009 (108) - --------- (.) 6. 07AUG2009 (112) - --------- (.)
Duration of AE	1. . 2. 64 3. . 4. . 5. . 6. .
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400083013

Parameter	Value
	5.
	6.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. INSUFFICIENT FOLLOW-UP
	2. RESOLVED
	3. INSUFFICIENT FOLLOW-UP
	4. IMPROVED
	5. IMPROVED
	6. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400083022

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400083022/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/71/WHITE/AUSTRALIA/YES
Medical history	Arrhythmia, Depression, Intervertebral disc operation, Drug hypersensitivity, Drug hypersensitivity, Gastric haemorrhage, Gastric ulcer, Hypertension, Hypothyroidism, Hysterectomy, Malaise, Musculoskeletal pain, Oedema peripheral, Back pain, Convulsion, Dyspnoea, Spinal laminectomy, Muscle twitching, Iodine allergy, Spondylolisthesis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AGAROL, AMOXYCILLIN, ATENOLOL, CANDESARTAN, CELESTONE CREAM, CLEXANE, CLONAZEPAM, CODAPANE, COLOXYL WITH SENNA, DEXAMETHASONE, DOXYCYCLINE, ENOXAPARIN, ESOMEPRAZOLE, FENTANYL, FENTANYL PATCH, FLUCLOXACILLIN, GABAPENTIN, GENTAMYCIN, GLYCERINE SUPPOSITORY, GLYCEROL SUPPOSITORY, GRANISETRON, HYDROCORT OINTMENT, LACTULOSE, LASIX, NORTRIPHYLINE, PANADEINE FORTE, PANADOL OSTEO, PARACETAMOL, PARACETAMOL SLOW RELEASE, PETHIDINE, PREGABALIN, SORBITOL, SPIRONOLADONE, STEMETIL, THYROXINE, TRAMADOL, TRIMETHOPRIM, WARFARIN
Adverse Events (AE) Preferred term	1. Headache 2. Cough 3. Headache 4. Epistaxis 5. Epistaxis 6. Rash 7. Oedema peripheral 8. Pseudarthrosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 19MAR2010 (5) - 19MAR2010 (5) 2. 23MAR2010 (9) - 05AUG2010 (144) 3. 16APR2010 (33) - --------- (.) 4. 22APR2010 (39) - 22APR2010 (39) 5. 29APR2010 (46) - 29APR2010 (46) 6. 06JUN2010 (84) - --------- (.) 7. 01AUG2010 (140) - --------- (.) 8. 29SEP2010 (199) - 12NOV2010 (243)
Duration of AE	1. 1 2. 136 3. . 4. 1 5. 1

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400083022

Parameter	Value
	6. .
	7. .
	8. 45
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. NONE
	3. OTHER
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. UNCHANGED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/62/WHITE/AUSTRALIA/YES
Medical history	Pneumonia primary atypical, Hepatic steatosis, Haemochromatosis, Liver disorder, Insomnia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, CEFTRIAXONE, CLEXANE, CLONAZEPAM, DILANTIN, MAXOLON, PANADOL [PARACETAMOL ALONE], PETHIDINE, TEMAZEPAM
Adverse Events (AE) Preferred term	1. Convulsion 2. Dizziness 3. Pruritus
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 07NOV2007 (7) - 08NOV2007 (8) 2. 08NOV2007 (8) - ---------- (.) 3. 16NOV2007 (16) - 07DEC2007 (37)
Duration of AE	1. 2 2. . 3. 22
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg
Dose status on AE onset	1. . 2. I 3. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. NONE 3. NONE
Outcome of event	1. RESOLVED 2. UNCHANGED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400093004[2)]	SEIZURES（PT：痙攣） 報告者は報告事象との関連性があると判断した。弊社は、本事象の発現後に本剤投与を再開してもその後再発がみられなかったことから、リバーロキサバンよりはむしろ Cefriaxone 治療を要した感染に起因した可能性が高いとして、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093017/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/84/WHITE/AUSTRALIA/YES
Medical history	Anaemia, Cataract operation, Glucose tolerance impaired, Hypertension, Osteoarthritis, Osteoporosis, Hip arthroplasty, Transient ischaemic attack
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATORVASTATIN, AVAPRO, CLEXANE, COLOXYL AND SENNA, ENDONE, FOSAMAX, LACTULOSE, MAXOLON, PANADOL, SERTRALINE
Adverse Events (AE) Preferred term	1. Ischaemic stroke 2. Hypercholesterolaemia 3. Lung infiltration 4. Lacunar infarction 5. Lacunar infarction 6. Platelet count decreased 7. Constipation 8. Depression 9. Ischaemic stroke 10. Nausea 11. Vomiting 12. Ischaemic stroke 13. Epistaxis 14. Anaemia 15. Mouth haemorrhage 16. Disseminated intravascular coagulation 17. Pancreatic carcinoma metastatic
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/YES 9. SEVERE/NO/YES/YES 10. MODERATE/NO/NO/YES 11. MODERATE/NO/NO/YES 12. SEVERE/NO/YES/YES 13. MILD/NO/NO/NO 14. MODERATE/NO/NO/NO 15. MILD/NO/NO/NO 16. SEVERE/NO/YES/NO 17. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 20JUL2008 (25) - 25JUL2008 (30) 2. 21JUL2008 (26) - --------- (.) 3. 21JUL2008 (26) - 16AUG2008 (52)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093017

Parameter	Value
	4. 21JUL2008 (26) - --------- (.)
	5. 21JUL2008 (26) - --------- (.)
	6. 21JUL2008 (26) - --------- (.)
	7. 23JUL2008 (28) - 26JUL2008 (31)
	8. 23JUL2008 (28) - --------- (.)
	9. 25JUL2008 (30) - --------- (.)
	10. 13AUG2008 (49) - 16AUG2008 (52)
	11. 13AUG2008 (49) - 16AUG2008 (52)
	12. 16AUG2008 (52) - --------- (.)
	13. 27SEP2008 (94) - 27SEP2008 (94)
	14. 27SEP2008 (94) - --------- (.)
	15. 29SEP2008 (96) - 29SEP2008 (96)
	16. 30SEP2008 (97) - --------- (.)
	17. 06OCT2008 (103) - 14OCT2008 (111)
Duration of AE	1. 6
	2. .
	3. 27
	4. .
	5. .
	6. .
	7. 4
	8. .
	9. .
	10. 4
	11. 4
	12. .
	13. 1
	14. .
	15. 1
	16. .
	17. 9
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093017

Parameter	Value
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
Dose status on AE onset	1. .
	2. I
	3. I
	4. I
	5. I
	6. I
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. F
	14. F
	15. F
	16. F
	17. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	13. NONE
	14. NONE
	15. NONE
	16. REMEDIAL DRUG THERAPY,OTHER
	17. NONE
Outcome of event	1. WORSENED
	2. UNCHANGED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093017

Parameter	Value
	7. RESOLVED
	8. UNCHANGED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED
	13. RESOLVED
	14. UNCHANGED
	15. RESOLVED
	16. UNCHANGED
	17. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093019

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093019/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/72/WHITE/AUSTRALIA/YES
Medical history	Headache, Hypertension, Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANGININE, CODRAL DAYTIME/NIGHTIME TABLETS, COLOXYL AND SENNA, DALTEPARIN, ENDONE, GASTROGEL, GTN PATCH, IBUPROFEN, LACTULOSE, MAXOLON, METOPROLOL, MORPHINE, MYLANTA [EXACT TYPE OF MYLANTA UNKNOWN], NAPROSYN, PANADEINE FORTE, PANADOL, PARACETAMOL, VITAMIN K, WARFARIN, XYLOCAINE VISCOUS
Adverse Events (AE) Preferred term	1. Dyspepsia 2. Constipation 3. Chest pain 4. Chest pain 5. Nausea 6. Lung neoplasm 7. Nasopharyngitis 8. Rash 9. Abdominal pain 10. Soft tissue injury 11. International normalised ratio increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MODERATE/NO/YES/YES 11. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 03JUL2008 (1) - 03JUL2008 (1) 2. 04JUL2008 (2) - 06JUL2008 (4) 3. 04JUL2008 (2) - 07JUL2008 (5) 4. 13JUL2008 (11) - 16JUL2008 (14) 5. 14JUL2008 (12) - 14JUL2008 (12) 6. 14JUL2008 (12) - 29DEC2008 (180) 7. 13AUG2008 (42) - 23AUG2008 (52) 8. 15OCT2008 (105) - 15OCT2008 (105) 9. 15OCT2008 (105) - 15OCT2008 (105) 10. 16NOV2008 (137) - 18NOV2008 (139) 11. 17NOV2008 (138) - 18NOV2008 (139)
Duration of AE	1. 1 2. 3 3. 4

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093019

Parameter	Value
	4. 4
	5. 1
	6. 169
	7. 11
	8. 1
	9. 1
	10. 3
	11. 2
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093019

Parameter	Value
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093021/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/30/WHITE/AUSTRALIA/YES
Medical history	Hypokalaemia, Night sweats, Palpitations, Pelvic inflammatory disease, Supraventricular tachycardia, Headache, Hepatic lesion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CECLOR, CHLORSIG EYE DROPS, ENOXAPARIN, FERROGRADUMENT C, METOPROLOL, OSTELIN 1000, PANADOL, PHOSPHATE-SANDOZ, VALETTE, WARFARIN
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Pain in extremity 3. Sinus tachycardia 4. Blood phosphorus decreased 5. Conjunctivitis 6. Dizziness 7. Lower respiratory tract infection 8. Iron deficiency
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 29JUL2008 (5) - 23SEP2008 (61) 2. 29JUL2008 (5) - 21AUG2008 (28) 3. 09AUG2008 (16) - 13NOV2008 (112) 4. 10AUG2008 (17) - 10AUG2008 (17) 5. 12AUG2008 (19) - 15AUG2008 (22) 6. 13AUG2008 (20) - 21AUG2008 (28) 7. 13OCT2008 (81) - 18OCT2008 (86) 8. 11DEC2008 (140) - 15JAN2009 (175)
Duration of AE	1. 57 2. 24 3. 97 4. 1 5. 4 6. 9 7. 6 8. 36
Dose on AE onset	1. 2. 3. 4. 5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093021

Parameter	Value
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093029/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/32/WHITE/AUSTRALIA/YES
Medical history	Obesity, Rosacea, Adenomyosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BLACKMORES IRON TABLETS, DIANE 35, DOXYCYCLINE, PANADEINE, VIBRA TABS
Adverse Events (AE) Preferred term	1. Menorrhagia
	2. Abdominal pain
	3. Anaemia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/NO
	2. MODERATE/NO/NO/YES
	3. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 30DEC2008 (1) - 06FEB2009 (39)
	2. 30DEC2008 (1) - --------- (.)
	3. 05JAN2009 (7) - 02APR2009 (94)
Duration of AE	1. 39
	2. .
	3. 88
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
Dose status on AE onset	1. .
	2. .
	3. .
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. OTHER
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400093029[4)]	ANAEMIA（PT：貧血） 治験担当医は、因果関係は否定できると判断した。弊社は、リバーロキサバンの抗凝固作用による併発症（月経過多）によるものと考えられ、リバーロキサバンとの因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093034

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093034/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/41/WHITE/AUSTRALIA/YES
Medical history	Nausea, Transient ischaemic attack, Vomiting
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENDONE, MAXOLON, MERSYNDOL DAY STRENGTH, OXYCONTIN SR, PANADEINE FORTE, PARACETAMOL
Adverse Events (AE) Preferred term	1. Headache 2. Oedema peripheral 3. Nausea 4. Liver function test abnormal 5. Fatigue 6. Musculoskeletal chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/YES/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 12MAY2009 (82) - 20MAY2009 (90) 2. 14MAY2009 (84) - 21JUL2009 (152) 3. 21JUN2009 (122) - 14SEP2009 (207) 4. 15JUL2009 (146) - 14SEP2009 (207) 5. 22JUL2009 (153) - 14SEP2009 (207) 6. 09AUG2009 (171) - 14SEP2009 (207)
Duration of AE	1. 9 2. 69 3. 86 4. 62 5. 55 6. 37
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. F 6. F
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093034

Parameter	Value
	3. NONE
	4. STUDY DRUG DISCONTINUED PERMANENTLY
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093040

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093040/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/46/WHITE/AUSTRALIA/YES
Medical history	Cushing's syndrome, Hypertension, Iron deficiency anaemia, Arthralgia, Mass, Obesity, Renal stone removal, Female sterilisation, Groin abscess, Gastric banding, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLIN, AUGMENTIN DUO FORTE, CALTRATE [CALCIUM CARBONATE], CEFTRIAXONE, CELEBREX, CLEXANE, DEXAMETHASONE, ENDONE, FERROGRAD C, FISH OIL, METOCLOPRAMIDE, METRONIDAZOLE, MICARDIS, MIDAZOLAM, MORPHINE SULFATE, MULTIVITAMIN, PARACETAMOL, PARECOXIB, PROPOFOL, RANITIDINE, SUXAMETHONIUM, TRAMADOL, UNFRACTIONATED HEPARIN, VITAMIN B12, VOLTAREN
Adverse Events (AE) Preferred term	1. Arthralgia 2. Pituitary tumour 3. Bronchitis 4. Anal abscess 5. Sepsis 6. Subcutaneous haematoma 7. Influenza 8. Productive cough
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/YES/NO/YES 4. SEVERE/NO/YES/YES 5. SEVERE/NO/YES/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 20SEP2009 (39) - 12NOV2009 (92) 2. 26OCT2009 (75) - --------- (.) 3. 14DEC2009 (124) - 28DEC2009 (138) 4. 12APR2010 (243) - 23APR2010 (254) 5. 12APR2010 (243) - 15APR2010 (246) 6. 15APR2010 (246) - 15APR2010 (246) 7. 01JUL2010 (323) - 09JUL2010 (331) 8. 02SEP2010 (386) - --------- (.)
Duration of AE	1. 54 2. . 3. 15 4. 12 5. 4 6. 1 7. 9 8. .
Dose on AE onset	1. 20 mg 2. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093040

Parameter	Value
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. I
	7. .
	8. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. OTHER
	7. REMEDIAL DRUG THERAPY
	8. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093041

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093041/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/67/WHITE/AUSTRALIA/YES
Medical history	Skin neoplasm excision, Traumatic fracture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, HEPARIN SODIUM, SOMAC, VITAMIN K, WARFARIN
Adverse Events (AE) Preferred term	1. Melaena 2. Duodenal ulcer 3. Duodenitis 4. Pain in extremity 5. Chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 22AUG2009 (2) - 26AUG2009 (6) 2. 25AUG2009 (5) - --------- (.) 3. 25AUG2009 (5) - --------- (.) 4. 28SEP2009 (39) - 23NOV2009 (95) 5. 24OCT2009 (65) - 25OCT2009 (66)
Duration of AE	1. 5 2. . 3. . 4. 57 5. 2
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. NONE 4. NONE 5. NONE
Outcome of event	1. RESOLVED 2. INSUFFICIENT FOLLOW-UP 3. INSUFFICIENT FOLLOW-UP 4. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093041

Parameter	Value
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093043

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093043/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/36/WHITE/AUSTRALIA/YES
Medical history	Depression, Eosinophilia, Ankle fracture, Menorrhagia, Obesity, Dysmenorrhoea, Female sterilisation, Tobacco user
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CENOVIS MAGNESIUM, CENOVIS MULTIVITAMIN, DEXAMETHASONE, ENDONE, ENOXAPARIN, IBUPROFEN, LOVAN, MERSYNDOL, MERSYNDOL DS, METOCLOPRAMIDE, MORPHINE, NUROFEN, OXYCONTIN, PANADOL, QUININE, RENNIE, WARFARIN
Adverse Events (AE) Preferred term	1. Dyspepsia 2. Non-cardiac chest pain 3. Dyspepsia 4. Non-cardiac chest pain 5. Menorrhagia 6. Viral rash 7. Eosinophilia 8. Pleuritic pain 9. Muscle spasms 10. Lower respiratory tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MODERATE/NO/YES/YES 7. MODERATE/NO/YES/YES 8. MODERATE/NO/YES/YES 9. MILD/NO/NO/YES 10. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 23SEP2009 (21) - 23SEP2009 (21) 2. 06OCT2009 (34) - 07OCT2009 (35) 3. 19OCT2009 (47) - 19OCT2009 (47) 4. 20OCT2009 (48) - 21OCT2009 (49) 5. 01DEC2009 (90) - 01MAR2010 (180) 6. 16DEC2009 (105) - 07JAN2010 (127) 7. 16DEC2009 (105) - 17DEC2009 (106) 8. 16DEC2009 (105) - 17DEC2009 (106) 9. 15JAN2010 (135) - 31MAR2010 (210) 10. 29MAR2010 (208) - 12APR2010 (222)
Duration of AE	1. 1 2. 2 3. 1 4. 2 5. 91 6. 23

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093043

Parameter	Value
	7. 2
	8. 2
	9. 76
	10. 15
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY,OTHER
	7. OTHER
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093043

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093044

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093044/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/67/WHITE/AUSTRALIA/YES
Medical history	Aortic arteriosclerosis, Arthritis, Benign neoplasm of cervix uteri, Cholecystectomy, Chronic obstructive pulmonary disease, Depression, Headache, Dizziness, Nausea, Obesity, Tendonitis, Pneumonia, Psoriasis, Vitamin D deficiency, Postmenopause, Glucose tolerance impaired, Hyperlipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROVENT, BRUFEN, CEFTRIAXONE, CHLORVESCENT, COLOXYL AND SENNA, DOXYCYCLINE, FISH OIL, FISH OIL CAPS, GASTROGEL, GLUCOSAMINE, HYDROCORTISONE, IBUPROFEN, LEXAPRO, MOXICLAV DUO FORTE, MYLANTA [ALUMINIUM HYDROXIDE GEL, DRIED,MAGNESIUM HYDROXIDE,SIMETICONE], OSTELIN, PARACETAMOL, POTASSIUM CHLORIDE, PREDNISOLONE, SERETIDE, SPIRIVA, VENTOLIN
Adverse Events (AE) Preferred term	1. Epistaxis 2. Lobar pneumonia 3. Chronic obstructive pulmonary disease 4. Hypokalaemia 5. Renal impairment 6. Gastrooesophageal reflux disease 7. Vertigo 8. Lethargy 9. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 09SEP2009 (1) - 09SEP2009 (1) 2. 16DEC2009 (99) - 11JAN2010 (125) 3. 16DEC2009 (99) - 26DEC2009 (109) 4. 18DEC2009 (101) - 19DEC2009 (102) 5. 18DEC2009 (101) - 24DEC2009 (107) 6. 19DEC2009 (102) - 23DEC2009 (106) 7. 06MAY2010 (240) - 09MAY2010 (243) 8. 04JUN2010 (269) - --------- (.) 9. 02JUL2010 (297) - 31AUG2010 (357)
Duration of AE	1. 1 2. 27 3. 11 4. 2 5. 7 6. 5

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093044

Parameter	Value
	7. 4
	8. .
	9. 61
Dose on AE onset	1. 15 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093044

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093045

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093045/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/67/ASIAN/AUSTRALIA/YES
Medical history	Appendicectomy, Encephalitis, Arthritis, Knee arthroplasty, Cataract operation, Neuropathy peripheral, Osteoporosis, Pulmonary hypertension, Cataract operation, Oophorectomy, Dyspnoea, Vitamin D deficiency, Postmenopause, Diastolic dysfunction, Deep vein thrombosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CALTRATE PLUS, CARDIZEM CD CAPSULE, COD LIVER OIL, COVERSYL, FISH OIL, FLAXSEED OIL, GLUCOSAMINE AND CHONDROITIN, POLY-TEARS EYEDROPS 0.3-0.1%
Adverse Events (AE) Preferred term	1. Neuropathy peripheral 2. Dyspnoea exertional 3. Pulmonary hypertension 4. Spinal osteoarthritis 5. Vertebral foraminal stenosis 6. Dyspnoea exertional 7. Contusion 8. Haemarthrosis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. SEVERE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MODERATE/NO/NO/NO 5. SEVERE/NO/NO/NO 6. SEVERE/NO/NO/NO 7. MILD/NO/NO/NO 8. SEVERE/NO/NO/NO
Start/stop date of event with relative date	1. 01JAN2010 (78) - --------- (.) 2. 09MAR2010 (145) - 07JUN2010 (235) 3. 07APR2010 (174) - --------- (.) 4. 26MAY2010 (223) - --------- (.) 5. 26MAY2010 (223) - --------- (.) 6. 07JUN2010 (235) - --------- (.) 7. 14JUN2010 (242) - 07JUL2010 (265) 8. 21JUL2010 (279) - 02AUG2010 (291)
Duration of AE	1. . 2. 91 3. . 4. . 5. . 6. . 7. 24 8. 13
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093045

Parameter	Value
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. F
	5. F
	6. F
	7. F
	8. F
Action taken	1. NONE
	2. NONE
	3. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. OTHER
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093048

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093048/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/81/WHITE/AUSTRALIA/YES
Medical history	Asbestosis, Skin neoplasm excision, Coronary artery disease, Coronary artery stenosis, Extrasystoles, Hypertension, Myocardial ischaemia, Skin neoplasm excision, Skin neoplasm excision, Benign prostatic hyperplasia, Thrombocytopenia, Toe amputation, Transurethral prostatectomy, Transurethral prostatectomy, Transurethral prostatectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, ATENOLOL, ENDONE, FINNACAR, LIPITOR, NOTEN, PANVAX H1N1 VACCINE, RAMIPRIL, ZANIDEP
Adverse Events (AE) Preferred term	1. Hypercholesterolaemia 2. Haematuria 3. Dysuria 4. Haematuria 5. Urinary retention 6. Anaemia 7. Fatigue 8. Haematuria 9. Iron deficiency
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/YES/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/YES/YES/YES 5. SEVERE/YES/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/YES/NO/NO
Start/stop date of event with relative date	1. 30OCT2009 (2) - --------- (.) 2. 14DEC2009 (47) - 14DEC2009 (47) 3. 19JUN2010 (234) - 19JUN2010 (234) 4. 27JUL2010 (272) - 28JUL2010 (273) 5. 27JUL2010 (272) - 28JUL2010 (273) 6. 28JUL2010 (273) - --------- (.) 7. 17AUG2010 (293) - 17AUG2010 (293) 8. 04OCT2010 (341) - 11OCT2010 (348) 9. 18NOV2010 (386) - --------- (.)
Duration of AE	1. . 2. 1 3. 1 4. 2 5. 2 6. . 7. 1 8. 8

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093048

Parameter	Value
	9. .
Dose on AE onset	1. 15 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. I
	7. .
	8. .
	9. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. OTHER
	4. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	5. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	6. NONE
	7. NONE
	8. NONE
	9. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093048

Parameter	Value
	9. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093049

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093049/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/60/WHITE/AUSTRALIA/YES
Medical history	Lymphadenopathy, Obesity, Sleep apnoea syndrome
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANGININE, ASPIRIN, BLACKMORES VITAMIN D, CELEBREX, COLOXYL AND SENNA, ENDONE, LACTULOSE, MODURETIC, PARACETAMOL
Adverse Events (AE) Preferred term	1. Constipation 2. Infrequent bowel movements 3. Rash 4. Headache 5. Vitamin D deficiency 6. Arthralgia 7. Musculoskeletal pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/YES/NO/YES 5. MILD/YES/NO/YES 6. MILD/YES/NO/YES 7. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 02NOV2009 (1) - 10MAY2010 (190) 2. 02NOV2009 (1) - 10MAY2010 (190) 3. 03NOV2009 (2) - 04NOV2009 (3) 4. 07NOV2009 (6) - 09NOV2009 (8) 5. 23NOV2009 (22) - --------- (.) 6. 06DEC2009 (35) - 01JUL2010 (242) 7. 18FEB2010 (109) - 19FEB2010 (110)
Duration of AE	1. 190 2. 190 3. 2 4. 3 5. . 6. 208 7. 2
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 20 mg 6. 20 mg 7. 20 mg
Dose status on AE onset	1. . 2. . 3. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093049

Parameter	Value
	4. .
	5. .
	6. .
	7. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093051

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093051/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/73/WHITE/AUSTRALIA/YES
Medical history	Anaemia, Diverticulum, Cough, Dyspnoea exertional, Gastrooesophageal reflux disease, Hypercholesterolaemia, Hypertension, Inguinal hernia repair, Myocardial ischaemia, Macrocytosis, Pulmonary hypertension, Abdominal discomfort, Transient ischaemic attack, Deafness bilateral, Abdominal hernia repair, Acute myocardial infarction
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, LIPITOR, MAXOLON, NORVASC, PRAVACHOL, RAMIPRIL, SWINE FLU VACCINATION, WARFARIN
Adverse Events (AE) Preferred term	1. Rash macular 2. Diverticulitis 3. Dizziness 4. Eye haemorrhage 5. Superficial vein prominence 6. Malaise 7. Migraine 8. Oropharyngeal pain 9. Nasopharyngitis 10. Nausea 11. Acute myocardial infarction 12. Nausea 13. Dizziness 14. Nasopharyngitis 15. Sensation of heaviness 16. Nausea 17. Malaise 18. Multiple myeloma 19. Nasopharyngitis 20. Orthostatic hypotension
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MODERATE/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MILD/NO/NO/YES 15. MODERATE/NO/NO/YES 16. MODERATE/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093051

Parameter	Value
	17. MODERATE/NO/NO/YES
	18. MILD/NO/YES/YES
	19. MILD/NO/NO/YES
	20. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --DEC2009 (.) - 01DEC2010 (371)
	2. --OCT2010 (.) - --------- (.)
	3. 03DEC2009 (8) - 03DEC2009 (8)
	4. 08FEB2010 (75) - 12FEB2010 (79)
	5. 20FEB2010 (87) - --------- (.)
	6. 13MAR2010 (108) - 14MAR2010 (109)
	7. 22MAR2010 (117) - 22MAR2010 (117)
	8. 22MAR2010 (117) - 24MAR2010 (119)
	9. 02APR2010 (128) - 17APR2010 (143)
	10. 18APR2010 (144) - 18APR2010 (144)
	11. 23MAY2010 (179) - 23MAY2010 (179)
	12. 23MAY2010 (179) - 23MAY2010 (179)
	13. 23MAY2010 (179) - 23MAY2010 (179)
	14. 24MAY2010 (180) - 07JUN2010 (194)
	15. 08JUN2010 (195) - 08JUN2010 (195)
	16. 08JUN2010 (195) - 30JUN2010 (217)
	17. 08JUN2010 (195) - 10JUN2010 (197)
	18. 28JUN2010 (215) - --------- (.)
	19. 13AUG2010 (261) - 23AUG2010 (271)
	20. 16SEP2010 (295) - --------- (.)
Duration of AE	1. .
	2. .
	3. 1
	4. 5
	5. .
	6. 2
	7. 1
	8. 3
	9. 16
	10. 1
	11. 1
	12. 1
	13. 1
	14. 15
	15. 1
	16. 23
	17. 3
	18. .
	19. 11
	20. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093051

Parameter	Value
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093051

Parameter	Value
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. NONE
	14. NONE
	15. NONE
	16. NONE
	17. NONE
	18. OTHER
	19. NONE
	20. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. UNCHANGED
	19. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093051

Parameter	Value
	20. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400093051[2)]	SUPERFICIAL BLEED IN RIGHT EYE（PT：眼出血） 治験担当医はエノキサパリンと報告事象との関連性があると判断した。弊社は、エノキサパリン投与終了約 9 週間後の発現であり、時間的関連性がないため、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093052

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093052/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/66/WHITE/AUSTRALIA/YES
Medical history	Acute myocardial infarction, Angina pectoris, Urinary incontinence, Hypercholesterolaemia, Hypertension, Neck pain, Myocardial ischaemia, Prostate cancer, Prostatectomy, Coronary artery bypass
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANGININE, ASPIRIN, ENOXAPARIN, FLUVAX, VYTORIN 10/80, WARFARIN
Adverse Events (AE) Preferred term	1. Urinary incontinence 2. Back pain 3. Dyspnoea exertional
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 27NOV2009 (1) - 06DEC2009 (10) 2. 30NOV2009 (4) - 07DEC2009 (11) 3. 23APR2010 (148) - 23APR2010 (148)
Duration of AE	1. 10 2. 8 3. 1
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. OTHER 3. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093053

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093053/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/29/WHITE/AUSTRALIA/YES
Medical history	Seasonal allergy, Obesity, Limb injury
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, IMODIUM, NATURE'S OWN MULTIVITAMIN + OMEGA 3, PANADOL RAPID, TELFAST, VITAMIN C, WARFARIN
Adverse Events (AE) Preferred term	1. Cough 2. Palpitations 3. Abdominal discomfort
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 27NOV2009 (1) - 21JAN2010 (56) 2. 05DEC2009 (9) - 06DEC2009 (10) 3. 17FEB2010 (83) - 18FEB2010 (84)
Duration of AE	1. 56 2. 2 3. 2
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. OTHER 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093056

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093056/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/74/WHITE/AUSTRALIA/YES
Medical history	Anxiety, Arthritis, Arthroscopy, Chronic obstructive pulmonary disease, Dyspnoea exertional, Headache, Hypertension, Hysterectomy, Myocardial ischaemia, Migraine, Osteoporosis, Panic attack, Thrombophlebitis superficial, Vitamin D deficiency, Rotator cuff repair, Bone operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AVAPRO HCT 300/12.5, BLACKMORES VITAMIN D/CALCIUM, CALTRATE PLUS, FRUSEMIDE, NOTEN, PANADOL, PANADOL OSTEO, SILICA COMPOUND, SLOW K, SORBOLENE CREAM, ZANIDIP
Adverse Events (AE) Preferred term	1. Varicose vein 2. Breast tenderness 3. Chest pain 4. Pain in extremity 5. Epistaxis 6. Sleep apnoea syndrome 7. Pruritus 8. Left ventricular failure 9. Costochondritis 10. Hypertension
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/YES/YES 9. MODERATE/NO/NO/YES 10. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. --JUL2010 (.) - --------- (.) 2. 28APR2010 (8) - 27JUL2010 (98) 3. 28APR2010 (8) - 27JUL2010 (98) 4. 01JUL2010 (72) - --------- (.) 5. 14JUL2010 (85) - 14JUL2010 (85) 6. 25JUL2010 (96) - --------- (.) 7. 10AUG2010 (112) - 31AUG2010 (133) 8. 01SEP2010 (134) - --------- (.) 9. 10SEP2010 (143) - --------- (.) 10. 27SEP2010 (160) - 10NOV2010 (204)
Duration of AE	1. . 2. 91 3. 91 4. . 5. 1

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093056

Parameter	Value
	6. .
	7. 22
	8. .
	9. .
	10. 45
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
Action taken	1. NONE
	2. NONE
	3. OTHER
	4. NONE
	5. OTHER
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. IMPROVED
	9. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093056

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093060

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093060/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/37/WHITE/AUSTRALIA/YES
Medical history	Basedow's disease, Tobacco user, Renal failure chronic, Type 1 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BLACKMORES SILICA COMPOUND TABLETS, CHAMPIX, COVERSYL, FISH OIL, GLUCOSAMINE, GLUCOSE, GNC OLIVE LEAF EXTRACT, IMPLANON IMPLANT, INNER HEALTH PLUS, LEVEMIR FLEXPEN, MARVELON 28, NEOMERCAZOLE, NOVORAPID, SWISSE MULTIVITAMIN
Adverse Events (AE) Preferred term	1. Hair texture abnormal 2. Onychomalacia 3. Contusion 4. Hypoglycaemia 5. Hypoglycaemia 6. Basedow's disease 7. Gingival bleeding 8. Blood blister
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. SEVERE/NO/YES/YES 6. MODERATE/NO/NO/YES 7. MILD/YES/NO/YES 8. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 15JUL2010 (37) - --------- (.) 2. 15JUL2010 (37) - --------- (.) 3. 25MAR2011 (290) - 31MAR2011 (296) 4. 07APR2011 (303) - 07APR2011 (303) 5. 21APR2011 (317) - 21APR2011 (317) 6. 10MAY2011 (336) - --------- (.) 7. 26MAY2011 (352) - 04JUL2011 (391) 8. 28MAY2011 (354) - 28MAY2011 (354)
Duration of AE	1. . 2. . 3. 7 4. 1 5. 1 6. . 7. 40 8. 1
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093060

Parameter	Value
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093062

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093062/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/30/WHITE/AUSTRALIA/YES
Medical history	Asthma, Lower respiratory tract infection, Oedema peripheral, Gamma-glutamyltransferase increased, Hypertension, Toothache, Post thrombotic syndrome, Tobacco user, Alcohol use, Chronic right ventricular failure, Cough, Pulmonary hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, ADRENALINE, AUGMENTIN DUO FORTE, BOSENTAN, CEFAZOLIN, CHLORVESCENT, CLAMOXYL DUO FORTE, CLEXANE, COLOXYL WITH SENNA, DOLASED, DOPAMINE HYDROCHLORIDE, ENOXAPARIN, ERYTHROMYCIN, ESOMEPRAZOLE, FENTANYL, FRUSEMIDE, HEPARIN, HYDROCORTISONE, ILOPROST TROMETAMOL, KALIXOCIN, LACTULOSE, LOW K PHOSPHATE, MAGNESIUM SULFATE, MAXOLON, MIDAZOLAM, MILRINONE LACTATE, MOVICOL, NICOTINE PATCH, NORADRENALINE ACID TARTRATE, PARACETAMOL, PERINDOPRIL, POTASSIUM, PROPOFOL, RESPERIDONE, SILDENAFIL, SLOW K, SODIUM BICARBONATE, SPAN K, SPIRACTIN, THIAMINE, VASOPRESSIN, VENTOLIN, WARFARIN
Adverse Events (AE) Preferred term	1. Cough 2. Blister 3. Dyspnoea exertional 4. Renal haemorrhage 5. Urinary sediment present 6. Proteinuria 7. Sinusitis 8. Lower respiratory tract infection 9. Hypokalaemia 10. Distributive shock 11. Metabolic disorder 12. Renal failure acute 13. Oral discomfort 14. Impaired gastric emptying 15. Pyrexia 16. Breath sounds abnormal 17. Rales 18. Constipation 19. Anxiety 20. Delirium 21. Headache 22. Epigastric discomfort 23. Syncope 24. Muscle twitching 25. Oral herpes
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093062

Parameter	Value
	6. MILD/NO/NO/YES
	7. MODERATE/NO/NO/YES
	8. MILD/NO/NO/YES
	9. MODERATE/NO/NO/YES
	10. SEVERE/NO/YES/YES
	11. SEVERE/NO/YES/YES
	12. MODERATE/NO/NO/YES
	13. MILD/NO/NO/YES
	14. MODERATE/NO/NO/YES
	15. MODERATE/NO/NO/YES
	16. MODERATE/NO/NO/YES
	17. MODERATE/NO/NO/YES
	18. MODERATE/NO/NO/YES
	19. MODERATE/NO/NO/YES
	20. MODERATE/NO/NO/YES
	21. MILD/NO/NO/YES
	22. MODERATE/NO/NO/YES
	23. MODERATE/NO/YES/NO
	24. MODERATE/NO/YES/NO
	25. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --JUL2011 (.) - --JUL2011 (.)
	2. 15SEP2010 (1) - 20NOV2010 (67)
	3. 20DEC2010 (97) - 13JAN2011 (121)
	4. 23FEB2011 (162) - 23FEB2011 (162)
	5. 23FEB2011 (162) - 23FEB2011 (162)
	6. 23FEB2011 (162) - 23FEB2011 (162)
	7. 01MAY2011 (229) - 15MAY2011 (243)
	8. 25MAY2011 (253) - 11JUL2011 (300)
	9. 24JUL2011 (313) - 31JUL2011 (320)
	10. 03AUG2011 (323) - 09AUG2011 (329)
	11. 03AUG2011 (323) - 15AUG2011 (335)
	12. 03AUG2011 (323) - 07AUG2011 (327)
	13. 04AUG2011 (324) - 05AUG2011 (325)
	14. 04AUG2011 (324) - 15AUG2011 (335)
	15. 04AUG2011 (324) - 15AUG2011 (335)
	16. 04AUG2011 (324) - 06AUG2011 (326)
	17. 04AUG2011 (324) - 06AUG2011 (326)
	18. 07AUG2011 (327) - 15AUG2011 (335)
	19. 08AUG2011 (328) - 12AUG2011 (332)
	20. 08AUG2011 (328) - 12AUG2011 (332)
	21. 08AUG2011 (328) - 09AUG2011 (329)
	22. 09AUG2011 (329) - 22AUG2011 (342)
	23. 11AUG2011 (331) - 11AUG2011 (331)
	24. 11AUG2011 (331) - 11AUG2011 (331)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093062

Parameter	Value
	25. 11AUG2011 (331) - 06SEP2011 (357)
Duration of AE	1. .
	2. 67
	3. 25
	4. 1
	5. 1
	6. 1
	7. 15
	8. 48
	9. 8
	10. 7
	11. 13
	12. 5
	13. 2
	14. 12
	15. 12
	16. 3
	17. 3
	18. 9
	19. 5
	20. 5
	21. 2
	22. 14
	23. 1
	24. 1
	25. 27
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093062

Parameter	Value
	19.
	20.
	21.
	22.
	23.
	24.
	25.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. OTHER
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093062

Parameter	Value
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. REMEDIAL DRUG THERAPY
	19. REMEDIAL DRUG THERAPY
	20. REMEDIAL DRUG THERAPY
	21. NONE
	22. REMEDIAL DRUG THERAPY
	23. REMEDIAL DRUG THERAPY
	24. REMEDIAL DRUG THERAPY
	25. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED
	23. RESOLVED
	24. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093062

Parameter	Value
	25. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093067

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400093067/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/53/WHITE/AUSTRALIA/YES
Medical history	Asthma, Rhinitis, Depression, Seasonal allergy, Hypertension, Menopause, Nasal polyps, Drug eruption
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CIPRAMIL, ENDONE, ENOXAPARIN, IBUPROFEN, PANADOL, PANADOL OSTEO, PREDNISOLONE, RHINOCORT, SERETIDE, TELFAST, VENTOLIN, WARFARIN
Adverse Events (AE) Preferred term	1. Asthma 2. Contusion 3. Muscle spasms 4. Musculoskeletal chest pain 5. Seasonal allergy 6. Chest pain 7. Spondylitis 8. Stress urinary incontinence 9. Foot fracture 10. Fibula fracture
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/YES/YES 10. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 09FEB2011 (1) - 01MAY2011 (82) 2. 13FEB2011 (5) - 27FEB2011 (19) 3. 28FEB2011 (20) - 01MAY2011 (82) 4. 05MAR2011 (25) - 28APR2011 (79) 5. 10MAR2011 (30) - 01MAY2011 (82) 6. 01APR2011 (52) - 01MAY2011 (82) 7. 26APR2011 (77) - --------- (.) 8. 03MAY2011 (84) - --------- (.) 9. 07JUL2011 (149) - 04AUG2011 (177) 10. 07JUL2011 (149) - 04AUG2011 (177)
Duration of AE	1. 82 2. 15 3. 63 4. 55 5. 53 6. 31 7. . 8. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093067

Parameter	Value
	9. 29
	10. 29
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	10. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. UNCHANGED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400093067

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400123004/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/83/WHITE/AUSTRALIA/YES
Medical history	Joint swelling, Breast cancer, Modified radical mastectomy, Rheumatoid arthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, AUGMENTIN DUO FORTE, AZITHROMYCIN, BENZYLPENICILLIN, CLEXANE, LASIX, PANADOL [PARACETAMOL ONLY], RULIDE, SLOW K, UREMIDE
Adverse Events (AE) Preferred term	1. Oedema peripheral 2. Epistaxis 3. Pneumonia 4. Dyspnoea exertional
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --OCT2007 (.) - 02JAN2008 (152) 2. 12AUG2007 (9) - 12AUG2007 (9) 3. 11OCT2007 (69) - 18OCT2007 (76) 4. 07NOV2007 (96) - 29NOV2007 (118)
Duration of AE	1. . 2. 1 3. 8 4. 23
Dose on AE onset	1. 2. 15 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. .
Action taken	1. REMEDIAL DRUG THERAPY 2. OTHER 3. REMEDIAL DRUG THERAPY 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123004

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400123007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/82/WHITE/AUSTRALIA/YES
Medical history	Blood alkaline phosphatase increased, Appendicectomy, Cholecystectomy, Cystocele, Gastrooesophageal reflux disease, Hypertension, Hysterectomy, Dyspepsia, Trigeminal neuralgia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATORVASTATIN, AUGMENTIN DUO FORTE, BENZYLPENICILLIN, CALCIUM SUPPLEMENT, CARTIA (ASPIRIN), COVERSAL PLUS, COVERSYL PLUS, DOXYCYCLINE, ENOXAPARIN, FELODIPINE, GAVISCON, LIPITOR, MICARDIS, MICARDIS PLUS, MINIPRESS, PARACETAMOL, PLENDIL, ROXITHROMYCIN, RULIDE, SALBUTAMOL NEBULISERS, TEGRETOL, WARFARIN
Adverse Events (AE) Preferred term	1. Chest discomfort 2. Trigeminal neuralgia 3. Pyrexia 4. Upper respiratory tract infection 5. Hypercholesterolaemia 6. Perineal haematoma 7. Dyspnoea 8. Syncope 9. Hypertension 10. Dizziness 11. Hypertension 12. Dyspnoea exertional 13. Lower respiratory tract infection 14. Dizziness postural 15. Wound haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MILD/NO/NO/YES 13. MODERATE/NO/YES/YES 14. MILD/NO/NO/YES 15. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --NOV2007 (.) - --DEC2007 (.) 2. --MAR2008 (.) - --------- (.) 3. 11OCT2007 (1) - 13OCT2007 (3) 4. 13OCT2007 (3) - 21OCT2007 (11) 5. 04DEC2007 (55) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123007

Parameter	Value
	6. 18FEB2008 (131) - 18FEB2008 (131)
	7. 21FEB2008 (134) - --APR2008 (.)
	8. 07MAR2008 (149) - 07MAR2008 (149)
	9. 07MAR2008 (149) - 21MAR2008 (163)
	10. 24MAR2008 (166) - --JUN2008 (.)
	11. 14APR2008 (187) - --SEP2008 (.)
	12. 10JUN2008 (244) - 12JUN2008 (246)
	13. 06AUG2008 (301) - 18AUG2008 (313)
	14. 22SEP2008 (348) - 04OCT2008 (360)
	15. 22OCT2008 (378) - 22OCT2008 (378)
Duration of AE	1. .
	2. .
	3. 3
	4. 9
	5. .
	6. 1
	7. .
	8. 1
	9. 15
	10. .
	11. .
	12. 3
	13. 13
	14. 13
	15. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Dose status on AE onset	1.
	2.
	3.
	4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123007

Parameter	Value
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. OTHER
	8. OTHER
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. INSUFFICIENT FOLLOW-UP
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123007

Parameter	Value
	15. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400123012/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/67/WHITE/AUSTRALIA/YES
Medical history	Alopecia, Anaemia, Anxiety, Appendicectomy, Chest pain, Depression, Diarrhoea, Nail discolouration, Fatigue, Hormone level abnormal, Hypertension, Hyponatraemia, Hysterectomy, Megacolon, Migraine, Gastrooesophageal reflux disease, Osteoarthritis, Drug hypersensitivity, Eye pain, Knee arthroplasty, Iodine allergy, Colectomy, Ileus paralytic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTONE [ALDACTONE CONTAINS SPIRONOLACTONE.], ALEPAM, ALODORM, BUSCOPAN, CELEBREX, DURO-TUSS DRY COUGH LIQUID (CONTAINS PHOLCODINE AND MULTIPLE ADDITIVES.), FIORINAL [CODIENE PHOSPATE, DOXYLAMINE SUCCINATE, PARACETAMOL], FLEET ENEMA [SODIUM PHOSPHATE MONOBASIC 19G AND SODIUM BIPHASIC 7G], FRAGMIN, IMODIUM [LOPERAMIDE HCI], MENOREST PATCH, MINAX, NEXIUM, NORMAL SALINE, NUROFEN, OESTEOEZE, PANADEINE, PANADEINE FORTE, PANADOL, QUESTRAN LITE, RULIDE, SYSTANE EYE DROPS, VIBRAMYCIN, ZOTON, ZYPREXA
Adverse Events (AE) Preferred term	1. Diarrhoea 2. Chest pain 3. Liver function test abnormal 4. Contusion 5. Headache 6. Pain 7. Lower gastrointestinal haemorrhage 8. Small intestinal obstruction 9. Abdominal pain upper 10. Hiatus hernia 11. Oesophagitis ulcerative 12. Contusion 13. Contusion 14. Vessel puncture site haemorrhage 15. Lower gastrointestinal haemorrhage 16. Influenza 17. Bronchitis 18. Epistaxis 19. Contusion 20. Dyspnoea 21. Chest pain 22. Presyncope 23. Contusion 24. Nausea 25. Decreased appetite 26. Epistaxis 27. Contusion 28. Vitamin D deficiency 29. Iron deficiency
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123012

Parameter	Value
	2. MILD/NO/NO/YES
	3. MILD/YES/NO/YES
	4. MILD/NO/NO/YES
	5. MILD/NO/NO/YES
	6. MILD/NO/NO/YES
	7. MILD/NO/NO/YES
	8. MODERATE/NO/YES/YES
	9. MODERATE/NO/NO/YES
	10. MILD/NO/NO/YES
	11. MODERATE/NO/NO/YES
	12. MILD/NO/NO/YES
	13. MILD/YES/NO/YES
	14. MILD/NO/NO/YES
	15. MILD/YES/NO/YES
	16. MILD/NO/NO/YES
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MILD/YES/NO/YES
	20. MILD/NO/NO/YES
	21. MILD/NO/NO/YES
	22. MILD/NO/NO/YES
	23. MILD/NO/NO/YES
	24. MILD/YES/NO/YES
	25. MILD/YES/NO/YES
	26. MILD/NO/NO/YES
	27. MILD/NO/NO/YES
	28. MILD/NO/NO/YES
	29. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JAN2008 (.) - --------- (.)
	2. --SEP2008 (.) - --OCT2008 (.)
	3. 28DEC2007 (1) - --JAN2008 (.)
	4. 29DEC2007 (2) - 30DEC2007 (3)
	5. 29DEC2007 (2) - 29DEC2007 (2)
	6. 30DEC2007 (3) - 30DEC2007 (3)
	7. 01FEB2008 (36) - 01FEB2008 (36)
	8. 01FEB2008 (36) - 04FEB2008 (39)
	9. 15FEB2008 (50) - 16FEB2008 (51)
	10. 11MAR2008 (75) - --------- (.)
	11. 11MAR2008 (75) - --------- (.)
	12. 21MAR2008 (85) - 02APR2008 (97)
	13. 26APR2008 (121) - -----2008 (.)
	14. 19MAY2008 (144) - 19MAY2008 (144)
	15. 22MAY2008 (147) - 24MAY2008 (149)
	16. 12JUN2008 (168) - 11JUL2008 (197)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123012

Parameter	Value
	17. 12JUN2008 (168) - 14JUL2008 (200)
	18. 16JUL2008 (202) - 16JUL2008 (202)
	19. 23AUG2008 (240) - 06SEP2008 (254)
	20. 23AUG2008 (240) - 23AUG2008 (240)
	21. 23AUG2008 (240) - 23AUG2008 (240)
	22. 24AUG2008 (241) - 24AUG2008 (241)
	23. 25AUG2008 (242) - 01SEP2008 (249)
	24. 27AUG2008 (244) - 01NOV2008 (310)
	25. 27AUG2008 (244) - 01NOV2008 (310)
	26. 09SEP2008 (257) - 17SEP2008 (265)
	27. 29SEP2008 (277) - 10OCT2008 (288)
	28. 21OCT2008 (299) - --------- (.)
	29. 23OCT2008 (301) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. 2
	5. 1
	6. 1
	7. 1
	8. 4
	9. 2
	10. .
	11. .
	12. 13
	13. .
	14. 1
	15. 3
	16. 30
	17. 33
	18. 1
	19. 15
	20. 1
	21. 1
	22. 1
	23. 8
	24. 67
	25. 67
	26. 9
	27. 12
	28. .
	29. .
Dose on AE onset	1.
	2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123012

Parameter	Value
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
	22. 20 mg
	23. 20 mg
	24. 20 mg
	25. 20 mg
	26. 20 mg
	27. 20 mg
	28. 20 mg
	29. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. I
	11. I
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123012

Parameter	Value
	18. .
	19. .
	20. .
	21. .
	22. .
	23. .
	24. .
	25. .
	26. .
	27. .
	28. .
	29. .
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	12. NONE
	13. NONE
	14. NONE
	15. STUDY DRUG DISCONTINUED AND RESTARTED
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. NONE
	19. NONE
	20. NONE
	21. NONE
	22. NONE
	23. NONE
	24. DOSE OF STUDY DRUG REDUCED
	25. NONE
	26. NONE
	27. NONE
	28. NONE
	29. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123012

Parameter	Value
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. UNCHANGED
	11. IMPROVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED
	23. RESOLVED
	24. RESOLVED
	25. RESOLVED
	26. RESOLVED
	27. RESOLVED
	28. INSUFFICIENT FOLLOW-UP
	29. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400123023/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/71/WHITE/AUSTRALIA/YES
Medical history	Arthritis, Bronchiectasis, Chest pain, Cholecystectomy, Diverticulitis, Drug hypersensitivity, Drug hypersensitivity, Drug hypersensitivity, Gastrooesophageal reflux disease, Hiatus hernia, Nausea, Obesity, Pneumonia, Pneumonia, Phlebitis, Iodine allergy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, METOCLOPRAMIDE, PANTOPRAZOLE, PARACETAMOL, RANITIDINE HYDROCHLORIDE, STEMETIL, WARFARIN, XYLOCAINE/MYLANTA KNOWN AS PINK LADY
Adverse Events (AE) Preferred term	1. Nausea 2. Dizziness 3. Rhinorrhoea 4. Dry throat 5. Dysphonia 6. International normalised ratio increased 7. Vertigo 8. Decreased appetite 9. Nausea 10. Abdominal pain 11. Headache 12. Decreased appetite 13. Abdominal distension 14. Headache 15. Urinary tract infection 16. Diarrhoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/YES/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/YES/YES 9. MILD/YES/NO/YES 10. MODERATE/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MODERATE/NO/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES 15. MILD/NO/NO/NO 16. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 21MAY2008 (9) - 22MAY2008 (10) 2. 21MAY2008 (9) - 22MAY2008 (10) 3. 21MAY2008 (9) - 21MAY2008 (9) 4. 21MAY2008 (9) - 21MAY2008 (9)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123023

Parameter	Value
	5. 21MAY2008 (9) - 21MAY2008 (9)
	6. 26MAY2008 (14) - 28MAY2008 (16)
	7. 26MAY2008 (14) - 30MAY2008 (18)
	8. 27MAY2008 (15) - 06JUN2008 (25)
	9. 27MAY2008 (15) - 06JUN2008 (25)
	10. 30MAY2008 (18) - 06JUN2008 (25)
	11. 30MAY2008 (18) - 30MAY2008 (18)
	12. 31MAY2008 (19) - 25JUN2008 (44)
	13. 31MAY2008 (19) - 06JUN2008 (25)
	14. 01JUN2008 (20) - --------- (.)
	15. 04JUN2008 (23) - 04JUN2008 (23)
	16. 22JUN2008 (41) - 22JUN2008 (41)
Duration of AE	1. 2
	2. 2
	3. 1
	4. 1
	5. 1
	6. 3
	7. 5
	8. 11
	9. 11
	10. 8
	11. 1
	12. 26
	13. 7
	14. .
	15. 1
	16. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123023

Parameter	Value
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. STUDY DRUG DISCONTINUED AND RESTARTED
	7. REMEDIAL DRUG THERAPY
	8. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. STUDY DRUG DISCONTINUED PERMANENTLY
	11. STUDY DRUG DISCONTINUED PERMANENTLY
	12. STUDY DRUG DISCONTINUED PERMANENTLY
	13. STUDY DRUG DISCONTINUED PERMANENTLY
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123023

Parameter	Value
	13. RESOLVED
	14. IMPROVED
	15. RESOLVED
	16. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400123023[4)]	ANOREXIA（PT：食欲減退） 治験担当医は、患者は他の薬剤に対する過敏症の一症状と考え、因果関係は否定できると判断した。弊社は、ワルファリン投与と報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400123029/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/76/WHITE/AUSTRALIA/YES
Medical history	Lower respiratory tract infection, Gout, Hypercholesterolaemia, Hypertension, Type 2 diabetes mellitus, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, CEPHALEXIN, ENOXAPARIN, METHYLDOPA, PERINDOPRIL, WARFARIN, ZOCOR
Adverse Events (AE) Preferred term	1. Contusion 2. Cellulitis 3. Contusion 4. Pain in extremity 5. Dyspnoea 6. Tachypnoea 7. Pain in extremity 8. Cellulitis 9. Lung neoplasm malignant 10. Cellulitis 11. Lung neoplasm malignant 12. Pneumonia 13. Venous thrombosis limb
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES 11. SEVERE/NO/YES/NO 12. MODERATE/NO/NO/NO 13. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 26AUG2008 (1) - 08OCT2008 (44) 2. 26AUG2008 (1) - 23SEP2008 (29) 3. 01SEP2008 (7) - 08OCT2008 (44) 4. 04SEP2008 (10) - 08SEP2008 (14) 5. 05SEP2008 (11) - 08OCT2008 (44) 6. 05SEP2008 (11) - 08OCT2008 (44) 7. 07SEP2008 (13) - 11SEP2008 (17) 8. 15SEP2008 (21) - --OCT2008 (.) 9. 15SEP2008 (21) - 17SEP2008 (23) 10. 17SEP2008 (23) - 08OCT2008 (44) 11. 18SEP2008 (24) - 22DEC2008 (119) 12. 18SEP2008 (24) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123029

Parameter	Value
	13. 22SEP2008 (28) - --------- (.)
Duration of AE	1. 44
	2. 29
	3. 38
	4. 5
	5. 34
	6. 34
	7. 5
	8. .
	9. 3
	10. 22
	11. 96
	12. .
	13. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123029

Parameter	Value
	5. OTHER
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. WORSENED
	10. RESOLVED
	11. DEATH
	12. INSUFFICIENT FOLLOW-UP
	13. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400123029[1)]	FATAL LUNG CARCINOMA（PT：肺の悪性新生物） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症であると判断し、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123037

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400123037/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/AUSTRALIA/YES
Medical history	Angina pectoris, Anxiety, Asthma, Carotid endarterectomy, Lower respiratory tract infection, Chronic obstructive pulmonary disease, Emphysema, Gastrooesophageal reflux disease, Hiatus hernia, Hypercholesterolaemia, Hypertension, Macular degeneration, Pulmonary tuberculosis, Pneumothorax, Transient ischaemic attack, Ex-tobacco user
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPRAZOLAM, ANAGRAINE, ASTRIX, ATROVENT, AUGMENTIN DUO FORTE, DOXYCYCLINE, DUCENE, FLUVAX, H1N1 VACCINATION, HYDROCORTISONE, LORAZEPAM, NATURE'S OWN CALCIUM + MAGNESIUM, OSTELIN D, PANADOL, PANTOPRAZOLE, PARACETAMOL, PERINDOPRIL ARGININE, PREDNISOLONE, PRISTIQ ER, SENEGA AND AMMONIA MIXTURE, SIMVASTATIN, SOMAC, SPIRIVA, SYMBICORT TURBUHALER, TIOTROPIUM BROMIDE, TRAMADOL, VENTOLIN, VENTOLIN NEBULES
Adverse Events (AE) Preferred term	1. Skin warm 2. Nausea 3. Decreased appetite 4. Back pain 5. Asthma 6. Vulvovaginal discomfort 7. Haematuria 8. Headache 9. Contusion 10. Dyspnoea 11. Chronic obstructive pulmonary disease 12. Contusion 13. Infective exacerbation of chronic obstructive airways disease 14. Haematoma 15. Anxiety 16. Infective exacerbation of chronic obstructive airways disease 17. Headache 18. Chronic obstructive pulmonary disease 19. Contusion 20. Contusion 21. Contusion 22. Contusion 23. Myalgia 24. Cough 25. Contusion 26. Contusion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123037

Parameter	Value
	6. MILD/NO/NO/YES
	7. MODERATE/YES/YES/YES
	8. MILD/NO/NO/YES
	9. MILD/NO/NO/YES
	10. MODERATE/NO/NO/YES
	11. MODERATE/NO/YES/YES
	12. MILD/NO/NO/YES
	13. MODERATE/NO/YES/YES
	14. MILD/NO/NO/YES
	15. MILD/NO/NO/YES
	16. MODERATE/NO/YES/YES
	17. MILD/NO/NO/YES
	18. MODERATE/NO/YES/YES
	19. MILD/NO/NO/YES
	20. MILD/NO/NO/YES
	21. MILD/NO/NO/YES
	22. MILD/NO/NO/YES
	23. MILD/NO/NO/YES
	24. MILD/NO/NO/YES
	25. MILD/NO/NO/YES
	26. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 06FEB2009 (1) - --------- (.)
	2. 09FEB2009 (4) - 13FEB2009 (8)
	3. 09FEB2009 (4) - 13FEB2009 (8)
	4. 09FEB2009 (4) - 09FEB2009 (4)
	5. 13FEB2009 (8) - 16FEB2009 (11)
	6. 20FEB2009 (15) - 01MAR2009 (24)
	7. 23FEB2009 (18) - 25FEB2009 (20)
	8. 23FEB2009 (18) - 25FEB2009 (20)
	9. 13APR2009 (67) - 03MAY2009 (87)
	10. 27APR2009 (81) - 07MAY2009 (91)
	11. 30APR2009 (84) - 07MAY2009 (91)
	12. 02MAY2009 (86) - --JUN2009 (.)
	13. 05JUN2009 (120) - 29JUN2009 (144)
	14. 09JUN2009 (124) - 01JUL2009 (146)
	15. 01JUL2009 (146) - 03AUG2009 (179)
	16. 01JUL2009 (146) - 14JUL2009 (159)
	17. 27JUL2009 (172) - 28JUL2009 (173)
	18. 29JUL2009 (174) - 07AUG2009 (183)
	19. 18AUG2009 (194) - 09SEP2009 (216)
	20. 29SEP2009 (236) - 13OCT2009 (250)
	21. 04OCT2009 (241) - 13OCT2009 (250)
	22. 24OCT2009 (261) - 03NOV2009 (271)
	23. 08NOV2009 (276) - 24DEC2009 (322)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123037

Parameter	Value
	24. 08NOV2009 (276) - 08NOV2009 (276)
	25. 30NOV2009 (298) - 05DEC2009 (303)
	26. 26FEB2010 (386) - --------- (.)
Duration of AE	1. .
	2. 5
	3. 5
	4. 1
	5. 4
	6. 10
	7. 3
	8. 3
	9. 21
	10. 11
	11. 8
	12. .
	13. 25
	14. 23
	15. 34
	16. 14
	17. 2
	18. 10
	19. 23
	20. 15
	21. 10
	22. 11
	23. 47
	24. 1
	25. 6
	26. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123037

Parameter	Value
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
	22. 20 mg
	23. 20 mg
	24. 20 mg
	25. 20 mg
	26. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
	18. .
	19. .
	20. .
	21. .
	22. .
	23. .
	24. .
	25. .
	26. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. STUDY DRUG DISCONTINUED AND RESTARTED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123037

Parameter	Value
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. NONE
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. NONE
	15. REMEDIAL DRUG THERAPY
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. REMEDIAL DRUG THERAPY
	19. NONE
	20. NONE
	21. NONE
	22. NONE
	23. REMEDIAL DRUG THERAPY
	24. NONE
	25. NONE
	26. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED
	23. RESOLVED
	24. RESOLVED
	25. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123037

Parameter	Value
	26. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123044

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400123044/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/59/WHITE/AUSTRALIA/YES
Medical history	Chronic obstructive pulmonary disease, Lipoma, Tobacco user
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN DUO FORTE, BISOLVON CHESTY ORAL LIQUID, CEPHALEXIN, CEPHAZOLIN, CLEXANE, DOXYCYLINE, ENOXAPARIN, PANADOL, PROBENCID, SALBUTOMOL, VITAMIN K, WARFARIN
Adverse Events (AE) Preferred term	1. Infective exacerbation of chronic obstructive airways disease 2. Oedema peripheral 3. Tenosynovitis 4. Localised infection 5. Toothache 6. Lower respiratory tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 03JUN2009 (5) - 12JUN2009 (14) 2. 27JUN2009 (29) - 30JUN2009 (32) 3. 30JUN2009 (32) - --------- (.) 4. 01JUL2009 (33) - 10JUL2009 (42) 5. 28JUL2009 (60) - 13AUG2009 (76) 6. 28JAN2010 (244) - 04FEB2010 (251)
Duration of AE	1. 10 2. 4 3. . 4. 10 5. 17 6. 8
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123044

Parameter	Value
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	3. NONE
	4. REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. WORSENED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123045

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400123045/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/61/WHITE/AUSTRALIA/YES
Medical history	Acute myocardial infarction, Cardiac pacemaker insertion, Depression, Fasciotomy, Gastrooesophageal reflux disease, Hypercholesterolaemia, Hypertension, Obesity, Plantar fasciitis, Vertigo, Alcohol use, Coronary arterial stent insertion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, COVERSYL, ESCITALOPRAM, LEXAPRO, METOPROLOL, NEXIUM, PANADEINE FORTE, PARACETAMOL, VENTOLIN, VYTORIN
Adverse Events (AE) Preferred term	1. Muscle spasms 2. Abdominal pain 3. Diarrhoea 4. Faecal incontinence 5. Spinal osteoarthritis 6. Back pain 7. Epistaxis 8. Conjunctival haemorrhage 9. Vision blurred 10. Haematuria 11. Muscular weakness 12. Contusion 13. Epistaxis 14. Epistaxis 15. Contusion 16. Depression 17. Wound haemorrhage 18. Contusion 19. Diarrhoea 20. Abdominal pain upper 21. Decreased appetite 22. Malaise 23. Faeces discoloured
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/YES/NO/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES 10. MILD/YES/YES/YES 11. MILD/NO/NO/YES 12. MILD/YES/NO/YES 13. MILD/YES/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123045

Parameter	Value
	14. MILD/YES/NO/YES
	15. MILD/NO/NO/YES
	16. MILD/NO/NO/YES
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MILD/NO/NO/YES
	20. MILD/NO/NO/YES
	21. MILD/NO/NO/YES
	22. MILD/NO/NO/NO
	23. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --MAY2010 (.) - --------- (.)
	2. 30JUN2009 (6) - 01JUL2009 (7)
	3. 30JUN2009 (6) - 01JUL2009 (7)
	4. 25AUG2009 (62) - 01FEB2010 (222)
	5. 25AUG2009 (62) - --------- (.)
	6. 27AUG2009 (64) - --FEB2010 (.)
	7. 01SEP2009 (69) - 01OCT2009 (99)
	8. 19SEP2009 (87) - --NOV2009 (.)
	9. 20SEP2009 (88) - --------- (.)
	10. 30SEP2009 (98) - 02OCT2009 (100)
	11. 25OCT2009 (123) - --------- (.)
	12. 11NOV2009 (140) - 23NOV2009 (152)
	13. 14NOV2009 (143) - 14NOV2009 (143)
	14. 23DEC2009 (182) - 10JUN2010 (351)
	15. 10JAN2010 (200) - 02FEB2010 (223)
	16. 10FEB2010 (231) - --------- (.)
	17. 17MAR2010 (266) - 17MAR2010 (266)
	18. 24APR2010 (304) - --------- (.)
	19. 13MAY2010 (323) - --------- (.)
	20. 01JUN2010 (342) - --------- (.)
	21. 01JUN2010 (342) - --------- (.)
	22. 01JUL2010 (372) - --------- (.)
	23. 12JUL2010 (383) - --------- (.)
Duration of AE	1. .
	2. 2
	3. 2
	4. 161
	5. .
	6. .
	7. 31
	8. .
	9. .
	10. 3
	11. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123045

Parameter	Value
	12. 13
	13. 1
	14. 170
	15. 24
	16. .
	17. 1
	18. .
	19. .
	20. .
	21. .
	22. .
	23. .
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
	22. 20 mg
	23. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123045

Parameter	Value
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
	18. .
	19. .
	20. .
	21. .
	22. F
	23. F
Action taken	1. OTHER
	2. NONE
	3. NONE
	4. OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. OTHER
	10. STUDY DRUG DISCONTINUED AND RESTARTED
	11. OTHER
	12. NONE
	13. OTHER
	14. NONE
	15. NONE
	16. REMEDIAL DRUG THERAPY
	17. OTHER
	18. NONE
	19. NONE
	20. NONE
	21. NONE
	22. OTHER
	23. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123045

Parameter	Value
	8. RESOLVED
	9. IMPROVED
	10. RESOLVED
	11. UNCHANGED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. UNCHANGED
	17. RESOLVED
	18. IMPROVED
	19. IMPROVED
	20. UNCHANGED
	21. UNCHANGED
	22. UNCHANGED
	23. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123051

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400123051/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/AUSTRALIA/YES
Medical history	Acute myocardial infarction, Acute myocardial infarction, Angina pectoris, Chronic lymphocytic leukaemia, Constipation, Gastrooesophageal reflux disease, Hypertension, Hyperthyroidism, Osteoporosis, Anal abscess, Sciatica, Spinal osteoarthritis, Stress, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMITRIPTYLINE, ANGININE, ASPIRIN, CANDESARTAN, COLOXYL WITH SENNA, COQ10, FELODUR ER, GLYCERIN SUPPOSITORIES, GLYCERYL TRINITRATE PATCH, HOMOPLEX HERBAL MIX, IMDUR, MAGNESIUM, MAXOLON, MORPHINE, MOVICOL, MYLANTA [MYLANTA: SIMTHICONE, MG HYDROXIDE AND AL HYDROXIDE], NEXIUM, NUROFEN, OXYCONTIN, PANADOL, RESTORE-A-CALM [HERBAL TO TREAT STRESS:STEM BARK PHELLODENDRO AMURENS;MAGNOLIA S, SENOKOT, SULPHUR-M [SPELLING IS CORRECT. NAME OF HERBAL MED.], XYLOCAINE VISCOUS
Adverse Events (AE) Preferred term	1. Hypersensitivity 2. Musculoskeletal pain 3. Headache 4. Nausea 5. Dizziness 6. Chest pain 7. Abdominal pain upper 8. Stress 9. Nasopharyngitis 10. Nasopharyngitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/YES/YES/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --AUG2009 (.) - --------- (.) 2. 01AUG2009 (3) - 03AUG2009 (5) 3. 03AUG2009 (5) - 03AUG2009 (5) 4. 03AUG2009 (5) - 03AUG2009 (5) 5. 03AUG2009 (5) - 03AUG2009 (5) 6. 13AUG2009 (15) - 17AUG2009 (19) 7. 14AUG2009 (16) - 14AUG2009 (16) 8. 01SEP2009 (34) - --SEP2009 (.) 9. 03SEP2009 (36) - 06SEP2009 (39) 10. 14OCT2009 (77) - 21OCT2009 (84)
Duration of AE	1. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123051

Parameter	Value
	2. 3
	3. 1
	4. 1
	5. 1
	6. 5
	7. 1
	8. .
	9. 4
	10. 8
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
Action taken	1. NONE
	2. OTHER
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123051

Parameter	Value
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400123051[2)]	SUDDEN ONSET CHEST PAIN OF UNKNOWN ETIOLOGY（PT：胸痛） 治験担当医はリバーロキサバンと報告事象との関連性があると判断した。弊社は、合併症（狭心症、高血圧）及び心筋梗塞の既往を有することから、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123056

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400123056/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/60/WHITE/AUSTRALIA/YES
Medical history	Nephritis, Appendicectomy, Lower respiratory tract infection, Cholecystectomy, Headache, Dyspepsia, Hypertension, Hysterectomy, Menorrhagia, Myopia, Obesity, Drug hypersensitivity, Adhesion, Ovarian haemorrhage
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANGININE, BERROCA, CLARITHROMYCIN, COVERSYL PLUS, ENDONE, ENOXAPARIN, GENOVIS WOMENS MULTI VITAMIN AND MINERALS, NATURES OWN MULTIVITAMINS, NUROFEN PLUS, PANADIENE, PANADOL, PERINDROPRIL (COVERSYL), PROMENSIL, PROMETHAZINE, ROXIMYCIN, STEMZINE, SYMBICORT
Adverse Events (AE) Preferred term	1. Rash morbilliform 2. Dyspnoea exertional 3. Viral infection 4. Otitis media 5. Upper respiratory tract infection 6. Nausea 7. Vomiting 8. Pyrexia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/NO 7. MILD/NO/NO/NO 8. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 21FEB2010 (3) - 05MAR2010 (15) 2. 18MAR2010 (28) - 10MAY2010 (81) 3. 03APR2010 (44) - 23APR2010 (64) 4. 08APR2010 (49) - 23APR2010 (64) 5. 03AUG2010 (166) - 20AUG2010 (183) 6. 13SEP2010 (207) - --------- (.) 7. 13SEP2010 (207) - 13SEP2010 (207) 8. 13SEP2010 (207) - 14SEP2010 (208)
Duration of AE	1. 13 2. 54 3. 21 4. 16 5. 18 6. . 7. 1 8. 2
Dose on AE onset	1. 15 mg 2. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123056

Parameter	Value
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. F
	7. F
	8. F
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. IMPROVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400123056[1)]	MORBILLIFORM RASH（PT：麻疹様発疹） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併用薬（リバーロキサバン)によるものであり、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123057

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400123057/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/76/WHITE/AUSTRALIA/YES
Medical history	Back pain, Cholecystectomy, Chronic obstructive pulmonary disease, Spinal compression fracture, Diverticulitis, Gastrooesophageal reflux disease, Hepatitis, Hiatus hernia, Hypercholesterolaemia, Hypertension, Menopause, Osteoarthritis, Osteoporosis, Peptic ulcer, Pulmonary fibrosis, Herpes zoster
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, AVAPRO, BRICANYL TURBOHALER, CALTRATE PLUS, ENDONE, ENOXAPARIN, FLU INJECTION, FOSAMAX, HYDROCORTISONE, KLACID, LACTULOSE, MAXALON, MORPHINE, NEXIUM, OSTELIN VIT D GEL CAPSULE, OXYCONTIN, PANADIENE FORTE, PANADOL, PARACETAMOL, PENTHRANE, PREDNISOLONE, ROBITUSSIN [GUAIFENESIN;ETOH,PROPYLENE GLYCOL,SACCHARIN NA,NA BENZOATE,SORBITOL], STREPSILS, TRIMETHOPRIM, WARFARIN, ZOTON
Adverse Events (AE) Preferred term	1. Nasopharyngitis 2. Gastrooesophageal reflux disease 3. Pleurisy 4. Back pain 5. Lower respiratory tract infection 6. Cough 7. Chest pain 8. Urinary tract infection 9. Urinary tract infection 10. Chronic obstructive pulmonary disease
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/NO 10. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 16APR2010 (2) - 22APR2010 (8) 2. 20APR2010 (6) - 27APR2010 (13) 3. 17MAY2010 (33) - 30MAY2010 (46) 4. 17MAY2010 (33) - 21JUN2010 (68) 5. 05JUL2010 (82) - 19JUL2010 (96) 6. 01AUG2010 (109) - --------- (.) 7. 22AUG2010 (130) - 26AUG2010 (134) 8. 24AUG2010 (132) - 27AUG2010 (135) 9. 10OCT2010 (179) - --------- (.) 10. 01NOV2010 (201) - --------- (.)
Duration of AE	1. 7 2. 8

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123057

Parameter	Value
	3. 14
	4. 36
	5. 15
	6. .
	7. 5
	8. 4
	9. .
	10. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123057

Parameter	Value
	7. RESOLVED
	8. RESOLVED
	9. IMPROVED
	10. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123062

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400123062/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/61/WHITE/AUSTRALIA/YES
Medical history	Arthritis, Gout, Alcohol use
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, AVANTIN FATTY OINTMENT, BARRIER CREAM I.E. SORBALENE, COLCHICINE, CORTISONE INJECTION, DOXYCYCLINE, ENOXAPARIN, GTN PATCH, METOPROLOL, MORPHINE, NUROFEN, OXYCODONE, PANADIENE FORTE, PANADOL, PREDNISOLONE, RADIOGRAPHIC CONTRAST MEDIUM, WARFARIN
Adverse Events (AE) Preferred term	1. Renal cyst 2. Liver function test abnormal 3. Bursitis 4. Gout 5. International normalised ratio increased 6. Urticaria 7. Pruritus 8. Contusion 9. Bursitis 10. Infected skin ulcer 11. Nasopharyngitis 12. Contusion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/YES/NO/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/NO 12. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --JAN2011 (.) - --------- (.) 2. 13DEC2010 (5) - 01FEB2011 (55) 3. 16DEC2010 (8) - --JAN2011 (.) 4. 16DEC2010 (8) - --JAN2011 (.) 5. 29DEC2010 (21) - 01JAN2011 (24) 6. 08JAN2011 (31) - 31JAN2011 (54) 7. 08JAN2011 (31) - 31JAN2011 (54) 8. 01FEB2011 (55) - 06FEB2011 (60) 9. 13MAR2011 (95) - --------- (.) 10. 12AUG2011 (247) - 26AUG2011 (261) 11. 16SEP2011 (282) - 23SEP2011 (289) 12. 25SEP2011 (291) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123062

Parameter	Value
Duration of AE	1. .
	2. 51
	3. .
	4. .
	5. 4
	6. 24
	7. 24
	8. 6
	9. .
	10. 15
	11. 8
	12. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED AND RESTARTED
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400123062

Parameter	Value
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400123062[4)]	ABNORMAL LFT'S (PREVIOUS LEFT ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION) (PT：肝機能検査異常) 治験担当医は、合併症（痛風）及び併用薬（コルヒチン、プレドニゾロン等)によるものであり、否定できると判断した。弊社は、エノキサパリン及びワルファリン投与と報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400153004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400153004/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/38/WHITE/AUSTRALIA/YES
Medical history	Asthma, Depression, Female sterilisation, Uterine leiomyoma, Vaginal haemorrhage
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLIN, ZOLOFT
Adverse Events (AE) Preferred term	1. Lower gastrointestinal haemorrhage 2. Vaginal haemorrhage 3. Vaginal haemorrhage 4. Chest pain 5. Vaginal haemorrhage 6. Influenza 7. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES 5. MODERATE/YES/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 19JUN2008 (2) - 19JUN2008 (2) 2. 01JUL2008 (14) - 19JUL2008 (32) 3. 16JUL2008 (29) - 01AUG2008 (45) 4. 20JUL2008 (33) - --------- (.) 5. 20JUL2008 (33) - 01AUG2008 (45) 6. 20AUG2008 (64) - 13OCT2008 (118) 7. 16DEC2008 (182) - 16DEC2008 (182)
Duration of AE	1. 1 2. 19 3. 17 4. . 5. 13 6. 55 7. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg 7. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400153004

Parameter	Value
	5. .
	6. .
	7. .
Action taken	1. NONE
	2. OTHER
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400153019

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400153019/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/28/WHITE/AUSTRALIA/YES
Medical history	Depression, Tendon rupture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CEPHALEXIN, CEPHALOTHIN, CLEXANE, ENOXAPARIN, OXYCODONE, PARACETAMOL, TRAMADOL SR, VENLAFAXINE XR, WARFARIN
Adverse Events (AE) Preferred term	1. Contusion 2. Tendon rupture 3. Incision site haemorrhage 4. Contusion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 19JAN2010 (34) - 13FEB2010 (59) 2. 13FEB2010 (59) - 22FEB2010 (68) 3. 13FEB2010 (59) - 14FEB2010 (60) 4. 19MAR2010 (93) - --------- (.)
Duration of AE	1. 26 2. 10 3. 2 4. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. F
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 3. NONE 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400153019

Parameter	Value
	4. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400153020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400153020/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/57/WHITE/AUSTRALIA/YES
Medical history	Abdominal pain lower, Flank pain, Gastrooesophageal reflux disease, Seminoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AGAROL MILKSHAKE, AMPICILLIN, AUGMENTIN DUO FORTE, COLOXYL WITH SENNA, ESOMEPRAZOLE, MOVICOL, OXYCODONE, PANTOPRAZOLE, PARACETAMOL
Adverse Events (AE) Preferred term	1. Constipation 2. Anaemia 3. Haemoptysis 4. Pneumonia 5. Wound haemorrhage 6. Wound haemorrhage 7. Wound haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/YES/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 04FEB2010 (1) - 07FEB2010 (4) 2. 05FEB2010 (2) - 13APR2010 (69) 3. 06FEB2010 (3) - 10FEB2010 (7) 4. 24FEB2010 (21) - 26FEB2010 (23) 5. 01APR2010 (57) - --APR2010 (.) 6. 01MAY2010 (87) - --MAY2010 (.) 7. 30AUG2010 (208) - 30AUG2010 (208)
Duration of AE	1. 4 2. 68 3. 5 4. 3 5. . 6. . 7. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 20 mg 6. 20 mg 7. 20 mg
Dose status on AE onset	1. . 2. . 3. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400153020

Parameter	Value
	4. .
	5. .
	6. .
	7. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400153021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400153021/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/34/WHITE/AUSTRALIA/YES
Medical history	Chest pain, Coronary artery occlusion, Hypercholesterolaemia, Hypertension, Myocardial infarction, Myocardial infarction
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATORVASTATIN, ENOXAPARIN, EZETIMIBE, FISH OIL, GLYCERYL TRINITRATE SPRAY, IMDUR, METOPROLOL, PERINDOPRIL, WARFARIN
Adverse Events (AE) Preferred term	1. Vessel puncture site haemorrhage 2. Wound haemorrhage 3. Alanine aminotransferase increased 4. Contusion 5. Contusion 6. Contusion 7. Contusion 8. Muscle haemorrhage 9. Wound haemorrhage 10. Contusion 11. Contusion 12. Contusion 13. Contusion 14. Contusion 15. Muscle haemorrhage 16. Muscle haemorrhage 17. Nasopharyngitis 18. Contusion 19. Muscle haemorrhage 20. Wound haemorrhage 21. Contusion 22. Contusion 23. Wound haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/YES/NO/YES 8. MILD/YES/NO/YES 9. MILD/YES/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400153021

Parameter	Value
	15. MILD/NO/NO/YES
	16. MILD/NO/NO/YES
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MILD/NO/NO/YES
	20. MILD/NO/NO/YES
	21. MILD/NO/NO/YES
	22. MILD/NO/NO/YES
	23. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 04DEC2010 (3) - 20SEP2011 (293)
	2. 14DEC2010 (13) - 14DEC2010 (13)
	3. 15DEC2010 (14) - 04JAN2011 (34)
	4. 26DEC2010 (25) - 24JAN2011 (54)
	5. 26DEC2010 (25) - 24JAN2011 (54)
	6. 27DEC2010 (26) - 24JAN2011 (54)
	7. 14JAN2011 (44) - --FEB2011 (.)
	8. 15JAN2011 (45) - --FEB2011 (.)
	9. 22JAN2011 (52) - 22JAN2011 (52)
	10. 24MAR2011 (113) - 03MAY2011 (153)
	11. 26MAR2011 (115) - 03MAY2011 (153)
	12. 27MAR2011 (116) - 03MAY2011 (153)
	13. 02APR2011 (122) - 26MAY2011 (176)
	14. 03APR2011 (123) - 26MAY2011 (176)
	15. 22APR2011 (142) - 26MAY2011 (176)
	16. 22APR2011 (142) - 26MAY2011 (176)
	17. 26MAY2011 (176) - 08JUL2011 (219)
	18. 25JUN2011 (206) - 01JUL2011 (212)
	19. 25JUN2011 (206) - 01JUL2011 (212)
	20. 27JUN2011 (208) - 30JUN2011 (211)
	21. 20AUG2011 (262) - 20SEP2011 (293)
	22. 20AUG2011 (262) - 20SEP2011 (293)
	23. 22AUG2011 (264) - 20SEP2011 (293)
Duration of AE	1. 291
	2. 1
	3. 21
	4. 30
	5. 30
	6. 29
	7. .
	8. .
	9. 1
	10. 41
	11. 39
	12. 38

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400153021

Parameter	Value
	13. 55
	14. 54
	15. 35
	16. 35
	17. 44
	18. 7
	19. 7
	20. 4
	21. 32
	22. 32
	23. 30
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400153021

Parameter	Value
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. NONE
	13. NONE
	14. NONE
	15. NONE
	16. NONE
	17. NONE
	18. NONE
	19. NONE
	20. NONE
	21. NONE
	22. NONE
	23. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400153021

Parameter	Value
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED
	23. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400163009/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/29/WHITE/AUSTRALIA/YES
Medical history	Caesarean section, Abortion induced, Uterine rupture, Substance abuse, Bipolar disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CELEBREX, ENOXAPARIN, PANADEINE FORTE, PARACETAMOL, TRAMADOL, WARFARIN
Adverse Events (AE) Preferred term	1. Respiratory tract haemorrhage 2. Pleuritic pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 06SEP2008 (3) - 07SEP2008 (4) 2. 07SEP2008 (4) - 11SEP2008 (8)
Duration of AE	1. 2 2. 5
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400163023/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/49/WHITE/AUSTRALIA/YES
Medical history	Alcohol abuse, Atrial flutter, Benign colonic neoplasm, Depression, Diverticulitis, Hypertension, Hypokalaemia, Laparotomy, Nausea, Thrombocytopenia, Vomiting
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXYCILLIN, BIOMAG [CAL. ASCORB; CHOLECALCIFEROL; MAGN. OXIDE; MAGN. PHOS.; MANGANESE AMINO, CELECOXIB, CHLORSIG EYE DROP, COVERSYL, DIAZEPAM, DOLASETRON, ENOXAPARIN, ESOMEPRAZOLE, FLUCLOXACILLIN, FOLIC ACID, GLYCERYL TRINITRATE, IBUPROFEN, MAXOLON, METOCLOPRAMIDE, MORPHINE, NAPROXEN, ORAL KCL, OXYCODONE, OXYNORM, PANADEINE FORTE, PANTOPRAZOLE, PARACETAMOL, PERINDOPRIL, ROXITHROMYCIN, SLOW K, SLOW RELEASE K, THIAMINE, TIMENTIN, TRAMADOL, TRAMADOL SR, WARFARIN
Adverse Events (AE) Preferred term	1. Contusion 2. Pleuritic pain 3. Haematemesis 4. Lower respiratory tract infection 5. Vomiting 6. Nausea 7. Abdominal pain 8. Vomiting 9. Chest pain 10. Nausea 11. Diarrhoea 12. Anxiety 13. Dizziness 14. Hypertension 15. Bladder injury 16. Cellulitis 17. Sinus tachycardia 18. Eye pain 19. Chest pain 20. Nausea 21. Nausea 22. Cough 23. Hypercholesterolaemia 24. Gastritis 25. Chest pain 26. Blood creatinine increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163023

Parameter	Value
	7. MODERATE/NO/YES/YES
	8. MILD/NO/NO/YES
	9. MILD/NO/NO/YES
	10. MILD/NO/NO/YES
	11. MILD/NO/NO/YES
	12. MILD/NO/NO/YES
	13. MILD/NO/NO/YES
	14. MILD/NO/NO/YES
	15. MILD/NO/NO/YES
	16. MILD/NO/NO/YES
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MODERATE/NO/YES/YES
	20. MILD/NO/NO/YES
	21. MILD/NO/NO/NO
	22. MILD/NO/NO/NO
	23. MILD/NO/NO/NO
	24. MILD/NO/NO/NO
	25. MODERATE/NO/YES/NO
	26. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 16MAR2009 (7) - 01MAY2009 (53)
	2. 23MAR2009 (14) - 25MAR2009 (16)
	3. 23MAR2009 (14) - 23MAR2009 (14)
	4. 23MAR2009 (14) - 30MAR2009 (21)
	5. 23MAR2009 (14) - 24MAR2009 (15)
	6. 24MAR2009 (15) - 24MAR2009 (15)
	7. 18APR2009 (40) - 23APR2009 (45)
	8. 18APR2009 (40) - 18APR2009 (40)
	9. 18APR2009 (40) - 18APR2009 (40)
	10. 18APR2009 (40) - 18APR2009 (40)
	11. 18APR2009 (40) - 22APR2009 (44)
	12. 18APR2009 (40) - 03MAY2009 (55)
	13. 19APR2009 (41) - 19APR2009 (41)
	14. 20APR2009 (42) - 22APR2009 (44)
	15. 20APR2009 (42) - 20APR2009 (42)
	16. 21APR2009 (43) - 22APR2009 (44)
	17. 21APR2009 (43) - --------- (.)
	18. 21APR2009 (43) - 23APR2009 (45)
	19. 01MAY2009 (53) - 07MAY2009 (59)
	20. 01MAY2009 (53) - 01MAY2009 (53)
	21. 04MAY2009 (56) - 04MAY2009 (56)
	22. 04MAY2009 (56) - 06MAY2009 (58)
	23. 04MAY2009 (56) - --------- (.)
	24. 07MAY2009 (59) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163023

Parameter	Value
	25. 17MAY2009 (69) - 20MAY2009 (72)
	26. 17MAY2009 (69) - 18MAY2009 (70)
Duration of AE	1. 47
	2. 3
	3. 1
	4. 8
	5. 2
	6. 1
	7. 6
	8. 1
	9. 1
	10. 1
	11. 5
	12. 16
	13. 1
	14. 3
	15. 1
	16. 2
	17. .
	18. 3
	19. 7
	20. 1
	21. 1
	22. 3
	23. .
	24. .
	25. 4
	26. 2
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163023

Parameter	Value
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163023

Parameter	Value
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. NONE
	14. NONE
	15. NONE
	16. REMEDIAL DRUG THERAPY
	17. NONE
	18. REMEDIAL DRUG THERAPY
	19. REMEDIAL DRUG THERAPY
	20. REMEDIAL DRUG THERAPY
	21. NONE
	22. REMEDIAL DRUG THERAPY
	23. REMEDIAL DRUG THERAPY
	24. REMEDIAL DRUG THERAPY
	25. REMEDIAL DRUG THERAPY
	26. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. INSUFFICIENT FOLLOW-UP
	18. RESOLVED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED
	23. UNCHANGED
	24. INSUFFICIENT FOLLOW-UP
	25. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163023

Parameter	Value
	26. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163034

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400163034/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/64/WHITE/AUSTRALIA/YES
Medical history	Alcoholism, Asthma, Chronic obstructive pulmonary disease, Colitis, Depression, Gastroenteritis, Hypertension, Hypoxia, Tachycardia, Type 2 diabetes mellitus, Pneumonia necrotising, Infective exacerbation of chronic obstructive airways disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN DUO FORTE, BRICANYL, CEPHALEXIN, CIPROFLOXACIN, CLARATYNE, ESOMEPRAZOLE, FELODIPINE XR, HYDROCORTISONE, IPRATROPIUM BROMIDE, METFORMIN XR, MULTIVITAMINS, PARACETAMOL, PREDNISOLONE, SALBUTAMOL INHALER, SERETIDE, SPIRIVA, TAMIFLU, THIAMINE, TIMENTIM, VITAMIN E CREAM
Adverse Events (AE) Preferred term	1. Purpura 2. Vomiting 3. Burning sensation 4. Seasonal allergy 5. Hypertension 6. Rash 7. Chronic obstructive pulmonary disease 8. Cellulitis 9. Chronic obstructive pulmonary disease 10. Chronic obstructive pulmonary disease 11. Tachycardia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/YES/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 27AUG2009 (6) - 10SEP2009 (20) 2. 27AUG2009 (6) - 27AUG2009 (6) 3. 08SEP2009 (18) - 01DEC2009 (102) 4. 10DEC2009 (111) - --------- (.) 5. 22DEC2009 (123) - 20JAN2010 (152) 6. 24DEC2009 (125) - 10MAR2010 (201) 7. 09MAR2010 (200) - 23APR2010 (245) 8. 13MAR2010 (204) - 20MAR2010 (211) 9. 16MAY2010 (268) - 24MAY2010 (276) 10. 20JUL2010 (333) - 10AUG2010 (354) 11. 20AUG2010 (364) - --------- (.)
Duration of AE	1. 15

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163034

Parameter	Value
	2. 1
	3. 85
	4. .
	5. 30
	6. 77
	7. 46
	8. 8
	9. 9
	10. 22
	11. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY,OTHER
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163034

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163035

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400163035/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/76/WHITE/AUSTRALIA/YES
Medical history	Gout, Hiatus hernia, Hypercholesterolaemia, Hypertension, Hypothyroidism, Knee arthroplasty, Knee arthroplasty, Knee arthroplasty, Knee arthroplasty, Muscle spasms, Obesity, Osteoarthritis, Vomiting, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALLOPURINOL, ATENOLOL, BISACODYL, COLOXYL AND SENNA, ESOMEPRAZOLE, GLYCEROL SUPPOSITORY, IBERSARTAN/HCT, MOVICOL, MUPIROCIN 2%, OXYCODONE, OXYNORM, PARACETAMOL, SIMVASTATIN, SORBITOL, THYROXINE, TRAMADOL
Adverse Events (AE) Preferred term	1. Constipation 2. Contusion 3. Facial bones fracture 4. Contusion 5. Joint swelling 6. Fall
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 10SEP2009 (2) - 13SEP2009 (5) 2. 28JAN2010 (142) - 09MAR2010 (182) 3. 28JAN2010 (142) - 28JAN2010 (142) 4. 28JAN2010 (142) - 09MAR2010 (182) 5. 28JAN2010 (142) - 09MAR2010 (182) 6. 28JAN2010 (142) - 28JAN2010 (142)
Duration of AE	1. 4 2. 41 3. 1 4. 41 5. 41 6. 1
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. I 3. I 4. I 5. I

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163035

Parameter	Value
	6. I
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	3. STUDY DRUG DISCONTINUED AND RESTARTED
	4. STUDY DRUG DISCONTINUED AND RESTARTED
	5. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163043

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400163043/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/66/WHITE/AUSTRALIA/YES
Medical history	Arthralgia, Behcet's syndrome, Intestinal obstruction, Fall, Colectomy, Hysterectomy, Insomnia, Pneumonia, Tremor, Gastrointestinal carcinoma, Abdominal adhesions, Diarrhoea, Intraocular lens implant
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CALCIUM SUPPLEMENT, DI STAPH, DORYX, ENOXAPARIN, FLU VACCINE, GASTRO STOP, INDERAL, METRONIDAZOLE, PARACETAMOL, PARIET, PREDNISOLONE, PREDNISONE, SOMAC, TEMAZ, WARFARIN
Adverse Events (AE) Preferred term	1. Nasopharyngitis 2. Diarrhoea 3. Abdominal pain 4. Giardiasis 5. Gastroenteritis 6. Folliculitis 7. Contusion 8. Pericardial effusion 9. Chest pain 10. Pericardial effusion 11. Pericardial effusion
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MODERATE/NO/YES/NO 11. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 30JUN2010 (5) - 15JUL2010 (20) 2. 25JUL2010 (30) - 24AUG2010 (60) 3. 25JUL2010 (30) - 24AUG2010 (60) 4. 31AUG2010 (67) - 31AUG2010 (67) 5. 27DEC2010 (185) - 31DEC2010 (189) 6. 04MAR2011 (252) - --------- (.) 7. 19MAR2011 (267) - 19APR2011 (298) 8. 11APR2011 (290) - 12JUL2011 (382) 9. 01JUN2011 (341) - --------- (.) 10. 13JUL2011 (383) - 20JUL2011 (390) 11. 21JUL2011 (391) - --------- (.)
Duration of AE	1. 16 2. 31 3. 31

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163043

Parameter	Value
	4. 1
	5. 5
	6. .
	7. 32
	8. 93
	9. .
	10. 8
	11. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. NONE
	10. NONE
	11. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400163043

Parameter	Value
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. WORSENED
	9. UNCHANGED
	10. RESOLVED
	11. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400193004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400193004/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/46/WHITE/AUSTRALIA/YES
Medical history	Benign breast neoplasm, Tobacco user
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANGININE, ENOXAPARIN, IBUPROFEN, MORPHINE, ONDANSETRON, PANADEINE FORTE, PANADOL, PARACETAMOL, WARFARIN
Adverse Events (AE) Preferred term	1. Chest pain 2. Vomiting 3. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 28FEB2008 (8) - 29FEB2008 (9) 2. 28FEB2008 (8) - 28FEB2008 (8) 3. 19MAY2008 (89) - --------- (.)
Duration of AE	1. 2 2. 1 3. .
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. REMEDIAL DRUG THERAPY 3. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400193011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400193011/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/58/WHITE/AUSTRALIA/YES
Medical history	Hypothyroidism, Menopause, Sciatica, Wrist fracture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ANGININE, ASPIRIN, AUGMENTIN DUO FORTE, COLOXYL AND SENNA, DIAZEPAM, ENDONE, IBUPROFEN, MORPHINE, PARACETAMOL, RULIDE, THYROXINE, TRAMADOL, VOLTAREN
Adverse Events (AE) Preferred term	1. Pleuritic pain 2. Pleurisy 3. Atrial fibrillation 4. Nausea 5. Vomiting 6. Constipation
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/NO 4. MILD/NO/NO/NO 5. MILD/NO/NO/NO 6. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 15SEP2008 (26) - 16SEP2008 (27) 2. 15SEP2008 (26) - 24SEP2008 (35) 3. 21FEB2009 (185) - 21FEB2009 (185) 4. 21FEB2009 (185) - 21FEB2009 (185) 5. 21FEB2009 (185) - 21FEB2009 (185) 6. 22FEB2009 (186) - 23FEB2009 (187)
Duration of AE	1. 2 2. 10 3. 1 4. 1 5. 1 6. 2
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. F 4. F 5. F 6. F
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400193011

Parameter	Value
	3. REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400193027

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400193027/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/61/WHITE/AUSTRALIA/YES
Medical history	Alcohol abuse, Atrial fibrillation, Varicose vein
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADRENALINE, AMIODARONE, ASPIRIN, CARVEDILOL, CEFALEXIN, CEPHAZOLIN, COMPOUND SODIUM LACTATE, DIGOXIN, FENTANYL, HEPARIN, INFLUVAC, MAXALON, METOPROLOL, MIDAZOLAM, NICOTINE PATCH, ONDANSETRON, PARACETAMOL, PERINDOPRIL, PROPOFOL, SPIRACTIN, SPIRONOLACTONE, THYROXINE, VECURONIUM BROMIDE
Adverse Events (AE) Preferred term	1. Pyrexia 2. Cardiac failure congestive 3. Hypotension 4. Nausea 5. Vomiting 6. Haematuria 7. Hypothyroidism
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/YES/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 23NOV2010 (1) - 24NOV2010 (2) 2. 24NOV2010 (2) - --------- (.) 3. 09DEC2010 (17) - 09DEC2010 (17) 4. 09DEC2010 (17) - 09DEC2010 (17) 5. 09DEC2010 (17) - 09DEC2010 (17) 6. 13DEC2010 (21) - 13DEC2010 (21) 7. 14JAN2011 (53) - --------- (.)
Duration of AE	1. 2 2. . 3. 1 4. 1 5. 1 6. 1 7. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 15 mg 6. 15 mg 7. 20 mg
Dose status on AE onset	1. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400193027

Parameter	Value
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400203008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400203008/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/55/WHITE/AUSTRALIA/YES
Medical history	Appendicectomy, Back disorder, Cystoscopy, Hypertension, Inguinal hernia repair, Skin neoplasm excision, Obesity, Conjunctival haemorrhage, Oedema peripheral, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXYCILLIN, ATROVENT, BLACKMORES MULTI-VITAMIN, BRICANYL, CECLOR, CEFTRIAXONE, COLOXYL WITH SENNA, ENDONE, MICARDIS, PANADOL, PREDNISONE, RULIDE, SOMAC, SYMBICORT, VENTOLIN
Adverse Events (AE) Preferred term	1. Muscular weakness 2. Pain in extremity 3. Influenza like illness 4. Pyrexia 5. Chest discomfort 6. Lower respiratory tract infection 7. Bronchitis 8. Pain in extremity 9. Pruritus 10. Gastrooesophageal reflux disease 11. Conjunctival haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/NO 4. MODERATE/NO/NO/NO 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. SEVERE/NO/YES/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --NOV2008 (.) - --------- (.) 2. --DEC2008 (.) - --------- (.) 3. 16JUL2008 (1) - 18AUG2008 (34) 4. 16JUL2008 (1) - 30JUL2008 (15) 5. 18JUL2008 (3) - 26JUL2008 (11) 6. 18JUL2008 (3) - 23JUL2008 (8) 7. 23JUL2008 (8) - 18AUG2008 (34) 8. 29JUL2008 (14) - 30JUL2008 (15) 9. 18AUG2008 (34) - --------- (.) 10. 10SEP2008 (57) - --------- (.) 11. 18OCT2008 (95) - 21OCT2008 (98)
Duration of AE	1. . 2. . 3. 34

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400203008

Parameter	Value
	4. 15
	5. 9
	6. 6
	7. 27
	8. 2
	9. .
	10. .
	11. 4
Dose on AE onset	1.
	2.
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
Action taken	1. OTHER
	2. OTHER
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400203008

Parameter	Value
	4. RESOLVED
	5. RESOLVED
	6. WORSENED
	7. RESOLVED
	8. RESOLVED
	9. IMPROVED
	10. IMPROVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400203019

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400203019/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/48/WHITE/AUSTRALIA/YES
Medical history	Skin neoplasm excision, Type 2 diabetes mellitus, Obesity, Cough
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, METFORMIN, PANADIENE FORTE, PANADOL, VENTOLIN, WARFARIN
Adverse Events (AE) Preferred term	1. Headache 2. Back pain 3. Myalgia 4. Dermatitis allergic
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MODERATE/NO/NO/YES 3. MODERATE/YES/NO/YES 4. MODERATE/YES/NO/YES
Start/stop date of event with relative date	1. 04JUL2010 (18) - 11JUL2010 (25) 2. 04JUL2010 (18) - 11JUL2010 (25) 3. 04JUL2010 (18) - 11JUL2010 (25) 4. 04JUL2010 (18) - 11JUL2010 (25)
Duration of AE	1. 8 2. 8 3. 8 4. 8
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. REMEDIAL DRUG THERAPY 3. NONE 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400203019

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400213001/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/61/WHITE/AUSTRALIA/YES
Medical history	Appendicectomy, Haemorrhoid operation, Hypertension, Urinary tract infection, Abdominal hernia, Metabolic syndrome
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CEFAZOLIN, COVERSYL PLUS 4, FLUCLOXACILLIN, FLUCOXACILLIN, NORVASC, PANADEINE FORTE, PARACETAMOL, VOLTAREN EMULGEL
Adverse Events (AE) Preferred term	1. Wound infection 2. Ligament sprain 3. Arthralgia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 10JUN2007 (3) - 16JUL2007 (39) 2. 30SEP2007 (115) - 08OCT2007 (123) 3. 30SEP2007 (115) - 08OCT2007 (123)
Duration of AE	1. 37 2. 9 3. 9
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400213003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/85/WHITE/AUSTRALIA/YES
Medical history	Hypertension, Malignant melanoma, Prostate cancer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AGAROL, ATENOLOL, CHLORTHALIDONE, CYPROTERONE ACETATE, ENOXAPARIN, KEFLEX, PANADOL [PARACETAMOL], WARFARIN
Adverse Events (AE) Preferred term	1. Basal cell carcinoma 2. Rash 3. Basal cell carcinoma 4. Basal cell carcinoma 5. Metastases to central nervous system 6. Meningioma 7. Melaena
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. SEVERE/NO/YES/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 15JUN2007 (1) - 08AUG2007 (55) 2. 19JUN2007 (5) - 29JUN2007 (15) 3. 27JUN2007 (13) - 25JUL2007 (41) 4. 27JUN2007 (13) - 25JUL2007 (41) 5. 05SEP2007 (83) - 01NOV2007 (140) 6. 05SEP2007 (83) - --------- (.) 7. 10OCT2007 (118) - 15OCT2007 (123)
Duration of AE	1. 55 2. 11 3. 29 4. 29 5. 58 6. . 7. 6
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213003

Parameter	Value
	4.
	5.
	6.
	7.
Action taken	1. OTHER
	2. NONE
	3. NONE
	4. OTHER
	5. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. DEATH
	6. UNCHANGED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400213003[4)]	MELAENA（PT：メレナ） 治験担当医は、エノキサパリンとの因果関係を否定できると判断した。弊社は、エノキサパリンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400213020/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/75/AMERICAN INDIAN OR ALASKA NATIVE/AUSTRALIA/YES
Medical history	Bladder neoplasm, Back pain, Osteoarthritis, Atrial fibrillation, Transurethral prostatectomy, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, RABEPRAZOLE SODIUM, SOTALOL HYDROCHLORIDE, WARFARIN
Adverse Events (AE) Preferred term	1. Haematuria 2. Injection site haematoma 3. Back pain 4. Haematuria 5. Bladder neoplasm 6. Rhinitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 15NOV2007 (3) - 22NOV2007 (10) 2. 18NOV2007 (6) - 07DEC2007 (25) 3. 30NOV2007 (18) - 18MAR2008 (127) 4. 12JAN2008 (61) - 12JAN2008 (61) 5. 31JAN2008 (80) - 31JAN2008 (80) 6. 04MAY2008 (174) - 08MAY2008 (178)
Duration of AE	1. 8 2. 20 3. 110 4. 1 5. 1 6. 5
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. DOSE OF STUDY DRUG REDUCED 2. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213020

Parameter	Value
	3. NONE
	4. NONE
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213028

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400213028/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/66/WHITE/AUSTRALIA/YES
Medical history	Cholecystectomy, Hypertension, Hysterectomy, Irritable bowel syndrome, Intracranial hypotension, Mastoidectomy, Tinnitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPINE, ENOXAPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Contusion 2. Acute lymphocytic leukaemia 3. Alanine aminotransferase increased 4. Hyperuricaemia 5. Gamma-glutamyltransferase increased 6. Acute abdomen 7. Nausea 8. Dizziness 9. Mouth ulceration 10. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/NO 5. MODERATE/NO/YES/NO 6. SEVERE/NO/YES/NO 7. MODERATE/NO/NO/NO 8. MILD/NO/NO/NO 9. MILD/NO/NO/NO 10. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 24FEB2008 (3) - --------- (.) 2. 29FEB2008 (8) - --------- (.) 3. 29FEB2008 (8) - --------- (.) 4. 03MAR2008 (11) - --------- (.) 5. 10MAR2008 (18) - --------- (.) 6. 21MAR2008 (29) - 23MAR2008 (31) 7. 21MAR2008 (29) - --------- (.) 8. 21MAR2008 (29) - 21MAR2008 (29) 9. 21MAR2008 (29) - --------- (.) 10. 22MAR2008 (30) - 22MAR2008 (30)
Duration of AE	1. . 2. . 3. . 4. . 5. . 6. 3 7. . 8. 1

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213028

Parameter	Value
	9. .
	10. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	3. OTHER
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. UNCHANGED
	6. DEATH
	7. UNCHANGED
	8. RESOLVED
	9. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213028

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213058

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400213058/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/52/WHITE/AUSTRALIA/YES
Medical history	Hypertension, Nausea, Tendon rupture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXIL, ATACAND PLUS, CEPHALEXIN, CEPHAZOLIN, COLOXYL WITH SENNA, DIAZEPAM, ENOXAPARIN, LACTULOSE, METOCLOPRAMIDE HYDROCHLORIDE, OSELTAMIVIR PHOSPHATE, PANADEINE FORTE, PANADOL, PARACETAMOL, TEMAZEPAM, TRAMADOL HYDROCHLORIDE, WARFARIN
Adverse Events (AE) Preferred term	1. Contusion 2. Constipation 3. Nausea 4. Postoperative wound infection 5. Insomnia 6. Hypotension 7. Lower respiratory tract infection 8. Muscle spasms
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 06MAR2009 (3) - 27MAR2009 (24) 2. 06MAR2009 (3) - 10MAR2009 (7) 3. 16MAR2009 (13) - --------- (.) 4. 24MAR2009 (21) - 15APR2009 (43) 5. 26MAR2009 (23) - 26MAR2009 (23) 6. 26MAR2009 (23) - 26MAR2009 (23) 7. 10MAY2009 (68) - 14MAY2009 (72) 8. 24MAY2009 (82) - 02OCT2009 (213)
Duration of AE	1. 22 2. 5 3. . 4. 23 5. 1 6. 1 7. 5 8. 132
Dose on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213058

Parameter	Value
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213069

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400213069/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/51/WHITE/AUSTRALIA/YES
Medical history	Anxiety, Depression, Seasonal allergy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DIAZEPAM, MIRTAZAPINE, OLANZAPINE, PARACETAMOL, QUETIAPINE FUMARATE, QUETIAPINE FUMARATE, SERTRALINE, SERTRALINE HYDROCHLORIDE, ZOLPIDEM TARTRATE, ZOPICIONE
Adverse Events (AE) Preferred term	1. Anxiety 2. Anxiety
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 25NOV2009 (77) - 12DEC2009 (94) 2. 04JAN2010 (117) - 11FEB2010 (155)
Duration of AE	1. 18 2. 39
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213071

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400213071/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/76/WHITE/AUSTRALIA/YES
Medical history	Arthritis, Gout, Polycythaemia vera, Raynaud's phenomenon
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, ENOXAPARIN, HYDROXYUREA, MORPHINE, NEXIUM, PANADOL, TEMAZEPAM, WARFARIN, ZYLOPRIM
Adverse Events (AE) Preferred term	1. Contusion 2. Mouth ulceration 3. Colitis 4. Neutropenia 5. Cardiomyopathy
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/YES/YES 4. SEVERE/NO/YES/YES 5. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 03FEB2010 (1) - 04MAR2010 (30) 2. 04FEB2010 (2) - --------- (.) 3. 22MAR2010 (48) - 29MAR2010 (55) 4. 22MAR2010 (48) - 31MAY2010 (118) 5. 13APR2010 (70) - --------- (.)
Duration of AE	1. 30 2. . 3. 8 4. 71 5. .
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. NONE 2. NONE 3. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER 4. NONE 5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. UNCHANGED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213071

Parameter	Value
	4. RESOLVED
	5. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400213071[3),3)]	GASTROINTESTINAL BLEEDING（PT：胃腸出血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、ワルファリンの薬剤特性及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。 RECTAL BLEEDING（PT：直腸出血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、ワルファリンの薬剤特性及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213080

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400213080/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/61/WHITE/AUSTRALIA/YES
Medical history	Prostate cancer, Cholecystectomy, Skin lesion, Tonsillectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN DUO FORTE, ENOXAPARIN, ONDANSETRON, PARACETAMOL, TEMAZEPAM, WARFARIN
Adverse Events (AE) Preferred term	1. Contusion 2. Haematuria 3. Prostate cancer 4. Syncope 5. Headache 6. Conjunctival haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/NO 6. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 14OCT2010 (8) - 30NOV2010 (55) 2. 17FEB2011 (134) - 18FEB2011 (135) 3. 17FEB2011 (134) - 19FEB2011 (136) 4. 18FEB2011 (135) - 18FEB2011 (135) 5. 02MAY2011 (208) - --------- (.) 6. 02MAY2011 (208) - --------- (.)
Duration of AE	1. 48 2. 2 3. 3 4. 1 5. . 6. .
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. NONE 2. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213080

Parameter	Value
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. NONE
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. IMPROVED
	6. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213082

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400213082/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/79/WHITE/AUSTRALIA/YES
Medical history	Hydronephrosis, Cystitis radiation, Depression, Glaucoma, Hypercholesterolaemia, Hypertension, Ileostomy, Bladder irritation, Mesothelioma, Myocardial infarction, Pneumaturia, Transurethral prostatectomy, Coronary artery bypass, Urinary tract infection, Prostatomegaly, Bacterial sepsis, Anaemia postoperative, Resection of rectum, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXYCILLIN, AMOXYCILLIN TRIHYDRATE, ASPRIN, CEPHALEXIN, ENOXAPARIN, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, FRUSEMIDE, GENTAMICIN SULFATE, MEGESTROL ACETATE, METOCLOPRAMIDE HYDROCHLORIDE, METOPROLOL TARTRATE, MIRTAZAPINE, MORPHINE, N-ACETYLCYSTEINE, NORFLAXACIN, OXYBUTYNIN HYDROCHLORIDE, PARACETAMOL, POTASSIUM CHLORIDE, SODIUM CITROTRATE, SOLIFENACIN SUCCINATE, TRIMETHOPRIM, VITAMIN K, WARFARIN, XALACOM EYE DROPS, ZOFRAN
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Vomiting 3. Gastrointestinal fistula 4. Haematuria 5. Urinary tract infection 6. Nausea 7. Acute myocardial infarction 8. Renal impairment 9. Urinary retention 10. Haematuria
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/YES/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 15OCT2010 (2) - 29OCT2010 (16) 2. 04NOV2010 (22) - 04NOV2010 (22) 3. 22NOV2010 (40) - --------- (.) 4. 02JAN2011 (81) - 10JAN2011 (89) 5. 02JAN2011 (81) - 01FEB2011 (111) 6. 02JAN2011 (81) - 06JAN2011 (85) 7. 03JAN2011 (82) - 04JAN2011 (83) 8. 04JAN2011 (83) - 11JAN2011 (90) 9. 04JAN2011 (83) - 10JAN2011 (89) 10. 17MAR2011 (155) - 17MAR2011 (155)
Duration of AE	1. 15

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213082

Parameter	Value
	2. 1
	3. .
	4. 9
	5. 31
	6. 5
	7. 2
	8. 8
	9. 7
	10. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. OTHER
	10. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213082

Parameter	Value
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213092

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400213092/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/50/WHITE/AUSTRALIA/YES
Medical history	Colon cancer, Osteoarthritis, Iron deficiency anaemia, Menorrhagia, Nausea, Pneumonia, Hysterectomy, Vomiting
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN DUO FORTE, BUPRENORPHINE, CEPHALEXAN, CHLORVESCENT, CLEXANE, DIAZAPAM, DOXYCYCLINE HYDROCHLORIDE, ENDONE, ENOXAPARIN, ENOXAPARIN SODIUM, ENOXAPARIN SODIUM, FENTANYL, FENTANYL PATCH, FRESH FROZEN PLASMA, FRUSEMIDE, GENTAMYCIN, IRON POLYMALTOSE COMPLEX, LOMOTIL [ATROPINE SULFATE AND DIPHENOXYLATE HYDROCHLORIDE], LYRICA, MAXALON, METOCLOPRAMIDE HYDROCHLORIDE, MORPHINE, MORPHINE SULFATE, ONDANSETRON, OXYCODONE HYDROCHLORIDE, PANADEINE FORTE, PARACETAMOL, PETHIDINE, PHYTOMENADIONE, SLOW K, URAL, WARFARIN
Adverse Events (AE) Preferred term	1. Headache 2. International normalised ratio increased 3. Osteoarthritis 4. Post procedural haemorrhage 5. Nausea 6. Thrombocytopenia 7. Diarrhoea 8. Hypokalaemia 9. Sleep disorder
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 16FEB2011 (2) - 16FEB2011 (2) 2. 18FEB2011 (4) - 18FEB2011 (4) 3. 13JUL2011 (149) - 21JUL2011 (157) 4. 15JUL2011 (151) - 16JUL2011 (152) 5. 15JUL2011 (151) - 15JUL2011 (151) 6. 15JUL2011 (151) - 15JUL2011 (151) 7. 18JUL2011 (154) - 20JUL2011 (156) 8. 20JUL2011 (156) - 20JUL2011 (156) 9. 03SEP2011 (201) - --------- (.)
Duration of AE	1. 1 2. 1 3. 9 4. 2

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213092

Parameter	Value
	5. 1
	6. 1
	7. 3
	8. 1
	9. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. OTHER
	5. REMEDIAL DRUG THERAPY
	6. OTHER
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400213092

Parameter	Value
	9. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400213092[4)]	POST OPERATIVE HAEMORRHAGE（PT：処置後出血） 治験担当医は、原疾患（肺塞栓症）によるものであり、否定できると判断した。弊社は、ワルファリン投与と報告事象発現との時間的関連性及び抗凝固作用から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400233003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400233003/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/70/WHITE/AUSTRALIA/YES
Medical history	Asthma, Dermatitis, Diarrhoea, Diverticulum, Granuloma annulare, Granuloma skin, Hypertension, Insomnia, Obesity, Skin ulcer, Varicose vein, Varicose vein operation, Osteopenia, Venous insufficiency, Hypercholesterolaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARISTOCORT OINTMENT, ASPIRIN, ATORVASTATIN, CEPHALEXIN, PANADIENE, RULIDE, SALBUTAMOL, TEMAZEPAM
Adverse Events (AE) Preferred term	1. Fatigue 2. Headache 3. Hand fracture 4. Cough 5. Chest discomfort 6. Epistaxis 7. Epistaxis 8. Urinary tract infection 9. Respiratory tract infection viral
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/YES/NO/YES 7. MILD/YES/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 09SEP2008 (14) - 25JUN2009 (303) 2. 09SEP2008 (14) - 25FEB2009 (183) 3. 10SEP2008 (15) - 22OCT2008 (57) 4. 13NOV2008 (79) - 25JUN2009 (303) 5. 24APR2009 (241) - 25APR2009 (242) 6. 06MAY2009 (253) - 06MAY2009 (253) 7. 07MAY2009 (254) - 07MAY2009 (254) 8. 26JUL2009 (334) - 09AUG2009 (348) 9. 29JUL2009 (337) - 19AUG2009 (358)
Duration of AE	1. 290 2. 170 3. 43 4. 225 5. 2 6. 1 7. 1 8. 15 9. 22

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400233003

Parameter	Value
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
Action taken	1. NONE
	2. NONE
	3. OTHER
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. OTHER
	7. OTHER
	8. REMEDIAL DRUG THERAPY
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400233003

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400233005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400233005/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/40/WHITE/AUSTRALIA/YES
Medical history	Anxiety, Arthroscopy, Asthma, Limb crushing injury, Duodenal ulcer, Cardiac murmur, Irritable bowel syndrome
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLINDAMYCIN, ENOXAPARIN, ESOMEPRAZOLE, FERROGRADUMET C, LORATADINE, MOVICOL, NORETHISTERONE, OXAZEPAM, OXYCODONE, PARACETAMOL, PERMETHRIN, QUIT X, SALBUTAMOL, SERETIDE, THEOPHYLLINE
Adverse Events (AE) Preferred term	1. Haemorrhagic anaemia 2. Menorrhagia 3. Headache 4. Sinusitis 5. Pain in extremity 6. Musculoskeletal chest pain 7. Dyspnoea 8. Tooth infection 9. Rash 10. Sinusitis 11. Acarodermatitis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MODERATE/YES/YES/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/YES/YES 7. MODERATE/NO/YES/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 14NOV2008 (8) - 01DEC2008 (25) 2. 14NOV2008 (8) - 01DEC2008 (25) 3. 18NOV2008 (12) - 21NOV2008 (15) 4. 19NOV2008 (13) - 21NOV2008 (15) 5. 27NOV2008 (21) - 28NOV2008 (22) 6. 16DEC2008 (40) - 04FEB2009 (90) 7. 16DEC2008 (40) - 04FEB2009 (90) 8. 18DEC2008 (42) - 24DEC2008 (48) 9. 04FEB2009 (90) - --------- (.) 10. 28FEB2009 (114) - --------- (.) 11. 30MAR2009 (144) - --------- (.)
Duration of AE	1. 18 2. 18 3. 4

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400233005

Parameter	Value
	4. 3
	5. 2
	6. 51
	7. 51
	8. 7
	9. .
	10. .
	11. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. OTHER
	6. OTHER
	7. OTHER
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400233005

Parameter	Value
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. UNCHANGED
	11. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400233006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400233006/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/66/WHITE/AUSTRALIA/YES
Medical history	Barrett's oesophagus, Dizziness, Haematuria, Haemorrhoids, Headache, Hypertension, Hysterectomy, Nausea, Osteoporosis, Palpitations, Palpitations, Drug hypersensitivity, Rectal prolapse, Sleep apnoea syndrome, Tinnitus, Traumatic haematoma, Hypercholesterolaemia, Cystocele repair
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, CALCIUM CARBONATE, COENZYME Q10, ENOXAPARIN, ESOMEPRAZOLE, MAGNESIUM, METOPROLOL, OLMETEC, OLMETEC PLUS, SERTRALINE, SIMVASTATIN, SLIPPERY ELM, TELMISARTAN, VERAPAMIL
Adverse Events (AE) Preferred term	1. Palpitations 2. Foreign body sensation in eyes 3. Palpitations 4. Chest discomfort 5. Dyspnoea 6. Diarrhoea 7. Hot flush 8. Hyperhidrosis 9. Palpitations 10. Malaise 11. Contusion 12. Contusion 13. Fatigue 14. Headache 15. Epistaxis 16. Haemorrhoidal haemorrhage 17. Diarrhoea 18. Hypertension 19. Hypertension 20. Anxiety 21. Depression 22. Palpitations 23. Contusion 24. Epistaxis 25. Epistaxis 26. Epistaxis 27. Pain in extremity 28. Rectal prolapse 29. Inguinal hernia 30. Productive cough
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400233006

Parameter	Value
	6. MILD/NO/NO/YES
	7. MILD/NO/NO/YES
	8. MILD/NO/NO/YES
	9. MILD/NO/NO/YES
	10. MILD/NO/NO/YES
	11. MILD/NO/NO/YES
	12. MILD/NO/NO/YES
	13. MODERATE/NO/NO/YES
	14. MODERATE/NO/NO/YES
	15. MILD/YES/NO/YES
	16. MILD/YES/NO/YES
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MILD/NO/NO/YES
	20. MILD/NO/NO/YES
	21. MILD/NO/NO/YES
	22. MODERATE/NO/YES/YES
	23. MILD/YES/NO/YES
	24. MILD/YES/NO/YES
	25. MILD/YES/NO/YES
	26. MILD/YES/NO/YES
	27. MILD/NO/NO/YES
	28. MILD/NO/NO/YES
	29. MILD/NO/NO/YES
	30. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 24FEB2009 (9) - 24FEB2009 (9)
	2. 05MAR2009 (18) - --------- (.)
	3. 06MAR2009 (19) - 06MAR2009 (19)
	4. 07MAR2009 (20) - 01MAY2009 (75)
	5. 07MAR2009 (20) - --------- (.)
	6. 07MAR2009 (20) - 01MAY2009 (75)
	7. 07MAR2009 (20) - 01MAY2009 (75)
	8. 07MAR2009 (20) - 01MAY2009 (75)
	9. 07MAR2009 (20) - 01MAY2009 (75)
	10. 09MAR2009 (22) - --------- (.)
	11. 14MAY2009 (88) - 25MAY2009 (99)
	12. 14MAY2009 (88) - 25MAY2009 (99)
	13. 14MAY2009 (88) - --------- (.)
	14. 14MAY2009 (88) - --------- (.)
	15. 17JUL2009 (152) - 19JUL2009 (154)
	16. 17JUL2009 (152) - 18JUL2009 (153)
	17. 17JUL2009 (152) - 18JUL2009 (153)
	18. 18JUL2009 (153) - 20JUL2009 (155)
	19. 22JUL2009 (157) - 26JUL2009 (161)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400233006

Parameter	Value
	20. 27JUL2009 (162) - --------- (.)
	21. 27JUL2009 (162) - --------- (.)
	22. 30JUL2009 (165) - 04AUG2009 (170)
	23. 14AUG2009 (180) - 14SEP2009 (211)
	24. 10SEP2009 (207) - 10SEP2009 (207)
	25. 11SEP2009 (208) - 11SEP2009 (208)
	26. 15OCT2009 (242) - 15OCT2009 (242)
	27. 06NOV2009 (264) - --------- (.)
	28. 23NOV2009 (281) - --------- (.)
	29. 30NOV2009 (288) - --------- (.)
	30. 04JAN2010 (323) - 15MAR2010 (393)
Duration of AE	1. 1
	2. .
	3. 1
	4. 56
	5. .
	6. 56
	7. 56
	8. 56
	9. 56
	10. .
	11. 12
	12. 12
	13. .
	14. .
	15. 3
	16. 2
	17. 2
	18. 3
	19. 5
	20. .
	21. .
	22. 6
	23. 32
	24. 1
	25. 1
	26. 1
	27. .
	28. .
	29. .
	30. 71
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400233006

Parameter	Value
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
	22. 20 mg
	23. 20 mg
	24. 20 mg
	25. 20 mg
	26. 20 mg
	27. 20 mg
	28. 20 mg
	29. 20 mg
	30. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. I
	12. I
	13. I
	14. I
	15. .
	16. .
	17. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400233006

Parameter	Value
	18. .
	19. .
	20. .
	21. .
	22. .
	23. .
	24. .
	25. .
	26. .
	27. .
	28. .
	29. .
	30. .
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. STUDY DRUG DISCONTINUED AND RESTARTED
	11. NONE
	12. NONE
	13. NONE
	14. NONE
	15. OTHER
	16. NONE
	17. NONE
	18. REMEDIAL DRUG THERAPY
	19. REMEDIAL DRUG THERAPY
	20. REMEDIAL DRUG THERAPY
	21. REMEDIAL DRUG THERAPY
	22. NONE
	23. NONE
	24. NONE
	25. NONE
	26. NONE
	27. NONE
	28. NONE
	29. NONE
	30. NONE
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400233006

Parameter	Value
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. IMPROVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. UNCHANGED
	11. RESOLVED
	12. RESOLVED
	13. IMPROVED
	14. IMPROVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED
	20. IMPROVED
	21. IMPROVED
	22. RESOLVED
	23. RESOLVED
	24. RESOLVED
	25. RESOLVED
	26. RESOLVED
	27. IMPROVED
	28. IMPROVED
	29. UNCHANGED
	30. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400233012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400233012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/66/WHITE/AUSTRALIA/YES
Medical history	Chronic obstructive pulmonary disease, Gastrointestinal disorder, Hypertension, Influenza, Osteoarthritis, Myocardial infarction
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN DUO FORTE, BRICANYL, CEFTRIAXONE, CELEBREX, COLOXYL AND SENNA, ENDONE, ENOXAPARIN, GASTROGEL, PANADEINE, PANTOPRAZOLE, PERINDOPRIL, SALBUTAMOL INHALER, SERETIDE, TEMAZEPAM, WARFARIN
Adverse Events (AE) Preferred term	1. Pyrexia 2. Pneumonia 3. Oropharyngeal pain 4. Contusion 5. Influenza 6. Varicose vein 7. Lower respiratory tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 30SEP2009 (1) - 30SEP2009 (1) 2. 05OCT2009 (6) - 13OCT2009 (14) 3. 13OCT2009 (14) - 16OCT2009 (17) 4. 27FEB2010 (151) - 01APR2010 (184) 5. 29MAR2010 (181) - 07APR2010 (190) 6. 01APR2010 (184) - --------- (.) 7. 29APR2010 (212) - --------- (.)
Duration of AE	1. 1 2. 9 3. 4 4. 34 5. 10 6. . 7. .
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400233012

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. OTHER
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400243003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400243003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/62/WHITE/AUSTRALIA/YES
Medical history	Asthma, Bronchiectasis, Musculoskeletal chest pain, Sleep apnoea syndrome
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CALTRATE [CALCIUM CARBONATE ONLY], DOXYCYCLINE HYDROCHLORIDE, ENOXAPARIN, HYDROCORTISONE, MONTELUKAST SODIUM, OMEPRAZOLE, OXYCODONE, PARACETAMOL, POTASSIUM CLAVULANATE/ TICARCILLIN SODIUM (TIMENTIN), ROXITHROMYCIN, SALBUTAMOL, SYMBICORT, TOBRAMYCIN, WARFARIN
Adverse Events (AE) Preferred term	1. Fatigue 2. Pain 3. Contusion 4. Bronchiectasis 5. Contusion 6. Bronchiectasis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES 5. MILD/YES/NO/YES 6. MILD/NO/YES/YES
Start/stop date of event with relative date	1. -----2008 (.) - --------- (.) 2. -----2008 (.) - --------- (.) 3. 02MAY2008 (29) - 06MAY2008 (33) 4. 16MAY2008 (43) - 22MAY2008 (49) 5. 17MAY2008 (44) - --MAY2008 (.) 6. 03JUN2008 (61) - 10JUN2008 (68)
Duration of AE	1. . 2. . 3. 5 4. 7 5. . 6. 8
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400243003

Parameter	Value
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. IMPROVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400243005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400243005/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/53/WHITE/AUSTRALIA/YES
Medical history	Bone pain, Depression, Ilium fracture, Nausea, Vomiting, Cervical vertebral fracture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, DOCUSATE SODIUM/SENNOSIDES A AND B, MULTIVITAMIN, OMEPRAZOLE, OXYCODONE, PARACETAMOL, SERTRALINE HYDROCHLORIDE, THIAMINE
Adverse Events (AE) Preferred term	1. Cough 2. Haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. --JUN2008 (.) - --JUN2008 (.) 2. 25MAY2008 (5) - --JUN2008 (.)
Duration of AE	1. . 2. .
Dose on AE onset	1. 2. 15 mg
Dose status on AE onset	1. 2. F
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400243021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400243021/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/70/WHITE/AUSTRALIA/YES
Medical history	Atrial fibrillation, Back pain, Hypertension, Neck pain, Upper respiratory tract infection, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROPINE, CEPHAZOLIN, CLEXANE, CLONIDINE, CODEINE PHOSPHATE; PARACETAMOL, DEXAMETHASONE, DIAZEPAM, ENOXAPARIN, FENTANYL, HARTMANNS, HEPARIN, MAGNESIUM SULPHATE, METARAMINOL, METOCLOPRAMIDE, METOPROLOL, MICONAZOLE, NEOSTIGMINE, OXAZEPAM, PROPOFOL, ROCURONIUM, TEMAZAPAM, THYROGEN, THYROXINE, TRAMADOL, WARFARIN
Adverse Events (AE) Preferred term	1. Dysgeusia 2. Eructation 3. Pain in extremity 4. General physical health deterioration 5. Hepatic cyst 6. Cholelithiasis 7. Diverticulum 8. Spinal osteoarthritis 9. Breast calcifications 10. Insomnia 11. Pulmonary hypertension 12. Tinea infection 13. Colonic polyp 14. Thyroid cancer 15. Cough 16. Oedema peripheral 17. Pneumonia 18. Cardiomegaly
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/YES/YES 15. MILD/NO/NO/YES 16. MILD/NO/NO/YES 17. MODERATE/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400243021

Parameter	Value
	18. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. --JUN2010 (.) - -----2011 (.)
	2. --AUG2010 (.) - --------- (.)
	3. --MAR2011 (.) - --------- (.)
	4. --APR2011 (.) - --------- (.)
	5. 06MAY2010 (1) - --------- (.)
	6. 06MAY2010 (1) - --------- (.)
	7. 06MAY2010 (1) - --------- (.)
	8. 06MAY2010 (1) - --------- (.)
	9. 07MAY2010 (2) - --------- (.)
	10. 11MAY2010 (6) - 15MAY2010 (10)
	11. 12MAY2010 (7) - --------- (.)
	12. 16MAY2010 (11) - 17MAY2010 (12)
	13. 25MAY2010 (20) - 25MAY2010 (20)
	14. 26JUL2010 (82) - 04AUG2010 (91)
	15. 30JUL2010 (86) - 01AUG2010 (88)
	16. 31OCT2010 (179) - --NOV2010 (.)
	17. 05FEB2011 (276) - -----2011 (.)
	18. 06FEB2011 (277) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. 5
	11. .
	12. 2
	13. 1
	14. 10
	15. 3
	16. .
	17. .
	18. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400243021

Parameter	Value
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
Action taken	1. NONE
	2. NONE
	3. OTHER
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. OTHER
	14. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	15. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400243021

Parameter	Value
	16. OTHER
	17. NONE
	18. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. IMPROVED
	4. IMPROVED
	5. UNCHANGED
	6. UNCHANGED
	7. UNCHANGED
	8. UNCHANGED
	9. UNCHANGED
	10. RESOLVED
	11. UNCHANGED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400243023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400243023/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/50/WHITE/AUSTRALIA/YES
Medical history	Anxiety, Insomnia, Nausea, Pneumonia, Bursitis, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMITRIPTYLINE, BENZYLPENICILLIN, COLOXYL WITH SENNA, CORTISONE, CORTISONE CREAM, FLUCONAZOLE, IBUPROFEN, INFLUENZA VACCINE, MAXALON, MERSYNDOL, MORPHINE, ONDANSETRON, OXYCODONE, PARACETAMOL, RECTINOL, TEMAZAPAM
Adverse Events (AE) Preferred term	1. Arthralgia 2. Skin exfoliation 3. Post procedural haemorrhage 4. Constipation 5. Headache 6. Lower gastrointestinal haemorrhage 7. Cough 8. Pain in extremity
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --OCT2010 (.) - --------- (.) 2. --MAY2011 (.) - --------- (.) 3. 24JUL2010 (2) - 24JUL2010 (2) 4. 24JUL2010 (2) - --------- (.) 5. 25JUL2010 (3) - --AUG2010 (.) 6. 25JUL2010 (3) - 25JUL2010 (3) 7. 15DEC2010 (146) - --------- (.) 8. 18MAY2011 (300) - --------- (.)
Duration of AE	1. . 2. . 3. 1 4. . 5. . 6. 1 7. . 8. .
Dose on AE onset	1. 2. 3. 15 mg 4. 15 mg 5. 15 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400243023

Parameter	Value
	6. 15 mg
	7. 20 mg
	8. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. OTHER
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
Outcome of event	1. IMPROVED
	2. UNCHANGED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-400243023[4)]	PER RECTAL BLEEDING（PT：下部消化管出血） 治験担当医は、合併症（便秘）によるものであり、否定できると判断した。弊社は、合併症（便秘）の可能性も考えられるが、リバーロキサバンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400253007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/AUSTRALIA/YES
Medical history	Colon cancer, Anaemia, Anxiety, Asthma, Chronic obstructive pulmonary disease, Cardiac failure congestive, Dehydration, Gastrooesophageal reflux disease, Metastases to liver, Hypertension, Hyperthyroidism, Hyponatraemia, Colectomy, Hyperthyroidism, Vitamin B12 deficiency, Decreased appetite
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	5 FU, AMLODIPINE, CARBIMAZOLE, CHLORAMPHENICOL EYE DROPS, COLOXL AND SENNA, ENOXAPARIN, ESOMEPRAZOLE, FOLINIC ACID, FRUSEMIDE, KCL, MAXALON, METACLOPRAMIDE, METOPROLOL, RAMIPRIL, SPIRIVA, SYMBICORT 400/12, WARFARIN
Adverse Events (AE) Preferred term	1. Back pain 2. Dizziness 3. Catheter site inflammation 4. Metastases to liver 5. Productive cough 6. Diarrhoea 7. Sepsis 8. Pyrexia 9. Dyspnoea 10. Weight decreased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/NO 6. MILD/NO/NO/NO 7. MODERATE/NO/YES/NO 8. MILD/NO/NO/NO 9. MILD/NO/NO/NO 10. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 14SEP2010 (-1) - 15SEP2010 (0) 2. 15SEP2010 (0) - 15SEP2010 (0) 3. 17SEP2010 (2) - 17SEP2010 (2) 4. 10NOV2010 (56) - --------- (.) 5. 07JAN2011 (114) - 14JAN2011 (121) 6. 11JAN2011 (118) - 11JAN2011 (118) 7. 12JAN2011 (119) - 20JAN2011 (127) 8. 12JAN2011 (119) - 12JAN2011 (119) 9. 13JAN2011 (120) - 13JAN2011 (120) 10. 13JAN2011 (120) - 17JAN2011 (124)
Duration of AE	1. 2 2. 1 3. 1 4. . 5. 8

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253007

Parameter	Value
	6. 1
	7. 9
	8. 1
	9. 1
	10. 5
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. NONE
	2. NONE
	3. OTHER
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY,OTHER
	8. NONE
	9. NONE
	10. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253007

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400253008/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/AUSTRALIA/YES
Medical history	Abdominal pain, Liver function test abnormal, Anaemia, Appendicectomy, Asthma, Congenital absence of bile ducts, Intestinal perforation, Cardiomegaly, Carpal tunnel syndrome, Cholangitis, Cholecystectomy, Colonic polyp, Chronic obstructive pulmonary disease, Depression, Diverticulum intestinal, Diverticulitis, Dizziness, Drug hypersensitivity, Drug hypersensitivity, Pyrexia, Gastrooesophageal reflux disease, Haemoglobin decreased, Haemoptysis, Haemorrhoids, Hiatus hernia, Hypercholesterolaemia, Hypertension, Hypoalbuminaemia, Hypokalaemia, Hypophosphataemia, Hysterectomy, Incisional hernia, Melaena, Nausea, Type 2 diabetes mellitus, Spinal osteoarthritis, Perinephric abscess, Pneumonia, Pyrexia, Splenomegaly, Vulvovaginal candidiasis, Weight decreased, Choledochoenterostomy, Lower gastrointestinal haemorrhage, Bacteraemia, Oophorectomy, Heart valve stenosis, Colostomy, Subdiaphragmatic abscess
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMITRYPTALLINE, AMLODIPINE, ATORVASTATIN, AUGMENTIN DF, AVAPRO HCT, AVAPRO-IRBESARTIN, CANESTAIN CREAM, CEFTRIAXONE, DEXAMETHASONE, ENDEP, ENOXAPARIN, ESOMEPRAZOLE, FRUSEMIDE, FRUSIMIDE, GENTMYCIN, GLICLIZIDE MR, IRON POLYMALTOSE, LORATADINE, PARACETAMOL, PARACETAMOL PRN, SALBUTAMOL NEBULISER, SERETIDE, SPRIVIA, TEMAZAPAM, TIMENTIN, WARFARIN
Adverse Events (AE) Preferred term	1. Ascites 2. Haematochezia 3. Chest pain 4. Constipation 5. Diarrhoea 6. Blister 7. Rash generalised 8. Chills 9. Headache 10. Bile duct cancer non-resectable 11. Pyrexia 12. Biliary sepsis 13. Lower gastrointestinal haemorrhage 14. Jaundice 15. Tachycardia 16. Hypophosphataemia 17. Hepatic failure 18. Asthenia 19. Lethargy 20. Urinary incontinence 21. Hypoalbuminaemia 22. Pyrexia 23. Contusion 24. Dehydration 25. Hypoxia 26. Dyspnoea exertional 27. Bilirubinuria

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253008

Parameter	Value
	28. Contusion
	29. Contusion
	30. Headache
	31. Arthralgia
	32. Malnutrition
	33. Haemoptysis
	34. Portal vein thrombosis
	35. Splenic lesion
	36. Abdominal hernia
	37. Splenomegaly
	38. Chest pain
	39. Vomiting
	40. Type 2 diabetes mellitus
	41. Blood potassium decreased
	42. Oedema
	43. Catheter site haemorrhage
	44. Wound secretion
	45. Oedema peripheral
	46. Tachycardia
	47. Blood urine present
	48. Ascites
	49. Skin disorder
	50. Dyspnoea
	51. Back pain
	52. Visual impairment
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MILD/NO/YES/YES
	3. SEVERE/NO/NO/YES
	4. MILD/NO/NO/YES
	5. MILD/NO/NO/YES
	6. MILD/YES/NO/YES
	7. MILD/NO/NO/YES
	8. MILD/NO/NO/YES
	9. MILD/NO/NO/YES
	10. SEVERE/NO/YES/YES
	11. MODERATE/NO/NO/YES
	12. MODERATE/NO/YES/YES
	13. MILD/YES/YES/YES
	14. MILD/NO/NO/YES
	15. MILD/NO/NO/YES
	16. MILD/NO/NO/YES
	17. SEVERE/NO/YES/YES
	18. MODERATE/NO/NO/YES
	19. MODERATE/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253008

Parameter	Value
	20. MILD/NO/NO/YES
	21. SEVERE/NO/NO/YES
	22. MILD/NO/NO/YES
	23. MILD/YES/NO/YES
	24. SEVERE/NO/YES/YES
	25. MILD/NO/NO/YES
	26. MILD/NO/NO/YES
	27. MODERATE/NO/NO/YES
	28. MILD/YES/NO/NO
	29. MILD/YES/NO/NO
	30. MILD/NO/NO/NO
	31. MILD/NO/NO/NO
	32. MODERATE/NO/NO/NO
	33. MILD/YES/YES/NO
	34. MILD/NO/NO/NO
	35. MILD/NO/NO/NO
	36. MILD/NO/NO/NO
	37. MILD/NO/NO/NO
	38. MILD/NO/NO/NO
	39. MILD/NO/NO/NO
	40. MILD/NO/NO/NO
	41. MILD/NO/NO/NO
	42. MILD/NO/NO/NO
	43. MILD/NO/NO/NO
	44. MILD/NO/NO/NO
	45. MILD/NO/NO/NO
	46. MILD/NO/NO/NO
	47. MILD/NO/NO/NO
	48. SEVERE/NO/NO/NO
	49. MILD/NO/NO/NO
	50. MILD/NO/NO/NO
	51. MODERATE/NO/NO/NO
	52. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --OCT2010 (.) - 11OCT2010 (26)
	2. 16SEP2010 (1) - 09OCT2010 (24)
	3. 19SEP2010 (4) - 19SEP2010 (4)
	4. 19SEP2010 (4) - 19SEP2010 (4)
	5. 19SEP2010 (4) - 20SEP2010 (5)
	6. 20SEP2010 (5) - 21SEP2010 (6)
	7. 20SEP2010 (5) - 23SEP2010 (8)
	8. 20SEP2010 (5) - 22SEP2010 (7)
	9. 21SEP2010 (6) - 21SEP2010 (6)
	10. 22SEP2010 (7) - 19OCT2010 (34)
	11. 22SEP2010 (7) - 23SEP2010 (8)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253008

Parameter	Value
	12. 23SEP2010 (8) - 18OCT2010 (33)
	13. 23SEP2010 (8) - --------- (.)
	14. 23SEP2010 (8) - --------- (.)
	15. 23SEP2010 (8) - 23SEP2010 (8)
	16. 23SEP2010 (8) - --------- (.)
	17. 23SEP2010 (8) - --------- (.)
	18. 23SEP2010 (8) - --------- (.)
	19. 23SEP2010 (8) - --------- (.)
	20. 23SEP2010 (8) - --------- (.)
	21. 23SEP2010 (8) - --------- (.)
	22. 23SEP2010 (8) - --------- (.)
	23. 24SEP2010 (9) - --------- (.)
	24. 24SEP2010 (9) - 27SEP2010 (12)
	25. 24SEP2010 (9) - --------- (.)
	26. 24SEP2010 (9) - --------- (.)
	27. 24SEP2010 (9) - --------- (.)
	28. 25SEP2010 (10) - 25SEP2010 (10)
	29. 26SEP2010 (11) - --------- (.)
	30. 26SEP2010 (11) - 26SEP2010 (11)
	31. 27SEP2010 (12) - --------- (.)
	32. 29SEP2010 (14) - --------- (.)
	33. 30SEP2010 (15) - 30SEP2010 (15)
	34. 30SEP2010 (15) - --------- (.)
	35. 30SEP2010 (15) - --------- (.)
	36. 30SEP2010 (15) - --------- (.)
	37. 30SEP2010 (15) - --------- (.)
	38. 01OCT2010 (16) - 01OCT2010 (16)
	39. 01OCT2010 (16) - 01OCT2010 (16)
	40. 01OCT2010 (16) - --------- (.)
	41. 03OCT2010 (18) - 06OCT2010 (21)
	42. 04OCT2010 (19) - --------- (.)
	43. 08OCT2010 (23) - --------- (.)
	44. 08OCT2010 (23) - --------- (.)
	45. 09OCT2010 (24) - 09OCT2010 (24)
	46. 09OCT2010 (24) - --------- (.)
	47. 12OCT2010 (27) - --------- (.)
	48. 12OCT2010 (27) - --------- (.)
	49. 12OCT2010 (27) - --------- (.)
	50. 15OCT2010 (30) - --------- (.)
	51. 15OCT2010 (30) - --------- (.)
	52. 17OCT2010 (32) - --------- (.)
Duration of AE	1. .
	2. 24
	3. 1

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253008

Parameter	Value
	4. 1
	5. 2
	6. 2
	7. 4
	8. 3
	9. 1
	10. 28
	11. 2
	12. 26
	13. .
	14. .
	15. 1
	16. .
	17. .
	18. .
	19. .
	20. .
	21. .
	22. .
	23. .
	24. 4
	25. .
	26. .
	27. .
	28. 1
	29. .
	30. 1
	31. .
	32. .
	33. 1
	34. .
	35. .
	36. .
	37. .
	38. 1
	39. 1
	40. .
	41. 4
	42. .
	43. .
	44. .
	45. 1
	46. .
	47. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253008

Parameter	Value
	48. .
	49. .
	50. .
	51. .
	52. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
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	30.
	31.
	32.
	33.
	34.
	35.
	36.
	37.
	38.
	39.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253008

Parameter	Value
	40.
	41.
	42.
	43.
	44.
	45.
	46.
	47.
	48.
	49.
	50.
	51.
	52.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
	27.
	28.
	29.
	30.
	31.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253008

Parameter	Value
	32.
	33.
	34.
	35.
	36.
	37.
	38.
	39.
	40.
	41.
	42.
	43.
	44.
	45.
	46.
	47.
	48.
	49.
	50.
	51.
	52.
Action taken	1. OTHER
	2. OTHER
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY,OTHER
	14. NONE
	15. NONE
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY,OTHER
	18. NONE
	19. NONE
	20. NONE
	21. REMEDIAL DRUG THERAPY
	22. REMEDIAL DRUG THERAPY
	23. OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253008

Parameter	Value
	24. OTHER
	25. NONE
	26. NONE
	27. NONE
	28. OTHER
	29. NONE
	30. REMEDIAL DRUG THERAPY
	31. NONE
	32. REMEDIAL DRUG THERAPY,OTHER
	33. NONE
	34. NONE
	35. NONE
	36. NONE
	37. NONE
	38. NONE
	39. NONE
	40. REMEDIAL DRUG THERAPY
	41. REMEDIAL DRUG THERAPY
	42. NONE
	43. OTHER
	44. REMEDIAL DRUG THERAPY,OTHER
	45. NONE
	46. NONE
	47. OTHER
	48. REMEDIAL DRUG THERAPY
	49. OTHER
	50. NONE
	51. NONE
	52. NONE
Outcome of event	1. WORSENED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. DEATH
	11. IMPROVED
	12. RESOLVED
	13. UNCHANGED
	14. UNCHANGED
	15. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253008

Parameter	Value
	16. UNCHANGED
	17. UNCHANGED
	18. UNCHANGED
	19. UNCHANGED
	20. UNCHANGED
	21. UNCHANGED
	22. UNCHANGED
	23. INSUFFICIENT FOLLOW-UP
	24. IMPROVED
	25. UNCHANGED
	26. UNCHANGED
	27. UNCHANGED
	28. WORSENED
	29. INSUFFICIENT FOLLOW-UP
	30. RESOLVED
	31. INSUFFICIENT FOLLOW-UP
	32. UNCHANGED
	33. RESOLVED
	34. INSUFFICIENT FOLLOW-UP
	35. INSUFFICIENT FOLLOW-UP
	36. INSUFFICIENT FOLLOW-UP
	37. INSUFFICIENT FOLLOW-UP
	38. RESOLVED
	39. RESOLVED
	40. UNCHANGED
	41. RESOLVED
	42. UNCHANGED
	43. INSUFFICIENT FOLLOW-UP
	44. UNCHANGED
	45. RESOLVED
	46. UNCHANGED
	47. INSUFFICIENT FOLLOW-UP
	48. UNCHANGED
	49. INSUFFICIENT FOLLOW-UP
	50. UNCHANGED
	51. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253008

Parameter	Value
	52. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400253012/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/43/WHITE/AUSTRALIA/YES
Medical history	Fibula fracture, Haemoptysis, Haemorrhoids, Blood cholesterol increased, Hypertension, Rib fracture, Tibia fracture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, AZITHROMYCIN, CEFTRIAXONE, CIPROFLOXACIN, DEXAMETHAZONE, DOXYCLYCLINE, ENDONE, ENOXAPARIN, FENTANYL, IBRUPROFEN, LOPERAMIDE, MEROPENUM, METOCLOPRAMIDE, MIDAZOLAM, NEXIUM, NORMAL SALINE, ONDANSETRON, PARACETAMOL, PAROBCOXIB, PHOLCODINE, PROPOFOL TCIC, RAMIPIL, ROSUVASTIN, ROXITHROMYCIN
Adverse Events (AE) Preferred term	1. Lobar pneumonia 2. Diarrhoea 3. Lower respiratory tract infection 4. Anxiety 5. Lethargy 6. Fatigue 7. Tachycardia 8. Cough 9. Dizziness 10. Headache 11. Diarrhoea 12. Haemorrhoidal haemorrhage 13. Gastrointestinal disorder
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/YES/NO/YES 13. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 30DEC2010 (1) - 05JAN2011 (7) 2. 04JAN2011 (6) - 11JAN2011 (13) 3. 11JAN2011 (13) - 18JAN2011 (20) 4. 11JAN2011 (13) - 11JAN2011 (13) 5. 11JAN2011 (13) - 11JAN2011 (13) 6. 11JAN2011 (13) - 11JAN2011 (13) 7. 12JAN2011 (14) - 14JAN2011 (16) 8. 13JAN2011 (15) - 13JAN2011 (15)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253012

Parameter	Value
	9. 13JAN2011 (15) - 13JAN2011 (15)
	10. 17JAN2011 (19) - 17JAN2011 (19)
	11. 18JAN2011 (20) - 18JAN2011 (20)
	12. 27JUN2011 (180) - 12JUL2011 (195)
	13. 28JUN2011 (181) - 12JUL2011 (195)
Duration of AE	1. 7
	2. 8
	3. 8
	4. 1
	5. 1
	6. 1
	7. 3
	8. 1
	9. 1
	10. 1
	11. 1
	12. 16
	13. 15
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
	10. 15 mg
	11. 15 mg
	12. 20 mg
	13. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. F

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400253012

Parameter	Value
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12.
	13. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400263001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/400263001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/26/WHITE/AUSTRALIA/YES
Medical history	Mammoplasty, Post procedural haematoma, Migraine
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BISOLVON, ENOXAPARIN, PANADOL, SYMBICORT, WARFARIN
Adverse Events (AE) Preferred term	1. Influenza like illness 2. Headache 3. Haemoptysis 4. Cough 5. Menstruation irregular 6. Dyspnoea exertional 7. Musculoskeletal chest pain 8. Pleural effusion 9. Polycythaemia vera 10. Polycythaemia vera 11. Medical device discomfort 12. Injection site haematoma 13. Platelet count decreased 14. Injection site haematoma 15. Menorrhagia 16. Animal bite 17. Injection site haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/YES/YES 10. MILD/NO/NO/NO 11. MILD/NO/NO/NO 12. MILD/YES/NO/NO 13. MODERATE/NO/NO/NO 14. MODERATE/YES/NO/NO 15. MODERATE/YES/NO/NO 16. MILD/NO/NO/NO 17. MILD/YES/NO/NO
Start/stop date of event with relative date	1. --MAY2011 (.) - 17JUN2011 (219) 2. 12NOV2010 (2) - --------- (.) 3. 26NOV2010 (16) - 26NOV2010 (16) 4. 26NOV2010 (16) - 26NOV2010 (16) 5. 26NOV2010 (16) - 04JAN2011 (55)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400263001

Parameter	Value
	6. 26NOV2010 (16) - 13DEC2010 (33)
	7. 26NOV2010 (16) - 11JAN2011 (62)
	8. 13DEC2010 (33) - 11MAY2011 (182)
	9. 14DEC2010 (34) - 17DEC2010 (37)
	10. 17DEC2010 (37) - --------- (.)
	11. 11JAN2011 (62) - --FEB2011 (.)
	12. 21JAN2011 (72) - 01FEB2011 (83)
	13. 02FEB2011 (84) - 14FEB2011 (96)
	14. 02FEB2011 (84) - 03MAR2011 (113)
	15. 07FEB2011 (89) - 16FEB2011 (98)
	16. 13FEB2011 (95) - 03MAR2011 (113)
	17. 04MAR2011 (114) - --------- (.)
Duration of AE	1. .
	2. .
	3. 1
	4. 1
	5. 40
	6. 18
	7. 47
	8. 150
	9. 4
	10. .
	11. .
	12. 12
	13. 13
	14. 30
	15. 10
	16. 19
	17. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400263001

Parameter	Value
	16.
	17.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY,OTHER
	10. REMEDIAL DRUG THERAPY,OTHER
	11. NONE
	12. NONE
	13. DOSE OF STUDY DRUG REDUCED
	14. NONE
	15. DOSE OF STUDY DRUG REDUCED
	16. NONE
	17. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 400263001

Parameter	Value
	9. IMPROVED
	10. UNCHANGED
	11. RESOLVED
	12. WORSENED
	13. RESOLVED
	14. IMPROVED
	15. RESOLVED
	16. RESOLVED
	17. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/63/WHITE/AUSTRIA/YES
Medical history	Dupuytren's contracture, Obesity, Hypercholesterolaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BALNEUM HERMAL PLUS POLIDOCANOL, DEFLAMAT, EZETROL, LOVENOX, NEXIUM, PANTOLOC, THROMBO ASS, XEFO
Adverse Events (AE) Preferred term	1. Pruritus generalised 2. Colonic polyp 3. Procedural pain 4. Arthritis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 25DEC2007 (90) - 23MAY2008 (240) 2. 07JAN2008 (103) - 14FEB2008 (141) 3. 14FEB2008 (141) - --------- (.) 4. 24APR2008 (211) - --------- (.)
Duration of AE	1. 151 2. 39 3. . 4. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. I 3. I 4. .
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER 3. REMEDIAL DRUG THERAPY,OTHER 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013004

Parameter	Value
	4. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013005/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/50/WHITE/AUSTRIA/YES
Medical history	Gastritis, Pneumonia, Tobacco abuse
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN (AMOXICILLIN TRIHYDRAT WITH CLAVULANATE POTASSIUM), AVELOX (MOXIFLOXACIN), BACTRIM FORTE (TRIMETHOPRIM+SULFAMETHOXAZOL), LASILACTON (FUROSEMIDE + SPIRINOLACTONE), OMEPRAZOL (OMEPRAZOL), PANTOLOC (PANTOPRAZOL)
Adverse Events (AE) Preferred term	1. Skin ulcer 2. Lung neoplasm malignant 3. Pyrexia 4. Pulmonary embolism 5. Alanine aminotransferase increased 6. Aspartate aminotransferase increased
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MILD/NO/NO/NO 4. SEVERE/NO/YES/NO 5. SEVERE/NO/YES/NO 6. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. --OCT2007 (.) - --------- (.) 2. 21OCT2007 (24) - --------- (.) 3. 25OCT2007 (28) - 25OCT2007 (28) 4. 07NOV2007 (41) - 09NOV2007 (43) 5. 09NOV2007 (43) - --------- (.) 6. 09NOV2007 (43) - --------- (.)
Duration of AE	1. . 2. . 3. 1 4. 3 5. . 6. .
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. 2. F 3. F 4. F 5. F 6. F
Action taken	1. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013005

Parameter	Value
	2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. DEATH
	5. UNCHANGED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013013/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/21/WHITE/AUSTRIA/YES
Medical history	Tobacco abuse
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, BELARA (EE2 + CHLORMADINON), CELEBREX, ENOXAPARIN, KONAKION, LOVENOX, MIRENA
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Alanine aminotransferase increased 3. Palpitations 4. Tremor 5. Vertigo 6. Headache 7. Dyspnoea 8. Tremor 9. Palpitations
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 30NOV2007 (18) - 30NOV2007 (18) 2. 30NOV2007 (18) - 11FEB2008 (91) 3. 08FEB2008 (88) - 08FEB2008 (88) 4. 08FEB2008 (88) - 08FEB2008 (88) 5. 08FEB2008 (88) - 08FEB2008 (88) 6. 02APR2008 (142) - 16SEP2008 (309) 7. 09APR2008 (149) - 09APR2008 (149) 8. 09APR2008 (149) - 09APR2008 (149) 9. 09APR2008 (149) - 09APR2008 (149)
Duration of AE	1. 1 2. 74 3. 1 4. 1 5. 1 6. 168 7. 1 8. 1 9. 1
Dose on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013013

Parameter	Value
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013021/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/46/WHITE/AUSTRIA/YES
Medical history	Anaemia, Cough, Epilepsy, Pyrexia, Gamma-glutamyltransferase increased, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, DICLOFENAC RETARD, NEXIUM, PANTOLOC, PARKEMED, TEGRETOL, TOPAMAX, UFH, UNFRACTIONATED HEPARIN, XEFO
Adverse Events (AE) Preferred term	1. Facial bones fracture 2. Contusion
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 20APR2008 (44) - 22APR2008 (46) 2. 20APR2008 (44) - 22APR2008 (46)
Duration of AE	1. 3 2. 3
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013028

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013028/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/74/WHITE/AUSTRIA/YES
Medical history	Osteoarthritis, Hyperlipidaemia, Hypertension, Muscle rupture, Polyarthritis, Sleep disorder, Coronary artery disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC, AUGMENTIN, COSAAR, DAFLON [DIOSMIN + BIOFLAVONOIDS + HERSPERIDIN], DALACIN [CLINDAMYCIN], ERBIUM169, LOVENOX, MARCOUMAR, MEXALEN, PANTOLOC, SIMVASTATIN, TUSSAMAG [THYMUS VULGARIS EXTRACT & CASTANEA SATIVA EXTRACT], XANOR, ZOLDEM
Adverse Events (AE) Preferred term	1. Epistaxis 2. Pain in extremity 3. Arthritis 4. Gingival bleeding 5. Pain in extremity 6. Osteoarthritis 7. Gingival bleeding 8. Osteoarthritis 9. Abdominal pain lower 10. Osteoarthritis 11. Lower respiratory tract infection 12. Pyrexia 13. Periphlebitis 14. Osteoarthritis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/YES/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MODERATE/NO/YES/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 24APR2008 (10) - 28APR2008 (14) 2. 30APR2008 (16) - --------- (.) 3. 03MAY2008 (19) - 18MAY2008 (34) 4. 04MAY2008 (20) - 02JUN2008 (49) 5. 19MAY2008 (35) - --------- (.) 6. 19MAY2008 (35) - 25FEB2009 (317) 7. 01JUL2008 (78) - 05AUG2008 (113) 8. 13OCT2008 (182) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013028

Parameter	Value
	9. 29NOV2008 (229) - --------- (.)
	10. 26FEB2009 (318) - 07MAR2009 (327)
	11. 28FEB2009 (320) - 09MAR2009 (329)
	12. 28FEB2009 (320) - 06MAR2009 (326)
	13. 02MAR2009 (322) - 04MAR2009 (324)
	14. 08MAR2009 (328) - --------- (.)
Duration of AE	1. 5
	2. .
	3. 16
	4. 30
	5. .
	6. 283
	7. 36
	8. .
	9. .
	10. 10
	11. 10
	12. 7
	13. 3
	14. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. I

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013028

Parameter	Value
	11. I
	12. I
	13. I
	14. .
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. OTHER
	14. NONE
Outcome of event	1. RESOLVED
	2. IMPROVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. WORSENED
	7. RESOLVED
	8. UNCHANGED
	9. IMPROVED
	10. IMPROVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013029/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/45/WHITE/AUSTRIA/YES
Medical history	
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	PANTOLOC
Adverse Events (AE) Preferred term	1. Pulmonary haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 21APR2008 (2) - 21APR2008 (2)
Duration of AE	1. 1
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013039

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013039/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/60/WHITE/AUSTRIA/YES
Medical history	Hyperlipidaemia, Hypertension, Hepatic steatosis, Postmenopause, Oral fungal infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BERODUALIN (FENOTEROL HYDROBROMID+IPRATROPIUM BROMID MONOHYDRAT), DIAMICRON MR (GLICLAZID), DIBONDRIN AMP., KLACID (CLARITHROMYCIN), MYCOSTATIN ORAL SUSPENSION (NYSTATIN), NERISONA OINTMENT (DIFLUCORTOLON 21-VALERAT), NOMEXOR (NEBIVOLOL HYDROCHLORID), NORVASC (AMLODIPIN BESILAT), PANTOLOC (PANTOPRAZOL NATRIUM SESQUIHYDRAT), RULIDE (ROXITHROMYCIN), SORTIS (ATORVASTATIN CALCIUM), TRENTAL (PENTOXIFYLLIN), VOLTAREN RAPID (DICLOFENAC KALIUM), ZOLDEM (ZOLPIDEM TARTRAT 2:1)
Adverse Events (AE) Preferred term	1. Type 2 diabetes mellitus 2. Insomnia 3. Tinea versicolour 4. Leukoencephalopathy 5. Leukoencephalopathy 6. Sinusitis 7. Exostosis 8. Paraparesis 9. Fall
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. SEVERE/NO/NO/YES 9. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 08SEP2008 (1) - --------- (.) 2. 09SEP2008 (2) - 15SEP2008 (8) 3. 11SEP2008 (4) - --------- (.) 4. 12SEP2008 (5) - 20OCT2008 (43) 5. 21OCT2008 (44) - --------- (.) 6. 09DEC2008 (93) - --------- (.) 7. 09DEC2008 (93) - --------- (.) 8. 09DEC2008 (93) - 13DEC2008 (97) 9. 09DEC2008 (93) - 09DEC2008 (93)
Duration of AE	1. . 2. 7 3. . 4. 39 5. . 6. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013039

Parameter	Value
	7. .
	8. 5
	9. 1
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. IMPROVED
	4. WORSENED
	5. UNCHANGED
	6. INSUFFICIENT FOLLOW-UP
	7. UNCHANGED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013039

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013045

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013045/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/45/WHITE/AUSTRIA/YES
Medical history	Nephrolithiasis, Hyperlipidaemia, Tobacco abuse
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, BUSCOPAN, CIPROXIN, ELOMEL, ENOXAPARIN, MARCOUMAR, MOTRIM, NEXIUM, NOVALGIN, SIMVASTATIN, VENOBENE
Adverse Events (AE) Preferred term	1. Nephrolithiasis 2. Haematuria 3. Headache 4. Nephrolithiasis 5. Nasopharyngitis 6. Nephrolithiasis 7. Cough 8. Fall 9. Facial bones fracture
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. ./NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. SEVERE/NO/YES/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 06NOV2008 (7) - 12NOV2008 (13) 2. 06NOV2008 (7) - 12NOV2008 (13) 3. 08NOV2008 (9) - 08NOV2008 (9) 4. 13NOV2008 (14) - 01DEC2008 (32) 5. 26NOV2008 (27) - 05JAN2009 (67) 6. 01DEC2008 (32) - 13DEC2008 (44) 7. 16MAR2009 (137) - 16MAR2009 (137) 8. 16MAR2009 (137) - 16MAR2009 (137) 9. 16MAR2009 (137) - --------- (.)
Duration of AE	1. 7 2. 7 3. 1 4. 19 5. 41 6. 13 7. 1 8. 1 9. .
Dose on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013045

Parameter	Value
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
	2. STUDY DRUG DISCONTINUED AND RESTARTED
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY,OTHER
	7. NONE
	8. NONE
	9. NONE
Outcome of event	1. IMPROVED
	2. RESOLVED
	3. RESOLVED
	4. WORSENED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013053

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013053/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/48/WHITE/AUSTRIA/YES
Medical history	Haemorrhoids, Headache, Hypertension, Nephrolithiasis, Oophorectomy, Ovarian cyst, Retinal detachment, Uterine leiomyoma, Female sterilisation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AUGMENTIN, DEXAGENTA EYEDROPS, DEXAGENTA EYEGEL, ENOXAPARIN, MEXALEN, OLEOVIT EYEDROPS; DEXPANTHENOL, RETINOL, PASPERTIN, PERFALGAN, RIVACOR PLUS
Adverse Events (AE) Preferred term	1. Nausea 2. Menorrhagia 3. Liver function test abnormal 4. Hypertension 5. Hiatus hernia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/NO/YES 2. SEVERE/YES/YES/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 03FEB2009 (1) - 11FEB2009 (9) 2. 07FEB2009 (5) - 19FEB2009 (17) 3. 09FEB2009 (7) - 17FEB2009 (15) 4. 09FEB2009 (7) - --------- (.) 5. 17FEB2009 (15) - --------- (.)
Duration of AE	1. 9 2. 13 3. 9 4. . 5. .
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER 3. NONE 4. REMEDIAL DRUG THERAPY 5. NONE
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013053

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-440013053[4)]	ELEVATED LIVER PARAMETERS（PT：肝機能検査異常） 治験担当医は、併用薬（Augmentin)によるものと考え、否定できると判断した。弊社は、エノキサパリン及びワルファリン投与と報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013073

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013073/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/47/WHITE/AUSTRIA/YES
Medical history	C-reactive protein increased
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ENOXAPARIN, KLACID UNO, NEXIUM
Adverse Events (AE) Preferred term	1. Lung neoplasm
	2. Headache
	3. Bronchial carcinoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES
	2. MILD/NO/NO/YES
	3. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 17JUL2009 (0) - --------- (.)
	2. 24JUL2009 (7) - 21AUG2009 (35)
	3. 30DEC2009 (166) - --------- (.)
Duration of AE	1. .
	2. 29
	3. .
Dose on AE onset	1.
	2.
	3.
Dose status on AE onset	1.
	2.
	3.
Action taken	1. NONE
	2. NONE
	3. OTHER
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013074

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013074/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/29/WHITE/AUSTRIA/YES
Medical history	Lipoma excision, Pulmonary granuloma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ENOXAPARIN
Adverse Events (AE) Preferred term	1. Alanine aminotransferase increased
	2. Bone pain
	3. Bone pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/YES/YES
	2. MILD/NO/NO/YES
	3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 11AUG2009 (16) - 08SEP2009 (44)
	2. 21AUG2009 (26) - 21AUG2009 (26)
	3. 24AUG2009 (29) - 25AUG2009 (30)
Duration of AE	1. 29
	2. 1
	3. 2
Dose on AE onset	1.
	2.
	3.
Dose status on AE onset	1.
	2.
	3.
Action taken	1. NONE
	2. NONE
	3. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013080

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013080/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/26/WHITE/AUSTRIA/YES
Medical history	Cough, Pleurisy, Pneumonia, Tobacco abuse
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC, ACENOCOUMAROL, ASPIRIN, AVELOX, BUCOPAN, BUSCOPAN, CHLORHEXAMED, CLAVAMOX, CONDYLOX, DISMENOL, ENOXAPARIN, FLUOREX PLUS, LOVENOX, MEXALEN, NOVALGIN, SAYANA, TRAMAL, VIKELA, VOLTAREN
Adverse Events (AE) Preferred term	1. Alanine aminotransferase increased 2. Genital candidiasis 3. Anogenital warts 4. Headache 5. Dysmenorrhoea 6. Headache 7. Oropharyngeal pain 8. Headache 9. Dysmenorrhoea 10. Headache 11. Dysmenorrhoea 12. Musculoskeletal pain 13. Nasopharyngitis 14. Dysmenorrhoea 15. Dysphonia 16. Vaginal discharge 17. Headache 18. Ear pain 19. Oropharyngeal pain 20. Headache 21. Headache 22. Ear pain 23. Diarrhoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/YES 14. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013080

Parameter	Value
	15. MILD/NO/NO/YES
	16. MILD/NO/NO/YES
	17. MILD/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MILD/NO/NO/YES
	20. MILD/NO/NO/YES
	21. MILD/NO/NO/YES
	22. MILD/NO/NO/NO
	23. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 09NOV2009 (11) - 25NOV2009 (27)
	2. 26NOV2009 (28) - 19APR2010 (172)
	3. 26NOV2009 (28) - 08JAN2010 (71)
	4. 28NOV2009 (30) - 28NOV2009 (30)
	5. 12DEC2009 (44) - 12DEC2009 (44)
	6. 13DEC2009 (45) - 13DEC2009 (45)
	7. 17DEC2009 (49) - 15JAN2010 (78)
	8. 26JAN2010 (89) - 26JAN2010 (89)
	9. 27JAN2010 (90) - 28JAN2010 (91)
	10. 17FEB2010 (111) - 17FEB2010 (111)
	11. 03MAR2010 (125) - 03MAR2010 (125)
	12. 08MAR2010 (130) - 15APR2010 (168)
	13. 27MAR2010 (149) - 07APR2010 (160)
	14. 12MAY2010 (195) - 13MAY2010 (196)
	15. 18JUN2010 (232) - 25JUN2010 (239)
	16. 14JUL2010 (258) - 24JUL2010 (268)
	17. 18JUL2010 (262) - 18JUL2010 (262)
	18. 15AUG2010 (290) - 16AUG2010 (291)
	19. 15AUG2010 (290) - 16AUG2010 (291)
	20. 21SEP2010 (327) - 21SEP2010 (327)
	21. 15OCT2010 (351) - 15OCT2010 (351)
	22. 31OCT2010 (367) - 16NOV2010 (383)
	23. 03NOV2010 (370) - 12NOV2010 (379)
Duration of AE	1. 17
	2. 145
	3. 44
	4. 1
	5. 1
	6. 1
	7. 30
	8. 1
	9. 2
	10. 1
	11. 1
	12. 39

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013080

Parameter	Value
	13. 12
	14. 2
	15. 8
	16. 11
	17. 1
	18. 2
	19. 2
	20. 1
	21. 1
	22. 17
	23. 10
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013080

Parameter	Value
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. NONE
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. REMEDIAL DRUG THERAPY
	19. REMEDIAL DRUG THERAPY
	20. REMEDIAL DRUG THERAPY
	21. REMEDIAL DRUG THERAPY
	22. REMEDIAL DRUG THERAPY
	23. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013080

Parameter	Value
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED
	23. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013085

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013085/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/77/WHITE/AUSTRIA/YES
Medical history	Anxiety, Colitis ulcerative, Hypertension, Macular degeneration, Polyneuropathy, Type 1 diabetes mellitus, Skin ulcer, Chronic right ventricular failure
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTONE [SPIRONOLACTON], BEPANTHEN PLUS CREAM, CO-DIOVAN, DIPRODERM CREAM 30 %, GLUCOSE 5%, HUMALOG, HUMINSULIN BASAL, LASIX, NITRATE MONOXIDE, NOMEXOR, OCULOTECT [POLYVIDONE], OXYGEN, PANTOLOC, PASPERTIN, PRAXITEN, PROMACULA MAX, ROHYPNOL, SOMNUBENE, TORASEMID, VARIHESIVE
Adverse Events (AE) Preferred term	1. Oedema peripheral 2. Tachypnoea 3. Dyspnoea 4. Decreased appetite 5. Cough 6. Rash 7. Anaemia 8. Pulmonary hypertension 9. Wound 10. Tricuspid valve incompetence 11. Dry eye 12. Leukopenia 13. Cough 14. Thrombocytopenia 15. Pyrexia 16. Anaemia 17. Anaemia 18. Pulmonary hypertension
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/YES/NO/YES 8. SEVERE/NO/YES/YES 9. MILD/NO/NO/YES 10. MILD/YES/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/NO 14. MILD/NO/NO/NO 15. MILD/NO/NO/NO 16. SEVERE/YES/YES/NO 17. MILD/YES/NO/NO

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013085

Parameter	Value
	18. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 13NOV2009 (1) - --------- (.)
	2. 19NOV2009 (7) - 20NOV2009 (8)
	3. 21NOV2009 (9) - 04JAN2010 (53)
	4. 01DEC2009 (19) - --------- (.)
	5. 03DEC2009 (21) - 11DEC2009 (29)
	6. 10DEC2009 (28) - --------- (.)
	7. 04JAN2010 (53) - 08FEB2010 (88)
	8. 04JAN2010 (53) - 09FEB2010 (89)
	9. 05JAN2010 (54) - --------- (.)
	10. 07JAN2010 (56) - --------- (.)
	11. 24JAN2010 (73) - --------- (.)
	12. 25JAN2010 (74) - --------- (.)
	13. 01FEB2010 (81) - 09FEB2010 (89)
	14. 01FEB2010 (81) - --------- (.)
	15. 04FEB2010 (84) - 06FEB2010 (86)
	16. 08FEB2010 (88) - 09FEB2010 (89)
	17. 09FEB2010 (89) - --------- (.)
	18. 10FEB2010 (90) - --------- (.)
Duration of AE	1. .
	2. 2
	3. 45
	4. .
	5. 9
	6. .
	7. 36
	8. 37
	9. .
	10. .
	11. .
	12. .
	13. 9
	14. .
	15. 3
	16. 2
	17. .
	18. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 20 mg
	7. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013085

Parameter	Value
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. F
	14. F
	15. F
	16. F
	17. F
	18. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. STUDY DRUG DISCONTINUED AND RESTARTED,STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. REMEDIAL DRUG THERAPY
	14. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013085

Parameter	Value
	15. OTHER
	16. OTHER
	17. NONE
	18. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. WORSENED
	4. UNCHANGED
	5. RESOLVED
	6. UNCHANGED
	7. WORSENED
	8. IMPROVED
	9. IMPROVED
	10. UNCHANGED
	11. IMPROVED
	12. UNCHANGED
	13. RESOLVED
	14. UNCHANGED
	15. RESOLVED
	16. IMPROVED
	17. UNCHANGED
	18. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-440013085[2),1),1)]	ANEMIA（PT：貧血） 治験担当医はリバーロキサバンと報告事象との関連性があると判断した。弊社は、リバーロキサバン投与と本剤投与中止後 12 日を経過しての発現であるため、リバーロキサバンとの因果関係は否定できると考える。 LEUCOPENIA（PT：白血球減少症） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、リバーロキサバン投与と本剤投与中止後 10 日以上経過してからの発現であるため、リバーロキサバンとの因果関係は否定できると考える。 THROMBOCYTOPENIA（PT：血小板減少症） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、リバーロキサバン投与と本剤投与中止後 10 日以上経過してからの発現であるため、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013100

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013100/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/51/WHITE/AUSTRIA/YES
Medical history	Cataract, Cerebrovascular accident, Cerebrovascular accident, Coronary artery occlusion, Heart transplant, Hyperlipidaemia, Hypertension, Hyperuricaemia, Nasal polypectomy, Angioedema, Sinusitis, Cholelithiasis, Renal failure chronic, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AUGMENTIN, BEZALIP, BLOPRESS, CELLCEPT, ENOXAPARIN, LOVENOX, MEXALEN, MG VERLA, NOVORAPID, PLAVIX, RAPAMUNE, SELOKEN, SORTIS, THROMBO ASS, TORASEMID, UROSIN, ZANTAC
Adverse Events (AE) Preferred term	1. Coronary artery disease
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 09JAN2011 (270) - 11JAN2011 (272)
Duration of AE	1. 3
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013124

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013124/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/AUSTRIA/YES
Medical history	Oral candidiasis, Chronic obstructive pulmonary disease, Depression, Hypertension, Hypothyroidism, Pneumonia, Sleep disorder, Postmenopause, Genitourinary tract infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, APREDNISOLON, ATACAND [CANDESARTAN], BERODUALIN, CAL-D-VITA, DAXAS, ENOXAPARIN, EUTHYROX, KLACID, LENDORM, MIRTABENE, MUCOBENE, NOMEXOR, PANTOLOC, SERETIDE DISCUS FORTE, SPIRIVA RESPIMAT
Adverse Events (AE) Preferred term	1. Rectal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/YES/YES
Start/stop date of event with relative date	1. 13MAR2011 (67) - 17MAR2011 (71)
Duration of AE	1. 5
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440013127

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440013127/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/70/WHITE/AUSTRIA/YES
Medical history	Anaemia, Ascites, Varices oesophageal, Hypothyroidism, Inguinal hernia repair, Oesophageal variceal ligation, Portal hypertension, Portal vein thrombosis, Umbilical hernia, obstructive
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AVELOX, EUTHYROX, FRAGMIN, INDERAL, ISMN, LASILACTON, LASIX, LOVENOX, PANTOPRAZOL
Adverse Events (AE) Preferred term	1. Ascites 2. Gastrointestinal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 27MAY2011 (105) - 27JUN2011 (136) 2. 01JUL2011 (140) - --------- (.)
Duration of AE	1. 32 2. .
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. IMPROVED 2. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440033013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440033013/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/38/WHITE/AUSTRIA/YES
Medical history	Pleurisy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, LOVENOX, MEXALEN, NOVALGIN, NUVA-RING, PERFALGAN
Adverse Events (AE) Preferred term	1. Pregnancy 2. Abortion induced
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 09FEB2009 (278) - 26FEB2009 (295) 2. 26FEB2009 (295) - 26FEB2009 (295)
Duration of AE	1. 18 2. 1
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. I
Action taken	1. OTHER 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440033026

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440033026/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/65/WHITE/AUSTRIA/YES
Medical history	Diabetes mellitus, Hypertension, Nephrolithiasis, Phimosis, Lung neoplasm, Obesity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACEMIN, ACENOCOUMAROL, AUGMENTIN, ENOXAPARIN, LOVENOX, NATRIUMCHLORID 0.9%, PERFALGAN
Adverse Events (AE) Preferred term	1. Carotid arteriosclerosis 2. Phimosis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 09DEC2008 (5) - -------- (.) 2. 02SEP2009 (272) - 04SEP2009 (274)
Duration of AE	1. . 2. 3
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. UNCHANGED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-440033026[1)]	PHIMOSIS（PT：包茎） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、投与中の偶発症と考え、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440033036

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440033036/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/74/WHITE/AUSTRIA/YES
Medical history	Hypertension, Hypothyroidism, Hysterectomy, Lichen planus, Phlebectomy, Adrenalectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACEMIN, ACENOCOUMAROL, ENOXAPARIN, EUTHYROX, KLACID, PARACETAMOL, SINTROM, TEBOFORTAN, THROMBO-ASS
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Laryngitis 3. Vomiting
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 05OCT2009 (14) - 09OCT2009 (18) 2. 24JUL2010 (306) - 03AUG2010 (316) 3. 28JUL2010 (310) - 28JUL2010 (310)
Duration of AE	1. 5 2. 11 3. 1
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY 3. OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440033040

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440033040/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/73/WHITE/AUSTRIA/YES
Medical history	Hypertension, Hyperuricaemia, Varicose vein, Renal failure chronic
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, CIPROXIN, CO-ENALAPRIL, COLCHIZIN, ENOXAPARIN, LIDOCAIN, MALOX, NACL, NITRO LINGUAL, NORVASC, OXYMETAZOLIN, PANTOLOC, SIMVASTATIN
Adverse Events (AE) Preferred term	1. Prostatic specific antigen increased 2. Prostatitis 3. Blood pressure increased 4. Hyperlipidaemia 5. Epistaxis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 16NOV2009 (4) - 26NOV2009 (14) 2. 27NOV2009 (15) - --------- (.) 3. 22DEC2009 (40) - 23DEC2009 (41) 4. 23DEC2009 (41) - --------- (.) 5. 06AUG2010 (267) - 06AUG2010 (267)
Duration of AE	1. 11 2. . 3. 2 4. . 5. 1
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY 5. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. UNCHANGED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440033040

Parameter	Value
	4. UNCHANGED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440043003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440043003/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/44/WHITE/AUSTRIA/YES
Medical history	Asthma, Seasonal allergy, Iodine allergy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BRICANYL, CEFUROXIM, CLAVAMOX, MIDAZOLAM, NITROLINGUAL, PANTOLOC, PERFALGAN, PULMICORT, SULTANOL, SYMBICORT, ZURCAL
Adverse Events (AE) Preferred term	1. Headache 2. Chest discomfort 3. Pain in extremity 4. Gastritis 5. Hypertension 6. Angina pectoris 7. Gastritis 8. Limb injury 9. Wound infection 10. Limb injury 11. Bronchitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. SEVERE/NO/YES/YES 11. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --APR2008 (.) - --------- (.) 2. --JAN2008 (.) - --JAN2008 (.) 3. 17OCT2007 (15) - 17OCT2007 (15) 4. 15DEC2007 (74) - 27DEC2007 (86) 5. 03FEB2008 (124) - --------- (.) 6. 09FEB2008 (130) - 23JUN2008 (265) 7. 23MAY2008 (234) - --------- (.) 8. 07SEP2008 (341) - 07SEP2008 (341) 9. 07SEP2008 (341) - 20SEP2008 (354) 10. 08SEP2008 (342) - 12SEP2008 (346) 11. 22SEP2008 (356) - 28SEP2008 (362)
Duration of AE	1. . 2. . 3. 1 4. 13 5. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440043003

Parameter	Value
	6. 136
	7. .
	8. 1
	9. 14
	10. 5
	11. 7
Dose on AE onset	1.
	2.
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1.
	2.
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
Action taken	1. NONE
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY,OTHER
	11. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440043003

Parameter	Value
	6. RESOLVED
	7. UNCHANGED
	8. WORSENED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440043027

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440043027/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/70/WHITE/AUSTRIA/YES
Medical history	Hyperlipidaemia, Hypertension, Postmenopause, Pneumonia, Varicose vein operation, Varicose vein operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, CLAVAMOX, ENOXAPARIN, LISINOPRIL, PANTOLOC, SIMVASTATIN
Adverse Events (AE) Preferred term	1. Epistaxis 2. Pain in extremity 3. Thyroid neoplasm 4. Goitre 5. Goitre 6. Hypocalcaemia 7. Back pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/YES/NO 6. MILD/NO/YES/NO 7. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 01OCT2008 (9) - --------- (.) 2. 04OCT2008 (12) - 04OCT2008 (12) 3. 18DEC2008 (87) - 18DEC2008 (87) 4. 18DEC2008 (87) - 04APR2009 (194) 5. 05APR2009 (195) - 11APR2009 (201) 6. 13APR2009 (203) - 21APR2009 (211) 7. 13APR2009 (203) - 16APR2009 (206)
Duration of AE	1. . 2. 1 3. 1 4. 108 5. 7 6. 9 7. 4
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440043027

Parameter	Value
	5.
	6.
	7.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440043030

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440043030/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/AUSTRIA/YES
Medical history	Chronic obstructive pulmonary disease, Depression, Hyperlipidaemia, Hypertension, Hysterectomy, Sleep disorder, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BELOC, CEFUROXIM, CIPRALEX, CLAVAMOX, DEANXIT, DIPIDOLOR, ESMERON, HALCION, LISINOPRIL, LOVENOX, MAXI-KALZ [CALCIUM CITRATE], MEXALEN, NOVALGIN, OMACOR, OMEPRAZOL, PANTOLOC, PERFALGAN, PIRITRAMID, PROPOFOL PERFUSION, SEREVENT, SIMVASTATIN, SPIRIVA, VERTIROSAN [DIMENHYDRINAT], VOLTAREN
Adverse Events (AE) Preferred term	1. Pain in extremity 2. Tibia fracture 3. Fibula fracture 4. Headache 5. Limb discomfort 6. Vertigo 7. Vertigo 8. Urinary tract infection 9. Oropharyngeal pain 10. Gingivitis 11. Pain in extremity
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/YES/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/YES/NO
Start/stop date of event with relative date	1. 23DEC2008 (8) - 30DEC2008 (15) 2. 22JAN2009 (38) - 06FEB2009 (53) 3. 22JAN2009 (38) - 06FEB2009 (53) 4. 19MAR2009 (94) - 19MAR2009 (94) 5. 10APR2009 (116) - 20APR2009 (126) 6. 07SEP2009 (266) - 16SEP2009 (275) 7. 17SEP2009 (276) - --------- (.) 8. 18NOV2009 (338) - 26NOV2009 (346) 9. 18NOV2009 (338) - 26NOV2009 (346) 10. 18NOV2009 (338) - 26NOV2009 (346) 11. 27JAN2010 (408) - 01FEB2010 (413)
Duration of AE	1. 8 2. 16

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440043030

Parameter	Value
	3. 16
	4. 1
	5. 11
	6. 10
	7. .
	8. 9
	9. 9
	10. 9
	11. 6
Dose on AE onset	1. 15 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. F
Action taken	1. OTHER
	2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440043030

Parameter	Value
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440043032

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440043032/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/76/WHITE/AUSTRIA/YES
Medical history	Breast mass, Cervix carcinoma, Hip arthroplasty, Hysterectomy, Radiotherapy, Sleep disorder, Tachycardia, Tonsillectomy, Pneumonia, Oophorectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARIMIDEX, AVELOX, CAL-D-VITA, CLAVAMOX, DICLOBENE, DOMINAL, LENDORM, LISINOPRIL, LOVENOX, PANTOPRAZOL, ZOLDEM
Adverse Events (AE) Preferred term	1. Breast cancer
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 24MAR2009 (33) - --------- (.)
Duration of AE	1. .
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. I
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440043045

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440043045/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/58/WHITE/AUSTRIA/YES
Medical history	Synovial cyst, Pleural effusion, Postmenopause, Activated protein C resistance, Pneumonia, Allergy to metals
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, CLAVAMOX, DICLOBENE, DIPIDOLOR, ENOXAPARIN, LOVENOX, MEXALEN, NEUROBION, PANTOLOC, PASPERTIN, SODIUM CHLORIDE SLOUTION, TAZONAM
Adverse Events (AE) Preferred term	1. Goitre 2. Goitre
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 01JUL2010 (14) - 18SEP2010 (93) 2. 19SEP2010 (94) - 24SEP2010 (99)
Duration of AE	1. 80 2. 6
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED 2. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440053008

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440053008/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/58/WHITE/AUSTRIA/YES
Medical history	Depression, Prostatic specific antigen abnormal, Deep vein thrombosis, Tobacco abuse
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ALNA RETARD, CIPROXIN, CITALOPRAM, ENOXAPARIN, LOVENOX, LUDIOMIL, NEUROTOP, RISPERDAL, SERACTIL FORTE, THROMBO ASS, TRUXAL
Adverse Events (AE) Preferred term	1. Prostatitis 2. Prostatic specific antigen increased 3. Back pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 15NOV2007 (25) - 20NOV2007 (30) 2. 27JUN2008 (250) - 28JUN2008 (251) 3. 30SEP2008 (345) - 06OCT2008 (351)
Duration of AE	1. 6 2. 2 3. 7
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440053041

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440053041/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/83/WHITE/AUSTRIA/YES
Medical history	Angiosclerosis, Chronic obstructive pulmonary disease, Hyperlipidaemia, Renal cyst, Peripheral artery angioplasty, Peripheral arterial occlusive disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AEROMUC, ALNA RETARD, APREDNISOLON, CIPROXIN, CLAVAMOX, COMBIVENT, ENOXAPARIN, FORADIL SPRAY, LASIX, LESCOL, MOVALIS, MYCOSTATIN GEL, PANTOLOC, RAMIPRIL, SERETIDE DISKUS FORTE, SIMVASTATIN, SPIRIVA, SPIROBENE, THEOSPIREX, UNASYN, UNIFYL
Adverse Events (AE) Preferred term	1. Prostatitis 2. Prostatitis 3. Oedema peripheral 4. Xeroderma 5. Chronic obstructive pulmonary disease 6. Hypertension 7. Dyspnoea 8. Oral candidiasis 9. Chronic obstructive pulmonary disease 10. Benign prostatic hyperplasia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/YES/YES 8. MILD/NO/NO/YES 9. SEVERE/NO/YES/YES 10. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 21DEC2009 (5) - --------- (.) 2. 21DEC2009 (5) - 12JAN2010 (27) 3. 04JAN2010 (19) - --------- (.) 4. 08JAN2010 (23) - 10FEB2010 (56) 5. 18JAN2010 (33) - 17MAR2010 (91) 6. 10FEB2010 (56) - --------- (.) 7. 02MAR2010 (76) - 17MAR2010 (91) 8. 30MAR2010 (104) - 26APR2010 (131) 9. 30MAR2010 (104) - 19APR2010 (124) 10. 15APR2010 (120) - --------- (.)
Duration of AE	1. . 2. 23 3. . 4. 34 5. 59

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440053041

Parameter	Value
	6. .
	7. 16
	8. 28
	9. 21
	10. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY,OTHER
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440053041

Parameter	Value
	10. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440053043

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440053043/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/73/WHITE/AUSTRIA/YES
Medical history	Depression, Glucose tolerance impaired, Hypertension, Lichen planus, Pain, Sleep disorder, Transient ischaemic attack, Postmenopause, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACELISINO COMB MITE, ACELISINO COMP FORTE, ACELISINO FORTE, ADVANTAN UNCTION 0.1%, AEROMUC, AMLODIPINE, BETAMETHASON UNCTION 0.5 MG/G, CERALIP LIP BALM, CIPRALEX, COLDISTOP NOSE OIL, DILATREND, DOMINAL FORTE, EXCIPIAL U LIPOLOTIO, GENTAMICIN 1MG/G, LANSOBENE, MYCOSTATIN, OCULOTECT EYE DROPS [POLYVIDONE], PANTOLOC, PLAVIX, PROTOPIC 0.1% UNCTION, REMINYL RET, SERACTIL, SIMVASTATIN, SINTROM, SORTIS, TEMESTA, THESIT 5%, THROMBO ASS, TIRIZIN, TRITTICO RETARD, XARELTO
Adverse Events (AE) Preferred term	1. Dementia 2. Gastrointestinal tract mucosal discolouration 3. Oesophageal candidiasis 4. Chest pain 5. Lichen planus 6. Oral candidiasis 7. Musculoskeletal chest pain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES 5. MILD/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 12FEB2010 (2) - --------- (.) 2. 18FEB2010 (8) - --------- (.) 3. 22FEB2010 (12) - 11MAY2010 (90) 4. 10MAY2010 (89) - 14MAY2010 (93) 5. 05NOV2010 (268) - 16DEC2010 (309) 6. 13DEC2010 (306) - 13JAN2011 (337) 7. 07JAN2011 (331) - 07JAN2011 (331)
Duration of AE	1. . 2. . 3. 79 4. 5 5. 42 6. 32 7. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 20 mg 5. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440053043

Parameter	Value
	6. 20 mg
	7. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. NONE
Outcome of event	1. UNCHANGED
	2. INSUFFICIENT FOLLOW-UP
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440063023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440063023/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/83/WHITE/AUSTRIA/YES
Medical history	Aortic arteriosclerosis, Hypertension, Malaria, Nephrolithiasis, Nephrolithiasis, Pneumonia, Inguinal hernia, Inguinal hernia, Spinal osteoarthritis, Cerebrovascular accident, Tinnitus, Osteoarthritis, Renal failure chronic, Aortic dilatation, Aortic elongation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACEMIN, ACENOCOUMAROL, ACETYLCYSTEINE, AUGMENTIN, COLONORM, DULCOLAX SUPP [BISACODYL], ELOMEL ISOTON, ENOXAPARIN, FRAGMIN, KLACID UNO, LAEVOLAC, LOVENOX, NEODOLPASSE, PARACODEIN
Adverse Events (AE) Preferred term	1. Renal cyst 2. Osteoarthritis 3. Drug hypersensitivity 4. Haemoptysis 5. Cough 6. Flank pain 7. Muscular weakness 8. Subclavian steal syndrome
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/YES/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 15APR2009 (1) - --------- (.) 2. 15APR2009 (1) - --------- (.) 3. 16APR2009 (2) - --------- (.) 4. 20APR2009 (6) - 22APR2009 (8) 5. 20APR2009 (6) - 22APR2009 (8) 6. 21JUN2009 (68) - 28SEP2009 (167) 7. 04OCT2009 (173) - 07OCT2009 (176) 8. 06OCT2009 (175) - --------- (.)
Duration of AE	1. . 2. . 3. . 4. 3 5. 3 6. 100 7. 4 8. .
Dose on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440063023

Parameter	Value
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. NONE
	3. OTHER
	4. STUDY DRUG DISCONTINUED AND RESTARTED
	5. NONE
	6. NONE
	7. NONE
	8. NONE
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440063027

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440063027/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/AUSTRIA/YES
Medical history	Depression, Ex-tobacco user, Hypertension, Panic attack, Pneumonia, Benign prostatic hyperplasia, Thrombophlebitis, Hypercholesterolaemia, Pulmonary arterial hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACECOMB SEMI, ACEMIN, ALNA RETARD, AUGMENTIN, AVODART, CIPRALEX, DULCOLAX SUPP [BISACODYL], EBRANTIL, FENISTIL-GEL, LAEVOLAC, LASIX, LOVENOX, MAGNOSOLV, NITROLINGUAL CAPSULA, NITROLINGUAL SPRAY, OCTENISEPT, PANTOLOC, PAROXETIN, PSYCHOPAX, SIMVASTATIN, TRAVOCORT
Adverse Events (AE) Preferred term	1. Abdominal pain upper 2. Hepatic steatosis 3. Pancreas lipomatosis 4. Hypertension 5. Intertrigo 6. Hypertension 7. Hypertension 8. Macule 9. Hypertension 10. Hypertension 11. Colonic polyp 12. Tachycardia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/YES/YES 12. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 04AUG2009 (5) - 04AUG2009 (5) 2. 05AUG2009 (6) - --------- (.) 3. 05AUG2009 (6) - --------- (.) 4. 07AUG2009 (8) - 04NOV2009 (97) 5. 08AUG2009 (9) - 20AUG2009 (21) 6. 05NOV2009 (98) - 05NOV2009 (98) 7. 06NOV2009 (99) - 15APR2010 (259) 8. 23MAR2010 (236) - 30MAR2010 (243) 9. 16APR2010 (260) - 16APR2010 (260) 10. 17APR2010 (261) - --------- (.) 11. 27APR2010 (271) - 28APR2010 (272)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440063027

Parameter	Value
	12. 28JUL2010 (363) - 28JUL2010 (363)
Duration of AE	1. 1
	2. .
	3. .
	4. 90
	5. 13
	6. 1
	7. 161
	8. 8
	9. 1
	10. .
	11. 2
	12. 1
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. I
	12. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440063027

Parameter	Value
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. STUDY DRUG DISCONTINUED AND RESTARTED
	12. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. UNCHANGED
	4. WORSENED
	5. RESOLVED
	6. IMPROVED
	7. WORSENED
	8. RESOLVED
	9. IMPROVED
	10. UNCHANGED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440063038

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440063038/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/71/WHITE/AUSTRIA/YES
Medical history	Prostatitis, Hiatus hernia, Hypertension, Ligament operation, Musculoskeletal pain, Tonsillectomy, Varicose vein, Facial paresis, Emphysema
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BUSCOPAN, CIPROXIN, DORMICUM, LOVENOX, MEPRIL, MYCOSTATIN, NERVENRUH (EXTRACTUM VALERIANAE 30.0000 MG), NEUROBION, NOMEXOR, PANTOLOC, PROPOFOL 1%, SYNOCROM, VENA CAVA FILTER
Adverse Events (AE) Preferred term	1. Colon cancer 2. Lung neoplasm 3. Hepatic cyst 4. Renal cyst 5. Lymphadenopathy 6. Urinary tract obstruction 7. Oesophageal candidiasis 8. Gastritis 9. Osteoarthritis 10. Medical device removal
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/YES/NO/YES 10. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 13SEP2010 (4) - 29SEP2010 (20) 2. 13SEP2010 (4) - --------- (.) 3. 13SEP2010 (4) - --------- (.) 4. 13SEP2010 (4) - --------- (.) 5. 13SEP2010 (4) - 21SEP2010 (12) 6. 14SEP2010 (5) - --------- (.) 7. 23SEP2010 (14) - 23OCT2010 (44) 8. 23SEP2010 (14) - --------- (.) 9. 19OCT2010 (40) - --------- (.) 10. 21OCT2010 (42) - 23OCT2010 (44)
Duration of AE	1. 17 2. . 3. . 4. . 5. 9 6. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440063038

Parameter	Value
	7. 31
	8. .
	9. .
	10. 3
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. I
	8. I
	9. .
	10. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. STUDY DRUG DISCONTINUED AND RESTARTED
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. UNCHANGED
	9. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440063038

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440103001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/440103001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/AUSTRIA/YES
Medical history	Drug hypersensitivity, Cataract, Cardiovascular disorder, Drug hypersensitivity, Hypertension, Macular degeneration, Drug hypersensitivity, Gastrooesophageal reflux disease, Osteoarthritis, Postmenopause, Iodine allergy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AQUA CARMINATIVA, ENOXAPARIN, IBOPROFEN, KEFZOL, LISINOPRIL, MAGNESIUM VERLA, MEXALEN, MONTANA [FOR NAUSEA: STROBULI LUPULI,RADIX GENTIANA,CORTEX CINNAMOMUM CEYLANIC,P, PANTOLOC, PARACODIN, RED BLOOD CONCENTRATE, TAVANIC, TEBOFORTAN, TOBRASIX, ULCOGANT [SUCRALFAT, ALUMINIU SACCHAROSE-HYDROGENSULFAT, ALUMINIU ION, CELLULOSE
Adverse Events (AE) Preferred term	1. Polyneuropathy 2. Cough 3. Pyrexia 4. Dizziness 5. Nausea 6. Anaemia 7. Thrombocytopenia 8. Melaena 9. Pyrexia 10. Leukopenia 11. Diverticulum 12. Hiatus hernia 13. Pleural effusion 14. Splenic infarction 15. Splenic haemorrhage 16. Anal prolapse 17. Haematoma 18. Fatigue 19. Diarrhoea 20. Sleep disorder 21. Pyrexia 22. Abdominal pain upper 23. Dyspnoea 24. Oropharyngeal pain 25. Skin candida 26. Rash 27. Histiocytosis haematophagic 28. Vasculitis 29. Procedural pain 30. B-cell lymphoma
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440103001

Parameter	Value
	4. MILD/NO/NO/YES
	5. MILD/NO/NO/YES
	6. MODERATE/NO/NO/YES
	7. MODERATE/NO/NO/YES
	8. MILD/YES/NO/YES
	9. MILD/NO/NO/YES
	10. MODERATE/NO/NO/YES
	11. MODERATE/NO/NO/YES
	12. MILD/NO/NO/YES
	13. MODERATE/NO/NO/YES
	14. SEVERE/NO/YES/YES
	15. SEVERE/YES/YES/YES
	16. MODERATE/NO/NO/YES
	17. MODERATE/NO/NO/NO
	18. MILD/NO/NO/NO
	19. MODERATE/NO/NO/NO
	20. MILD/NO/NO/NO
	21. MODERATE/NO/NO/NO
	22. MODERATE/NO/NO/NO
	23. MODERATE/NO/NO/NO
	24. MODERATE/NO/NO/NO
	25. MODERATE/NO/NO/NO
	26. MODERATE/NO/NO/NO
	27. SEVERE/NO/YES/NO
	28. MODERATE/NO/NO/NO
	29. MODERATE/NO/NO/NO
	30. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. --JUN2010 (.) - --JUL2010 (.)
	2. 02MAY2010 (3) - 02MAY2010 (3)
	3. 02MAY2010 (3) - 16JUN2010 (48)
	4. 02MAY2010 (3) - 06MAY2010 (7)
	5. 02MAY2010 (3) - --------- (.)
	6. 05MAY2010 (6) - --------- (.)
	7. 05MAY2010 (6) - 29MAY2010 (30)
	8. 06MAY2010 (7) - 06MAY2010 (7)
	9. 06MAY2010 (7) - 06MAY2010 (7)
	10. 06MAY2010 (7) - 20MAY2010 (21)
	11. 07MAY2010 (8) - --------- (.)
	12. 07MAY2010 (8) - --------- (.)
	13. 09MAY2010 (10) - --------- (.)
	14. 10MAY2010 (11) - 28MAY2010 (29)
	15. 10MAY2010 (11) - 28MAY2010 (29)
	16. 12MAY2010 (13) - --------- (.)
	17. 13MAY2010 (14) - 17MAY2010 (18)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440103001

Parameter	Value
	18. 13MAY2010 (14) - --------- (.)
	19. 14MAY2010 (15) - 28MAY2010 (29)
	20. 14MAY2010 (15) - --JUN2010 (.)
	21. 15MAY2010 (16) - 15MAY2010 (16)
	22. 15MAY2010 (16) - 16MAY2010 (17)
	23. 15MAY2010 (16) - 16MAY2010 (17)
	24. 20MAY2010 (21) - 16JUN2010 (48)
	25. 21MAY2010 (22) - 04JUN2010 (36)
	26. 23MAY2010 (24) - 07JUN2010 (39)
	27. 26MAY2010 (27) - 18OCT2010 (172)
	28. 27MAY2010 (28) - 10JUN2010 (42)
	29. 28MAY2010 (29) - 03JUN2010 (35)
	30. 07JUN2010 (39) - 18OCT2010 (172)
Duration of AE	1. .
	2. 1
	3. 46
	4. 5
	5. .
	6. .
	7. 25
	8. 1
	9. 1
	10. 15
	11. .
	12. .
	13. .
	14. 19
	15. 19
	16. .
	17. 5
	18. .
	19. 15
	20. .
	21. 1
	22. 2
	23. 2
	24. 28
	25. 15
	26. 16
	27. 146
	28. 15
	29. 7
	30. 134
Dose on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440103001

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
	27.
	28.
	29.
	30.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440103001

Parameter	Value
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
	27.
	28.
	29.
	30.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. NONE
	12. NONE
	13. NONE
	14. STUDY DRUG DISCONTINUED PERMANENTLY
	15. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
	16. NONE
	17. NONE
	18. NONE
	19. REMEDIAL DRUG THERAPY
	20. REMEDIAL DRUG THERAPY
	21. NONE
	22. REMEDIAL DRUG THERAPY
	23. NONE
	24. REMEDIAL DRUG THERAPY
	25. REMEDIAL DRUG THERAPY
	26. NONE
	27. REMEDIAL DRUG THERAPY
	28. NONE
	29. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 440103001

Parameter	Value
	30. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. UNCHANGED
	12. UNCHANGED
	13. UNCHANGED
	14. RESOLVED
	15. RESOLVED
	16. UNCHANGED
	17. RESOLVED
	18. UNCHANGED
	19. RESOLVED
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED
	23. RESOLVED
	24. RESOLVED
	25. RESOLVED
	26. RESOLVED
	27. RESOLVED
	28. RESOLVED
	29. RESOLVED
	30. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-440103001[3),3)]	ANEMIA（PT：貧血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリン及びアセノクマロールの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。また、後に判明した併発症（Ｂ細胞性リンパ腫）による影響とも考えられる。 HAEMOCCULT TEST POSITIVE（PT：便潜血陽性） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリン及びアセノクマロールの抗凝固作用による出血リスクを考慮し、因果関係は否定できないと考える。また、合併症（食道炎及び憩室炎）による影響とも考えられる。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460033012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460033012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/46/WHITE/HUNGARY/YES
Medical history	Arthritis, Ligament rupture, Knee operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ATROPIN, CIPROBAY, DOPAMIN, ENOXAPARIN, FRONTIN, NA-HEPARIN, TONOGEN
Adverse Events (AE) Preferred term	1. Pulmonary embolism
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 13JUN2008 (2) - 13JUN2008 (2)
Duration of AE	1. 1
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460033031

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460033031/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/79/WHITE/HUNGARY/YES
Medical history	Blindness traumatic, Hepatitis, Osteoporosis, Spinal osteoarthritis, Cerebrovascular accident, Tonsillectomy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AFLAMIN, CAVINTON, CLEXANE, DOPAMIN, ENOXAPARIN, MYDETON, RINDEX 5, SAL. SOL. A 0.9%NACL
Adverse Events (AE) Preferred term	1. Adrenal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 12MAY2009 (13) - 26MAY2009 (27)
Duration of AE	1. 15
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460053043

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460053043/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/70/WHITE/HUNGARY/YES
Medical history	Arteriosclerosis, Hypertension, Benign prostatic hyperplasia, Myocardial ischaemia, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	COVERCARD, GLIPREX, GLUCOBAY, LOKREN, PENTOXIFYLLIN, VENORUTON FORTE
Adverse Events (AE) Preferred term	1. Vertigo positional
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 22DEC2009 (210) - 31DEC2009 (219)
Duration of AE	1. 10
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460053045

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460053045/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/83/WHITE/HUNGARY/YES
Medical history	Cardiac aneurysm, Cerebral haemorrhage, Renal failure chronic, Femur fracture, Hyperlipidaemia, Hypertension, Myocardial infarction, Thrombocytopenia, Ventricular tachycardia, Thyroidectomy, Cataract operation, Peripheral arterial occlusive disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CARDILOPIN, CORDARONE, DECHOLEST [ATORVASTATIN], DIOVAN, HYDROCHLORTIAZID, PROPOFOL
Adverse Events (AE) Preferred term	1. Ventricular tachycardia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 05JUL2009 (5) - 05JUL2009 (5)
Duration of AE	1. 1
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460063020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460063020/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/43/WHITE/HUNGARY/YES
Medical history	Bronchitis, Aspartate aminotransferase increased, Nephrolithiasis, Pneumonia, Bronchial hyperreactivity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ALGOPYRIN, AVELOX, BILOBIL, CLEXANE, ENOXAPARIN, HUMA-FOLACID, MAGNE B6, PEPONEN, RINGER- LACTATE INFUSION, TAVANIC, VITAMIN-C
Adverse Events (AE) Preferred term	1. Alanine aminotransferase increased 2. Aspartate aminotransferase increased 3. Hyperhomocysteinaemia 4. Haematoma 5. Paranasal sinus haematoma 6. Road traffic accident 7. Paranasal sinus haematoma 8. Rib fracture 9. Cervical vertebral fracture 10. Concussion 11. Pleural effusion 12. Pneumonia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/YES/NO/YES 5. MODERATE/YES/NO/YES 6. SEVERE/NO/YES/YES 7. MODERATE/YES/NO/YES 8. MODERATE/NO/NO/YES 9. SEVERE/NO/NO/YES 10. MODERATE/NO/NO/YES 11. MILD/NO/NO/YES 12. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 02JAN2009 (1) - 16JAN2009 (15) 2. 02JAN2009 (1) - 15JAN2009 (14) 3. 25FEB2009 (55) - --------- (.) 4. 07APR2009 (96) - 09JUN2009 (159) 5. 07APR2009 (96) - 09JUN2009 (159) 6. 07APR2009 (96) - 09JUN2009 (159) 7. 07APR2009 (96) - 09JUN2009 (159) 8. 07APR2009 (96) - 09JUN2009 (159) 9. 07APR2009 (96) - 09JUN2009 (159) 10. 07APR2009 (96) - 09JUN2009 (159) 11. 08APR2009 (97) - 21APR2009 (110) 12. 15APR2009 (104) - 24APR2009 (113)
Duration of AE	1. 15 2. 14

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460063020

Parameter	Value
	3. .
	4. 64
	5. 64
	6. 64
	7. 64
	8. 64
	9. 64
	10. 64
	11. 14
	12. 10
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. DOSE OF STUDY DRUG REDUCED
	2. DOSE OF STUDY DRUG REDUCED
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED
	5. STUDY DRUG DISCONTINUED AND RESTARTED
	6. STUDY DRUG DISCONTINUED AND RESTARTED
	7. STUDY DRUG DISCONTINUED AND RESTARTED
	8. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	9. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	10. STUDY DRUG DISCONTINUED AND RESTARTED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460063020

Parameter	Value
	11. NONE
	12. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-460063020[4),4)]	BLEEDING INTO THE RIGHT MAXILLARY SINUS（PT：副鼻腔血腫） 治験担当医は、偶発症（交通事故）によるものであり、否定できると判断した。弊社は、エノキサパリン及びアセノクマロールの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。 BLEEDING INTO THE RIGHT SPHENOID SINUS（PT：鼻出血） 治験担当医は、偶発症（交通事故）によるものであり、否定できると判断した。弊社は、エノキサパリン及びアセノクマロールの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460063029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460063029/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/41/WHITE/HUNGARY/YES
Medical history	Obesity, Pleurisy, Haematuria
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AKTIFERRIN, CLEXANE FORTE, COVEREX AS, INDOMETACINUM, QUAMATEL
Adverse Events (AE) Preferred term	1. Hypertension 2. Hepatic steatosis 3. Iron deficiency 4. Epistaxis 5. Alanine aminotransferase increased 6. Aspartate aminotransferase increased 7. Iron deficiency anaemia 8. Hiatus hernia 9. Nasal septum deviation 10. Alanine aminotransferase increased 11. Hepatitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/YES/YES 6. MILD/YES/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 10APR2009 (2) - --------- (.) 2. 10APR2009 (2) - --------- (.) 3. 15APR2009 (7) - --------- (.) 4. 10AUG2009 (124) - 12AUG2009 (126) 5. 12AUG2009 (126) - 30NOV2009 (236) 6. 12AUG2009 (126) - 03MAR2010 (329) 7. 09SEP2009 (154) - --------- (.) 8. 10SEP2009 (155) - --------- (.) 9. 11SEP2009 (156) - --------- (.) 10. 30NOV2009 (236) - 14APR2010 (371) 11. 14APR2010 (371) - --------- (.)
Duration of AE	1. . 2. . 3. . 4. 3 5. 111 6. 204

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460063029

Parameter	Value
	7. .
	8. .
	9. .
	10. 136
	11. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. I
	11. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED
	6. STUDY DRUG DISCONTINUED AND RESTARTED
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. NONE
	10. NONE
	11. OTHER
Outcome of event	1. IMPROVED
	2. UNCHANGED
	3. UNCHANGED
	4. RESOLVED
	5. IMPROVED
	6. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460063029

Parameter	Value
	7. IMPROVED
	8. UNCHANGED
	9. UNCHANGED
	10. WORSENED
	11. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-460063029[2)]	EVATED LEVEL OF ALT (>3X, DURATION: 4 WEEKS) (PT：アラニンアミノトランスフェラーゼ増加) 治験担当医はリバーロキサバンと報告事象との関連性があると判断した。弊社は、患者は元々ALT 値が高く、再投与しても ALT 値は上がらなかったことから、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460063050

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460063050/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/39/WHITE/HUNGARY/YES
Medical history	Asthma, Blood creatine phosphokinase increased, Hepatic steatosis, Cardiomegaly, Hypertension, Pleural effusion, Prostatitis, Intervertebral disc protrusion, Left ventricular hypertrophy, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ANDAXIN, ATORVA TEVA, CLEXANE, DEPAKINE CHRONO, ENOXAPARIN, FRONTIN, HALOPERIDOL, LERTAZIN, LISONORM, MILGAMMA, PROSTAMOL UNO, TIAPRIDAL, TRITACE, TRITTICO AC
Adverse Events (AE) Preferred term	1. Mitral valve incompetence 2. Hypertransaminasaemia 3. Oedema peripheral 4. Spinal osteoarthritis 5. Subarachnoid haemorrhage 6. Cervical vertebral fracture 7. Brain contusion 8. Concussion 9. Muscular weakness 10. Diplopia 11. Pollakiuria 12. Mental disorder due to a general medical condition 13. Intervertebral disc disorder
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/YES/YES/YES 6. SEVERE/NO/YES/YES 7. SEVERE/NO/YES/YES 8. MODERATE/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. SEVERE/NO/YES/YES 13. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 15JUN2010 (9) - --------- (.) 2. 21JUN2010 (15) - 08JUL2010 (32) 3. 15JUL2010 (39) - --------- (.) 4. 26AUG2010 (81) - --------- (.) 5. 24DEC2010 (201) - 29DEC2010 (206) 6. 24DEC2010 (201) - 28FEB2011 (267) 7. 24DEC2010 (201) - 29DEC2010 (206) 8. 24DEC2010 (201) - 26JAN2011 (234) 9. 24DEC2010 (201) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460063050

Parameter	Value
	10. 24DEC2010 (201) - --------- (.)
	11. 24DEC2010 (201) - 01MAR2011 (268)
	12. 29DEC2010 (206) - 26JAN2011 (234)
	13. 28FEB2011 (267) - --------- (.)
Duration of AE	1. .
	2. 18
	3. .
	4. .
	5. 6
	6. 67
	7. 6
	8. 34
	9. .
	10. .
	11. 68
	12. 29
	13. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Action taken	1. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460063050

Parameter	Value
	2. NONE
	3. NONE
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED
	6. STUDY DRUG DISCONTINUED AND RESTARTED
	7. STUDY DRUG DISCONTINUED AND RESTARTED
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	13. NONE
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. UNCHANGED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. IMPROVED
	10. IMPROVED
	11. RESOLVED
	12. RESOLVED
	13. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-460063050[2)]	MINIMAL SUBARACHNOIDAL HEMORRHAGE（PT：くも膜下出血） 治験担当医はエノキサパリンと報告事象との関連性があると判断した。弊社は、、エノキサパリン投与中止 6 か月後の発現であり、時間的関連性がないため、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460063056

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460063056/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/77/WHITE/HUNGARY/YES
Medical history	Atrioventricular block second degree, Cholelithiasis, Hypertension, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALGOPYRIN, ARTERENOL, ATROPIN, CERUCAL, CLEXANE, CONTROLOC, CORDARONE, DOBUTAMIN, DOPAMIN, DORMICUM, EBRANTILL, FENTANYL, GELIFUNDOL, KCL, MGSO4, NAHCO3 8.4 %, NO-SPA, NORMODIPINE, OXYGEN, PANCREOFLAT, QUAMATEL, SALSOL, TIENAM, TONOGEN, TRITACE, TRITACE HCT, VENTER
Adverse Events (AE) Preferred term	1. Duodenal ulcer
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 07JUN2011 (232) - 09JUN2011 (234)
Duration of AE	1. 3
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-460063056[1),1),1)]	DUODENUM PERFORATION（PT：十二指腸穿孔） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症（十二指腸潰瘍）の合併症によるものであり、リバーロキサバン投与との因果関係は否定できると考える。 GALL BLADDER PERFORATION（PT：胆嚢穿孔） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症（十二指腸潰瘍）の合併症によるものであり、リバーロキサバン投与との因果関係は否定できると考える。 SUDDEN CARDIOPULMONARY ARREST（PT：心肺停止） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、十二指腸潰瘍治療のための開腹手術、合併症（心疾患）、併発症（十二指腸穿孔及び胆嚢穿孔）に起因したものであり、リバーロキサバン投与との因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460063059

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460063059/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/63/WHITE/HUNGARY/YES
Medical history	Prostate cancer, Retinopexy, Diabetes mellitus, Dizziness, Hypertension, Hyperuricaemia, Inguinal hernia repair, Myocardial ischaemia, Cardiomyopathy, Hyperlipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACCUPRO, ACCUZIDE, AMARYL, ANDROCUR, ATORIS, ATORVA-TEVA, CONCOR, DUPHALAC [LACTULOSE], MILURIT, NORMODIPINE, TISASEN, XANAX SR
Adverse Events (AE) Preferred term	1. Colon neoplasm
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 26MAY2011 (104) - 17JUN2011 (126)
Duration of AE	1. 23
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460093009/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/73/WHITE/HUNGARY/YES
Medical history	Angina pectoris, Appendicectomy, Cholecystectomy, Gastritis haemorrhagic, Haemorrhoids, Hypercholesterolaemia, Hypertension, Hypothyroidism, Goitre, Osteoporosis, Thrombocytopenia, Thyroidectomy, Gastrooesophageal reflux disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTONEL TRIO [OSTEOPOROSIS], ASPIRIN PROTECT, ATORIS, BETALOC-ZOK, DOMPERIDON EP100 [THE DOMPERIDON EP100 MADE BY EXTRACTUM PHARMA. INGREDIENTS: DO, DUOPRIL, L-THYROXIN, NEXIUM, NITRODERM TTS 5, REFLUXON, REPARON OINTMENT
Adverse Events (AE) Preferred term	1. Influenza 2. Oedema peripheral 3. Eyelid oedema 4. Haemorrhoidal haemorrhage 5. Abdominal pain 6. Abdominal distension 7. Gastritis haemorrhagic 8. Gastrooesophageal reflux disease 9. Anal haemorrhage 10. Anal haemorrhage 11. Diarrhoea
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/YES/YES/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 10APR2008 (7) - 25APR2008 (22) 2. 23APR2008 (20) - 25APR2008 (22) 3. 25APR2008 (22) - 25APR2008 (22) 4. 30APR2008 (27) - 01SEP2008 (151) 5. 15AUG2008 (134) - 03OCT2008 (183) 6. 15AUG2008 (134) - 03OCT2008 (183) 7. 15SEP2008 (165) - 13APR2009 (375) 8. 15SEP2008 (165) - --------- (.) 9. 02OCT2008 (182) - 10OCT2008 (190) 10. 25JAN2009 (297) - 27FEB2009 (330) 11. 02FEB2009 (305) - --------- (.)
Duration of AE	1. 16 2. 3

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093009

Parameter	Value
	3. 1
	4. 125
	5. 50
	6. 50
	7. 211
	8. .
	9. 9
	10. 34
	11. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. NONE
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093009

Parameter	Value
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED
	10. RESOLVED
	11. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093032

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460093032/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/50/WHITE/HUNGARY/YES
Medical history	Hypertension, Obesity, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATROPIN, DYCINONE, ERGAM, EXACYL, MIDAZOLAM, NOLICIN, TRAMADOL
Adverse Events (AE) Preferred term	1. Genital haemorrhage
	2. Uterine leiomyoma
	3. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES
	2. MILD/NO/YES/YES
	3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 16APR2009 (85) - 04MAY2009 (103)
	2. 04MAY2009 (103) - --------- (.)
	3. 19SEP2009 (241) - 30SEP2009 (252)
Duration of AE	1. 19
	2. .
	3. 12
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-460093032[4)]	GENITAL BLEEDING（PT：性器出血） 治験担当医は、リバーロキサバンとの因果関係を否定できると判断した。弊社は、リバーロキサバンの抗凝固作用により出血リスクが高まったと考えられることから、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093038

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460093038/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/HUNGARY/YES
Medical history	Hypertension, Lower limb fracture, Back pain, Menopause, Osteoporosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACLASTA, APRANAX, CITROCALCIUM, CONTROLOC, DEXA-RATIOPHARM, FRAGMIN, HOTEMIN, METYPRED, MILGAMMA, NACL INFUSION, NEBILET, SIRDALUD, THIOGAMMA, TISASEN, VITAMIN B12, VITAMIN D3, VOLTAREN, VOLUVEN, ZIMPAX
Adverse Events (AE) Preferred term	1. Back pain 2. Pernicious anaemia 3. Gastritis erosive
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 26MAY2009 (52) - --------- (.) 2. 15OCT2009 (194) - 03DEC2009 (243) 3. 01MAR2010 (331) - --------- (.)
Duration of AE	1. . 2. 50 3. .
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED 2. RESOLVED 3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093039

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460093039/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/76/WHITE/HUNGARY/YES
Medical history	Cataract, Emphysema, Hyperlipidaemia, Hypertension, Hyperuricaemia, Benign prostatic hyperplasia, Varicose vein, Hernia repair, Gastrointestinal neoplasm
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, CORDAFLEX, DUOPRIL 20/12,5, ENOXAPARIN, LEVOLAC SOLUTION, MONO MACK DEPOT, SYNCUMAR, THEOSPIREX
Adverse Events (AE) Preferred term	1. Chest pain 2. Constipation 3. Hypertension 4. Cataract 5. Intestinal polyp
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/NO 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/YES/YES
Start/stop date of event with relative date	1. --APR2009 (.) - 21APR2009 (6) 2. 16APR2009 (1) - 21APR2009 (6) 3. 21APR2009 (6) - 21APR2009 (6) 4. 08MAY2009 (23) - 12MAY2009 (27) 5. 14SEP2009 (152) - 17SEP2009 (155)
Duration of AE	1. . 2. 6 3. 1 4. 5 5. 4
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. NONE 5. OTHER
Outcome of event	1. RESOLVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093039

Parameter	Value
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093043

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460093043/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/45/WHITE/HUNGARY/YES
Medical history	
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	RUBOPHEN, SIBELIUM, SIRDALUD MR
Adverse Events (AE) Preferred term	1. Periarthritis
	2. Pneumonia
	3. Headache
	4. Lung squamous cell carcinoma stage unspecified
	5. Encephalomalacia
	6. Tinnitus
	7. Headache
	8. Hypertension
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES
	2. MODERATE/NO/NO/YES
	3. MODERATE/NO/NO/YES
	4. MODERATE/NO/YES/YES
	5. MILD/NO/NO/YES
	6. MILD/NO/NO/NO
	7. MILD/NO/NO/NO
	8. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 10JUL2009 (22) - --------- (.)
	2. 03AUG2009 (46) - 13AUG2009 (56)
	3. 07AUG2009 (50) - 28AUG2009 (71)
	4. 14AUG2009 (57) - --------- (.)
	5. 18AUG2009 (61) - --------- (.)
	6. 20MAR2010 (275) - --------- (.)
	7. 20MAR2010 (275) - --------- (.)
	8. 20MAR2010 (275) - --------- (.)
Duration of AE	1. .
	2. 11
	3. 22
	4. .
	5. .
	6. .
	7. .
	8. .
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093043

Parameter	Value
	8. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. F
	7. F
	8. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED PERMANENTLY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY,OTHER
	5. NONE
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. UNCHANGED
	7. UNCHANGED
	8. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093049

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460093049/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/42/WHITE/HUNGARY/YES
Medical history	Cardiac failure congestive, Hypertension, Hypertriglyceridaemia, Myopia, Type 2 diabetes mellitus, Obesity, Ovarian cyst torsion, Synchysis scintillans
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, CIPRALEX, CLEXANE, DIGOXIN, ENOXAPARIN, FENOBRAT, LIBRIUM, METFORMIN, RAMIPRIL, RIVOTRIL, TENSIOMIN, TRIODENE
Adverse Events (AE) Preferred term	1. Headache 2. Hypertension 3. Genital haemorrhage 4. Cervical dysplasia 5. Diabetes mellitus 6. Depression 7. Menorrhagia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 25JUL2009 (2) - 25JUL2009 (2) 2. 27JUL2009 (4) - 28JUL2009 (5) 3. 01AUG2009 (9) - --------- (.) 4. 29OCT2009 (98) - 02NOV2009 (102) 5. 02DEC2009 (132) - --------- (.) 6. 14DEC2009 (144) - --------- (.) 7. 02JUL2010 (344) - 20JUL2010 (362)
Duration of AE	1. 1 2. 2 3. . 4. 5 5. . 6. . 7. 19
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093049

Parameter	Value
	3.
	4.
	5.
	6.
	7.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. RESOLVED
	5. IMPROVED
	6. UNCHANGED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093053

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460093053/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/48/WHITE/HUNGARY/YES
Medical history	Iron deficiency anaemia, Cervical conisation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, NEOFERROFOLGAMMA, OXYTOCINE
Adverse Events (AE) Preferred term	1. Menorrhagia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 22OCT2009 (10) - 03NOV2009 (22)
Duration of AE	1. 13
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-460093053[3)]	ANEMIA（PT：出血性貧血） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、リバーロキサバンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093054

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460093054/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/65/WHITE/HUNGARY/YES
Medical history	Acute sinusitis, Atrial fibrillation, Atrial fibrillation, Spinal osteoarthritis, Ventricular extrasystoles, Hypertension, Bundle branch block left, Peripheral nerve lesion, Obesity, Osteoporosis, Benign prostatic hyperplasia, Left ventricular hypertrophy
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CARDURA, HYPLAFIN, OMNIC, TENSIOMIN
Adverse Events (AE) Preferred term	1. Ventricular tachycardia 2. Hypertension 3. Dizziness 4. Dizziness 5. Contusion 6. Dizziness
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/NO 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 17OCT2009 (1) - 17OCT2009 (1) 2. 17OCT2009 (1) - 17OCT2009 (1) 3. 31OCT2009 (15) - 09NOV2009 (24) 4. 15JAN2010 (91) - 15JAN2010 (91) 5. 02FEB2010 (109) - 02FEB2010 (109) 6. 30MAR2010 (165) - 05APR2010 (171)
Duration of AE	1. 1 2. 1 3. 10 4. 1 5. 1 6. 7
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. . 6. .
Action taken	1. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093054

Parameter	Value
	2. REMEDIAL DRUG THERAPY
	3. OTHER
	4. NONE
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093057

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460093057/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/69/WHITE/HUNGARY/YES
Medical history	Angina pectoris, Cholecystectomy, Essential tremor, Hypertension, Menopause, Obesity, Radius fracture, Parkinson's disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AKINETON RETARD, ASPIRIN PROTECT, ATORIS, BETALOC-ZOK, CONTROLOC, CORINFAR, COVERCARD, COVEREX COMB, NITROGLYCERIN AEROSOL, NITROMINT AEROSOL, NITROMINT NT PATCH, NORMODIPINE, PREDUCTAL MR
Adverse Events (AE) Preferred term	1. Bronchitis 2. Hypertension 3. Angina pectoris 4. Angina pectoris
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/NO
Start/stop date of event with relative date	1. 22JAN2010 (9) - 10FEB2010 (28) 2. 13APR2010 (90) - 14APR2010 (91) 3. 29APR2010 (106) - 29APR2010 (106) 4. 24JAN2011 (376) - 25JAN2011 (377)
Duration of AE	1. 20 2. 2 3. 1 4. 2
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. F
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093057

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093059

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460093059/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/57/WHITE/HUNGARY/YES
Medical history	Lower limb fracture, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, AVELOX, FRAGMIN
Adverse Events (AE) Preferred term	1. Pneumonia
	2. Lung neoplasm malignant
	3. Pleural haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/NO/YES
	2. SEVERE/NO/YES/YES
	3. SEVERE/NO/NO/YES
Start/stop date of event with relative date	1. --APR2010 (.) - --------- (.)
	2. 28APR2010 (50) - 20MAY2010 (72)
	3. 28APR2010 (50) - --------- (.)
Duration of AE	1. .
	2. 23
	3. .
Dose on AE onset	1.
	2. 20 mg
	3. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED PERMANENTLY,OTHER
Outcome of event	1. UNCHANGED
	2. DEATH
	3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093063

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460093063/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/62/WHITE/HUNGARY/YES
Medical history	Rib fracture, Hypertension, Splenectomy, Varicose vein
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ASPIRIN DIRECT, ASPIRIN PROTECT, ATORVASTATIN, AUGMENTIN, AUGMENTIN DUO, BETALOC, CATAFLAM, CLEXANE, CONTROLOC, DETRALEX, DIGOXIN, ENOXAPARIN, FURON, HERPESIN, KALIUM, NITRODERM TTS, PLAVIX, QUAMATEL, THEOSPIREX, TORVACARD, TRITACE
Adverse Events (AE) Preferred term	1. Herpes zoster 2. Liver function test abnormal 3. Contusion 4. Acute myocardial infarction 5. Liver function test abnormal 6. Obstructive airways disorder 7. Acute myocardial infarction
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 11APR2011 (146) - 20MAY2011 (185) 2. 18APR2011 (153) - 05MAY2011 (170) 3. 23APR2011 (158) - --------- (.) 4. 14JUN2011 (210) - 20JUN2011 (216) 5. 16JUN2011 (212) - 13JUL2011 (239) 6. 17JUN2011 (213) - --------- (.) 7. 07OCT2011 (325) - 14OCT2011 (332)
Duration of AE	1. 40 2. 18 3. . 4. 7 5. 28 6. . 7. 8
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460093063

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. IMPROVED
	4. RESOLVED
	5. RESOLVED
	6. IMPROVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460103017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460103017/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/HUNGARY/YES
Medical history	Appendicectomy, Cholecystectomy, Hypertension, Osteoarthritis, Pleurisy, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, BETALOC ZOK, CARDURA XL, CLEXANE, COVERCARD, DETRALEX, DIONIN, ENOXAPARIN, FRONTIN, FURON, FUROSEMID, FUROSEMID AL, KALDYUM, LISONORM, NEBILET, THEOSPIREX
Adverse Events (AE) Preferred term	1. Hypertension 2. Cervical polyp 3. Head injury 4. Haemoptysis 5. Cardiac failure acute 6. Hypertension 7. Anxiety 8. Thyroid neoplasm 9. Cardiac failure acute 10. Haemoptysis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/YES/NO 10. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 22JUN2009 (4) - 29JUN2009 (11) 2. 25JUN2009 (7) - --------- (.) 3. 30MAY2010 (346) - 12JUN2010 (359) 4. 31MAY2010 (347) - 31MAY2010 (347) 5. 31MAY2010 (347) - 12JUN2010 (359) 6. 31MAY2010 (347) - 24JUN2010 (371) 7. 02JUN2010 (349) - 12JUN2010 (359) 8. 04JUN2010 (351) - --------- (.) 9. 17JUN2010 (364) - 29JUN2010 (376) 10. 20JUN2010 (367) - 20JUN2010 (367)
Duration of AE	1. 8 2. . 3. 14 4. 1 5. 13 6. 25 7. 11

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460103017

Parameter	Value
	8. .
	9. 13
	10. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. NONE
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460103017

Parameter	Value
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460103026

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460103026/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/42/WHITE/HUNGARY/YES
Medical history	Inguinal hernia, Thrombophlebitis, Skin ulcer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, DETRALEX, FUROSEMID, LIOTON 100000 GEL, THEOSPIREX, TRAMADOLOR, WARFARIN
Adverse Events (AE) Preferred term	1. Myalgia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 24JUL2011 (234) - 27JUL2011 (237)
Duration of AE	1. 4
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460113001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460113001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/80/WHITE/HUNGARY/YES
Medical history	Conduction disorder, Hyperlipidaemia, Hypertension, Nephrectomy, Obesity, Azotaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACC, ACENOCOUMAROL, ASPIRIN, ASPIRIN PROTECT, ATORIS, ATORIS 40 MG., BETALOC, CARDILOPIN, CIFRAN, CLOPIDOGREL, CONTRAMAL, CORVATON RETARD, COVEREX AS 5 MG., COVEREX AS5 MG., ENOXAPARIN, ENOXAPARINE, ENTEROBENE, EXFORGE, FRONTIN, FUROSEMID, HEPARIN-NATRIUM, JUMEX 5 MG., KARDOGREL, MAGNE B6, MINIPRESS 1 MG., MODUXIN, NITROMINT PATCH, NITROMINT SPRAY, NITROPOHL, NORVASC, PANTOPRAZOL, POTASSIUM, RIVOTRIL, SALSOL, TENAXUM 1 MG., XETER
Adverse Events (AE) Preferred term	1. Parkinson's disease 2. Hypotension 3. Myocardial infarction 4. Nephropathy toxic 5. Pneumonia 6. Anxiety 7. Diarrhoea 8. Anaemia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 20SEP2010 (8) - --------- (.) 2. 23SEP2010 (11) - 24SEP2010 (12) 3. 31OCT2010 (49) - 09NOV2010 (58) 4. 10NOV2010 (59) - 14FEB2011 (155) 5. 18NOV2010 (67) - 24NOV2010 (73) 6. 18NOV2010 (67) - --------- (.) 7. 22NOV2010 (71) - 28NOV2010 (77) 8. 30NOV2010 (79) - 01DEC2010 (80)
Duration of AE	1. . 2. 2 3. 10 4. 97 5. 7 6. . 7. 7 8. 2
Dose on AE onset	1. 2.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460113001

Parameter	Value
	3.
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY,OTHER
	4. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. OTHER
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. IMPROVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460113002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460113002/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/77/WHITE/HUNGARY/YES
Medical history	Acute respiratory failure, Cardiac failure congestive, Hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, CARDILOPIN, COVERCARD, COVERES-AS KOMB, FLUIMUCIL, FUROSEMID, NEBILET, NOACID, OXYGEN, RIVOTRIL, SALSOL/NACL/ INFUSION, TENAXUM
Adverse Events (AE) Preferred term	1. Renal failure acute 2. Renal failure acute 3. Hypertension
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 12OCT2010 (7) - 14OCT2010 (9) 2. 21OCT2010 (16) - 10NOV2010 (36) 3. 10NOV2010 (36) - --------- (.)
Duration of AE	1. 3 2. 21 3. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg
Dose status on AE onset	1. . 2. . 3. F
Action taken	1. DOSE OF STUDY DRUG REDUCED,STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. DOSE OF STUDY DRUG REDUCED,STUDY DRUG DISCONTINUED PERMANENTLY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460123002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/460123002/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/70/WHITE/HUNGARY/YES
Medical history	Angina pectoris, Anxiety, Cholecystectomy, Cardiac failure chronic, Blood cholesterol increased, Hypertension, Hysterectomy, Obesity, Pneumonia, Tendonitis, Thrombophlebitis superficial, Umbilical hernia repair, Spinal cord operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BETALOC ZOK, CARDURA, CONTROLOC, COVERCARD, COVEREX AS KOMB, EUPHYLONG, FUROSEMID, KALDYUM, LANSOPTOL, LESCOL XL, MERCKFORMIN, ROCEPHIN, XANAX
Adverse Events (AE) Preferred term	1. Diabetes mellitus 2. Atrial fibrillation 3. Urinary tract infection 4. Haematuria
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/NO 4. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 12MAR2010 (9) - --------- (.) 2. 26MAR2010 (23) - --------- (.) 3. 26MAY2010 (84) - 03JUN2010 (92) 4. 28MAY2010 (86) - 02JUN2010 (91)
Duration of AE	1. . 2. . 3. 9 4. 6
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. F 4. F
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. UNCHANGED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 460123002

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 500033011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/500033011/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/81/WHITE/BRAZIL/YES
Medical history	Metastases to central nervous system, Cerebrovascular accident, Femur fracture, Hypothyroidism, Lung lobectomy, Lymphoma, Pneumonia, Postmenopause, Lung neoplasm, Central nervous system necrosis, Central nervous system necrosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLCYSTEINE, CALCIUM CARBONATE, CLONAZEPAM, DEXAMETHASONE, ENOXAPARIN, FOLIC ACID, HIDANTAL, IPRATROPIUM OF BROMIDE, LEVOTHYROXINE, NAFAZOLINE OF HYDROCHLORIDE, OF KETOROLAC TROMETAMOL, OMEPRAZOLE, PARACETAMOL, PHENYTOIN, PREDNISONE, SIMVASTATIN, TRAMADOL HYDROCHLORIDE, VITAMIN D, WARFARIN
Adverse Events (AE) Preferred term	1. Constipation 2. Productive cough 3. Pain in extremity 4. Eye haemorrhage 5. Productive cough 6. Convulsion 7. Pneumonia 8. Pyrexia 9. Haemoglobin decreased 10. Acute respiratory failure 11. Haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. SEVERE/NO/YES/YES 7. SEVERE/NO/NO/YES 8. MILD/NO/NO/NO 9. MILD/NO/NO/NO 10. SEVERE/NO/YES/NO 11. SEVERE/YES/NO/NO
Start/stop date of event with relative date	1. 02DEC2008 (3) - 02DEC2008 (3) 2. 02DEC2008 (3) - 02DEC2008 (3) 3. 02DEC2008 (3) - 02DEC2008 (3) 4. 03DEC2008 (4) - --------- (.) 5. 03DEC2008 (4) - 05DEC2008 (6) 6. 30DEC2008 (31) - 30DEC2008 (31) 7. 31DEC2008 (32) - 09FEB2009 (72) 8. 10JAN2009 (42) - 10JAN2009 (42) 9. 23JAN2009 (55) - 24JAN2009 (56) 10. 24JAN2009 (56) - 12FEB2009 (75) 11. 25JAN2009 (57) - 03FEB2009 (66)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 500033011

Parameter	Value
Duration of AE	1. 1
	2. 1
	3. 1
	4. .
	5. 3
	6. 1
	7. 41
	8. 1
	9. 2
	10. 20
	11. 10
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY,INFUSION RATE OF STUDY DRUG REDUCED
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. OTHER
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 500033011

Parameter	Value
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. WORSENED
	8. RESOLVED
	9. RESOLVED
	10. DEATH
	11. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-500033011[1)]	SEPTIC SHOCK（PT：敗血症性ショック） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、基礎疾患（肺癌）の脳及び肺転移によるものであり、ワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 500033024

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/500033024/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/24/WHITE/BRAZIL/YES
Medical history	Anaemia, Mammoplasty, Muscle atrophy, Polycystic ovaries, Urinary tract infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BUSONID NASAL, CEFALEXIN, CIPROFLOXACIN, CIPROFLOXACINA, CLAVULIN BD, DIPIRONA, ENOXAPARIN, FLUCONAZOL, FRONTAL, GLIFAGE, KEFLEX, LISADOR, LOSEC, OMEPRAZOL, PANTOCAL, PREDSIM, PROFENID, TYLENOL [PARACETAMOL], WARFARIN, ZINA (LEVOCETIRIZINE HYDROCHLORIDE), ZINNAT
Adverse Events (AE) Preferred term	1. Vulvovaginal candidiasis 2. Breast pain 3. Incision site haemorrhage 4. Postoperative wound infection 5. Wound dehiscence 6. Skin bacterial infection 7. Incision site haemorrhage 8. Incision site haemorrhage 9. Headache 10. Incision site haemorrhage 11. Tonsillitis 12. Chest pain 13. Back pain 14. Tonsillitis 15. Pyrexia 16. Haematuria 17. Dyspnoea 18. Tachycardia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/YES/YES 7. MODERATE/YES/NO/YES 8. MODERATE/YES/NO/YES 9. SEVERE/NO/NO/YES 10. MILD/YES/NO/YES 11. MODERATE/NO/NO/YES 12. MILD/NO/NO/YES 13. MODERATE/NO/NO/YES 14. MILD/NO/NO/YES 15. MILD/NO/NO/YES 16. MILD/YES/NO/YES 17. MILD/NO/NO/NO 18. MILD/NO/NO/NO

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 500033024

Parameter	Value
Start/stop date of event with relative date	1. 09FEB2010 (3) - 12FEB2010 (6) 2. 05MAR2010 (27) - 10MAR2010 (32) 3. 24MAR2010 (46) - 30MAR2010 (52) 4. 24MAR2010 (46) - 30MAR2010 (52) 5. 01APR2010 (54) - 25JUN2010 (139) 6. 01APR2010 (54) - 25JUN2010 (139) 7. 26MAY2010 (109) - 26MAY2010 (109) 8. 27MAY2010 (110) - 04JUN2010 (118) 9. 18JUN2010 (132) - --------- (.) 10. 24JUN2010 (138) - 25JUN2010 (139) 11. 05JUL2010 (149) - 08JUL2010 (152) 12. 10JUL2010 (154) - 26JUL2010 (170) 13. 10JUL2010 (154) - 01AUG2010 (176) 14. 21JUL2010 (165) - 31JUL2010 (175) 15. 21JUL2010 (165) - 22JUL2010 (166) 16. 27JUL2010 (171) - 28JUL2010 (172) 17. 12AUG2010 (187) - 12AUG2010 (187) 18. 12AUG2010 (187) - 12AUG2010 (187)
Duration of AE	1. 4 2. 6 3. 7 4. 7 5. 86 6. 86 7. 1 8. 9 9. . 10. 2 11. 4 12. 17 13. 23 14. 11 15. 2 16. 2 17. 1 18. 1
Dose on AE onset	1. 2. 3. 4. 5. 6. 7. 8.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 500033024

Parameter	Value
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	7. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	8. STUDY DRUG DISCONTINUED AND RESTARTED
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
	16. STUDY DRUG DISCONTINUED AND RESTARTED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 500033024

Parameter	Value
	17. NONE
	18. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. IMPROVED
	8. RESOLVED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 500063002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/500063002/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/42/BLACK/BRAZIL/YES
Medical history	Varicose vein, Sterilisation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CATAFLAN, CELEBRA, CICLO 21
Adverse Events (AE) Preferred term	1. Menorrhagia 2. Tendonitis 3. Thrombophlebitis superficial 4. Gastritis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MODERATE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. SEVERE/YES/NO/NO
Start/stop date of event with relative date	1. 22JAN2009 (43) - 28JAN2009 (49) 2. 10MAR2009 (90) - 20MAR2009 (100) 3. 30MAR2009 (110) - --------- (.) 4. 10MAY2009 (151) - 25JUN2009 (197)
Duration of AE	1. 7 2. 11 3. . 4. 47
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. F
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 500063002

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540053009/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/58/ASIAN/CHINA/YES
Medical history	Bronchitis, Concussion, Cor pulmonale, Platelet count decreased, Respiratory failure, Respiratory papilloma, White blood cell count decreased, Cardiac failure
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMIODARONE HYDROCHLORIDE, CEFMINOX, DOPAMINE INJECTION, ENOXAPARIN, FAMOTIDINE, GEFARNATE, GLUCUROLACTONE, HUGAN PIAN(CHINESE TRADITIONAL MEDICINE), ISOSORBIDE DINITRATE TABLET, LACTULOSE ORAL SOLUTION, LEUCOGEN TABLET, POTASSIUM CHLORIDE INJECTION, POTASSIUM CHLORIDE SUSTAINED-RELEASE TABLET, POTASSIUM CHLORIDE SUSTAINED-RELEASE TABLETS, VITAMINE C, VITAMINE K, VOLUVEN, WARFARIN
Adverse Events (AE) Preferred term	1. Supraventricular tachycardia 2. Atrial fibrillation 3. Hypokalaemia 4. Abdominal discomfort 5. Hepatic function abnormal 6. Subcutaneous haematoma 7. Atrial fibrillation 8. Overdose 9. Supraventricular tachycardia 10. Extrasystoles 11. Ecchymosis 12. Extrasystoles
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/YES/NO/YES 7. MODERATE/NO/YES/YES 8. MODERATE/YES/YES/YES 9. MODERATE/NO/YES/YES 10. MILD/NO/NO/YES 11. MILD/YES/NO/YES 12. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 20MAR2009 (1) - 20MAR2009 (1) 2. 20MAR2009 (1) - 20MAR2009 (1) 3. 21MAR2009 (2) - 02APR2009 (14) 4. 27MAR2009 (8) - 30MAR2009 (11) 5. 01APR2009 (13) - 17APR2009 (29) 6. 10MAY2009 (52) - 19MAY2009 (61) 7. 15MAY2009 (57) - 15MAY2009 (57) 8. 15MAY2009 (57) - 16MAY2009 (58) 9. 15MAY2009 (57) - 15MAY2009 (57)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053009

Parameter	Value
	10. 10JUN2009 (83) - 19JUN2009 (92)
	11. 15SEP2009 (180) - 25SEP2009 (190)
	12. 25SEP2009 (190) - 16OCT2009 (211)
Duration of AE	1. 1
	2. 1
	3. 13
	4. 4
	5. 17
	6. 10
	7. 1
	8. 2
	9. 1
	10. 10
	11. 11
	12. 22
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053009

Parameter	Value
	6. DOSE OF STUDY DRUG REDUCED
	7. REMEDIAL DRUG THERAPY
	8. DOSE OF STUDY DRUG REDUCED,REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. DOSE OF STUDY DRUG REDUCED
	12. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540053010/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/57/ASIAN/CHINA/YES
Medical history	Carotid artery stenosis, Cerebral infarction, Hypertension, Pneumonia, Pulmonary hypertension, Varicose vein, Cerebral infarction
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPROSTADIL, ASPIRIN ENTERIC-COATED TABLETS, ATORVASTATIN, BRUFEN, BUFLOMEDIL, CEFMINOX, COMPOUND GLYCYRRHIZE MIXTURE(CHINESE TRADITIONAL MEDICINE), DALTEPARIN SODIUM, DILTHIAZEM, EXTENDED RELEASE NIFEDIPINE TABLETS, EXTRACT OF GINKGO BILOBA LEAF INJECTION, FOSINOPRIL, GLYCERINE ENEMA, MOXIFLOXACIN, MOXIFLOXACIN TABLET, SODIUM OZAGREL
Adverse Events (AE) Preferred term	1. Transient ischaemic attack 2. Ischaemic stroke 3. Alanine aminotransferase increased
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 11MAY2009 (22) - 19MAY2009 (30) 2. 18MAY2009 (29) - --------- (.) 3. 22MAY2009 (33) - 18JUN2009 (60)
Duration of AE	1. 9 2. . 3. 28
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg
Dose status on AE onset	1. . 2. I 3. I
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. NONE 3. NONE
Outcome of event	1. RESOLVED 2. UNCHANGED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540053012/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/73/ASIAN/CHINA/YES
Medical history	Affective disorder, Aphasia, Cerebral infarction, Hepatic steatosis, Haemorrhoids, Hyperlipidaemia, Menopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBROXOL HYDROCHLORIDE TABLETS, ASPIRIN ENTERIC COATED TABLET, ATORVASTATIN, DOMPERIDONE TABLETS, ENOXAPARIN, FAMOTIDINE, FAMOTIDINE TABLETS, GEFARNATE TABLETS, GLYCERINE ENEMA, LORAZEPAM TABLET, METOPROLOL, OXIRACETAM, SHUANG HUANG LIAN KOU FU YE(CHINESE TRADITIONAL MEDICINE), WARFARIN
Adverse Events (AE) Preferred term	1. Dyspnoea 2. Dyspnoea 3. Tachycardia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 23OCT2009 (92) - 21DEC2009 (151) 2. 21DEC2009 (151) - 31DEC2009 (161) 3. 25DEC2009 (155) - 25DEC2009 (155)
Duration of AE	1. 60 2. 11 3. 1
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. WORSENED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-540053012[1)]	DYSPNEA（PT：呼吸困難） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリン投与終了約5か月後の発現であり、時間的関連性がないため、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053014

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540053014/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/80/ASIAN/CHINA/YES
Medical history	Cor pulmonale acute, Cholecystitis chronic, Viral hepatitis carrier, Hypertension, Respiratory failure, Senile dementia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DIAMMONIUM GLYCYRRHIZINATE CAPSULE, ENOXAPARIN, GLUCUROLACTONE, GLYCEROL ENEMA, ISOSORBIDE MONONITRATE, LACTULOSE ORAL SOLUTION, NOREPINEPHRINE, POTASSIUM CHLORIDE SUSTAINED RELEASE TABLETS, SIMOTANG ORAL SOLUTION(CHINESE TRADITIONAL MEDICINE), SULPERAZON, VITAMIN K INJECTION, WARFARIN
Adverse Events (AE) Preferred term	1. Transaminases increased 2. Cholecystitis acute 3. Epistaxis 4. Hypokalaemia 5. Myocardial ischaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/NO 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 08SEP2009 (1) - 21SEP2009 (14) 2. 10SEP2009 (3) - 16SEP2009 (9) 3. 14SEP2009 (7) - 14SEP2009 (7) 4. 15SEP2009 (8) - 27SEP2009 (20) 5. 16SEP2009 (9) - --------- (.)
Duration of AE	1. 14 2. 7 3. 1 4. 13 5. .
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY 5. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053014

Parameter	Value
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053028

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540053028/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/70/ASIAN/CHINA/YES
Medical history	Hypertension, Menopause, Obesity, Arthralgia, Pulmonary embolism, Sleep apnoea syndrome, Pharyngitis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPINE BESILATE, COMPOUND TOBRAMYCIN EYE DROPS, CYDIODINE, DICLOFENAC SODIUM EYE DROPS, ENOXAPARIN, ETIMICIN, HYDROCHLOROTHIAZIDE TABLET, JIN HOU JIAN SPRAY(CHINESE TRADITIONAL MEDICINE), ORNIDAZOLE, PANTOPRAZOLE, QI RONG RUN CHANG KOU FU YE (CHINESE TRADITIONAL MEDICINE) [HERBAL PREP TO TREAT, SPIRONOLACTONE, WARFARIN
Adverse Events (AE) Preferred term	1. Haemoptysis 2. Constipation 3. Conjunctivitis 4. Appendicitis 5. Pyrexia 6. Abdominal pain 7. Ventricular extrasystoles 8. Petechiae
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 25JUN2010 (3) - 25JUN2010 (3) 2. 28JUN2010 (6) - 30JUN2010 (8) 3. 28JUN2010 (6) - 07JUL2010 (15) 4. 23JAN2011 (215) - 30JAN2011 (222) 5. 08FEB2011 (231) - 18FEB2011 (241) 6. 08FEB2011 (231) - 18FEB2011 (241) 7. 18FEB2011 (241) - 22APR2011 (304) 8. 01MAY2011 (313) - --MAY2011 (.)
Duration of AE	1. 1 2. 3 3. 10 4. 8 5. 11 6. 11 7. 64 8. .
Dose on AE onset	1. 2. 3.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053028

Parameter	Value
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540053029/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/85/ASIAN/CHINA/YES
Medical history	Conjunctivitis, Renal cyst, Haematuria, Hypoxia, Pulmonary tuberculosis, Varicose vein, Bronchitis, Lacunar infarction, Arthritis, Cervicobrachial syndrome, Eye prosthesis insertion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBROXOL HYDROCHLORIDE INJECTION, BUDESONIDE AEROSOL, CEFACLOR CAPSULES, CEFMINOX, CEFUROXIME, COMPMND LIQUORICE TABLETS, DIPROPHYLLINE INJECTION, ENOXAPARIN, ENOXAPARIN SODIUM, FEILIKE JIAONANG(CHINESE TRADITIONAL MEDICINE), GANMAO QINGRE KELI(CHINESE TRADITIONAL MEDICINE), GLYCERINE ENEMA, IBUPROFEN SUSTAINED RELEASE CAPSULES, LACTULOSE ORAL SOLUTION, LORATADINE, OFLOXACIN EYE OINTMENT, OFLOXACIN OPHTHALMIC SOLUTIONS, PARACETAMOL SUSTAINED-RELEASE TABLETS, POTASSIUM CHLORIDE SUSTAINED-RELEASE TABLETS, RELINQING (CHINESE TRADITIONAL MEDICINE), SALBUTAMOL, SULPERAZONE, THEOPHYLLINE, VITAMIN C INJECTION, WARFARIN
Adverse Events (AE) Preferred term	1. Injection site haematoma 2. Hypokalaemia 3. Contusion 4. Bronchitis 5. Eczema 6. Ecchymosis 7. Urinary tract infection 8. Haematuria
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. SEVERE/NO/YES/YES 5. MILD/NO/NO/YES 6. MILD/YES/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 05JUL2010 (4) - 15JUL2010 (14) 2. 08JUL2010 (7) - 30JUL2010 (29) 3. 11JUL2010 (10) - 22JUL2010 (21) 4. 12JUL2010 (11) - 21JUL2010 (20) 5. 15SEP2010 (76) - 26OCT2010 (117) 6. 16SEP2010 (77) - 08OCT2010 (99) 7. 09NOV2010 (131) - 23NOV2010 (145) 8. 14NOV2010 (136) - 23NOV2010 (145)
Duration of AE	1. 11 2. 23 3. 12 4. 10 5. 42 6. 23

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053029

Parameter	Value
	7. 15
	8. 10
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED AND RESTARTED
	7. REMEDIAL DRUG THERAPY
	8. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-540053029[1)]	PERIBRONCHITIS EXACERBATION（PT：気管支炎） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、エノキサパリン投与中止後の発現であることから、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053036

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540053036/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/57/ASIAN/CHINA/YES
Medical history	Hypertension, Hypoproteinaemia, Menopause, Neurofibroma, Neurofibroma, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALUMINIUM PHOSPHATE GEL, CANDESARTAN, DIPHENHYDRAMINE, FAMOTIDINE, FAMOTIDINE TABLETS, FERROUS SUCCINATE TABLETS, FOLIC ACID TABLETS, GLYCERINE ENEMA, LACTULOSE ORAL SOLUTION, MOXIFLOXACIN HYDROCHLORIDE INJECTION, OMEPRAZOLE, YUNNAN BAIYAO POWDER(CHINESE TRADITIONAL MEDICINE)
Adverse Events (AE) Preferred term	1. Epistaxis 2. Haemoglobin decreased 3. Gastrointestinal haemorrhage 4. Gastric cancer 5. Metastases to liver 6. Hypokalaemia 7. Leukopenia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/YES 5. SEVERE/NO/YES/YES 6. MILD/NO/NO/NO 7. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 03NOV2010 (7) - 03NOV2010 (7) 2. 04NOV2010 (8) - --------- (.) 3. 07NOV2010 (11) - 17NOV2010 (21) 4. 09NOV2010 (13) - 05JAN2011 (70) 5. 09NOV2010 (13) - 05JAN2011 (70) 6. 16NOV2010 (20) - 19NOV2010 (23) 7. 19NOV2010 (23) - 22NOV2010 (26)
Duration of AE	1. 1 2. . 3. 11 4. 58 5. 58 6. 4 7. 4
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 15 mg 6. 15 mg 7. 15 mg
Dose status on AE onset	1. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053036

Parameter	Value
	2. .
	3. .
	4. .
	5. .
	6. F
	7. F
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY,OTHER
	4. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	5. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. RESOLVED
	4. DEATH
	5. DEATH
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-540053036[4)]	HEMOGLOBIN DECREASING（PT：ヘモグロビン減少） 治験担当医は、因果関係を否定できると判断した。弊社は、リバーロキサバンの抗凝固作用を考慮し、因果関係は否定できないと考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053038

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540053038/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/77/ASIAN/CHINA/YES
Medical history	Spinal osteoarthritis, Hypertension, Pneumonia, Cataract operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBROXOL HYDROCHLORIDE, AMINOPHYLLINE, BETALOC, BISOPROLOL FUMARATE, CEFOPERAZONE SODIUM SULBACTAM INJECTION, CHINESE TRADITIONAL MEDICINE, DIPROPHYLLINE, MOXIFLOXACIN HYDROCHLORIDE, TRIMETAZIDINE HYDROCHLORIDE
Adverse Events (AE) Preferred term	1. Haemorrhoids 2. Haematochezia 3. Ischaemic stroke 4. Pneumonia 5. Rash
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/NO 4. MILD/NO/NO/NO 5. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --MAY2011 (.) - --------- (.) 2. 01MAY2011 (123) - --JUL2011 (.) 3. 08JUL2011 (191) - 10AUG2011 (224) 4. 16JUL2011 (199) - --------- (.) 5. 19JUL2011 (202) - --------- (.)
Duration of AE	1. . 2. . 3. 34 4. . 5. .
Dose on AE onset	1. 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. 2. . 3. F 4. F 5. F
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY 5. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540053038

Parameter	Value
	3. RESOLVED
	4. IMPROVED
	5. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540063042

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540063042/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/55/ASIAN/CHINA/YES
Medical history	Hypertension, Phlebitis, Traumatic fracture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	:OXYCODONE & ACETAMINOPHEN, AESCUVEN FORTE TABLETS, ASPRIN, CAPTOPRIL, CLOPIDOGREL HYDROGEN, DICLOFENAC SODIUM ENTERIC-COATED TABLETS, ENOXAPARIN, EXTRACT OF GINKGO BILOBA LEAVES LNJECTION(TCM), GINKGO DIPYRIDOLUM INJECTION(TCM), ISOKET, LEVAMLODIPINEBESYLATETABLETS, LEVOFLOXACIN INJECTION, MELILOTUS EXTRACT TABLETS, METOPROLOL TARTRATE TABLETS, MEVALOTIN, NORFLOXACIN, WARFARIN
Adverse Events (AE) Preferred term	1. Diarrhoea 2. Abdominal pain 3. Acute myocardial infarction
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 27JUN2009 (9) - 03JUL2009 (15) 2. 14OCT2009 (118) - --------- (.) 3. 28OCT2009 (132) - 30OCT2009 (134)
Duration of AE	1. 7 2. . 3. 3
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. IMPROVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540083003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540083003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/59/ASIAN/CHINA/YES
Medical history	Hypertension, Amenorrhoea
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	10%POTASSIUM CITRATE, AMINOMETHYLBENZOIC ACID, AMINOPYRINE AND ANTIPYRINE COMPOUND INJECTION, AMLODIPINE, BROMHEXINE, CALCIUM GLUCONATE, CECLOR, DOMPERIDONE, ENOXAPARIN, ETAMSYLATE, FOSINOPRIL, GLYCERIN ENEMA, LEVOFLOXACIN HYDROCHLORIDE AND SODIUM CHLORIDE INJECTION, MULTIPLE VITAMINS, OMEPRAZOLE, POTASSIUM CHLORIDE, RADICAL BRANCH SYRUP(TCM), SHUANGHUANGLIAN ORAL LIQUID(TCM), SILYMARIN, THROMBIN, VALSARTAN, WARFARIN, YUNNANBAIYAO (TCM)
Adverse Events (AE) Preferred term	1. Hypokalaemia 2. Upper respiratory tract infection 3. Hepatic function abnormal 4. Hyperlipidaemia 5. Constipation 6. Renal cyst 7. Hepatic cyst 8. Cholelithiasis 9. Venous thrombosis 10. Hiccups 11. Gastrooesophageal reflux disease 12. Upper gastrointestinal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 19DEC2008 (1) - 21DEC2008 (3) 2. 21DEC2008 (3) - 31DEC2008 (13) 3. 22DEC2008 (4) - 16JAN2009 (29) 4. 22DEC2008 (4) - -----2009 (.) 5. 22DEC2008 (4) - 22DEC2008 (4) 6. 23DEC2008 (5) - --------- (.) 7. 23DEC2008 (5) - --------- (.) 8. 23DEC2008 (5) - --------- (.) 9. 24DEC2008 (6) - 06JAN2010 (384) 10. 29DEC2008 (11) - 31DEC2008 (13)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540083003

Parameter	Value
	11. 29DEC2008 (11) - 31DEC2008 (13)
	12. 21SEP2009 (277) - 28SEP2009 (284)
Duration of AE	1. 3
	2. 11
	3. 26
	4. .
	5. 1
	6. .
	7. .
	8. .
	9. 379
	10. 3
	11. 3
	12. 8
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540083003

Parameter	Value
	7. NONE
	8. NONE
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED
	7. UNCHANGED
	8. UNCHANGED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540083007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540083007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/71/ASIAN/CHINA/YES
Medical history	Appendicectomy, Rectal cancer, Metastases to lung, Metastases to lung, Metastases to lung, Rectal cancer, Rectal cancer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BATROXOBIN INJECTION, CAPECITABINE, DIPROSPAN, ENOXAPARIN, EXTRACT OF GINKGO BILOBA LEAVES, NADROPARIN, PINGXIAO CAPSLUE (TCM), WARFARIN
Adverse Events (AE) Preferred term	1. Sudden hearing loss 2. Ischaemic stroke 3. Cerebral atrophy 4. Sinusitis 5. Petechiae 6. Sudden hearing loss
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 03MAY2009 (33) - 10JUN2009 (71) 2. 03MAY2009 (33) - --------- (.) 3. 04MAY2009 (34) - --------- (.) 4. 04MAY2009 (34) - --------- (.) 5. 26MAY2009 (56) - 02JUN2009 (63) 6. 10JUN2009 (71) - --------- (.)
Duration of AE	1. 39 2. . 3. . 4. . 5. 8 6. .
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540083007

Parameter	Value
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. UNCHANGED
	3. UNCHANGED
	4. UNCHANGED
	5. RESOLVED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540103009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540103009/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/25/ASIAN/CHINA/YES
Medical history	Anaemia, Constipation, Pulmonary arterial hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CHLORATUM KALIUM INJECTION, FERROUS SUCCINATE TABLETS, FUROSEMIDE TABLETS, GLYCERINE ENEMA, SHUXUETONG INJECTION(TCM), TONGBIANLINGJIAONANG(TCM)
Adverse Events (AE) Preferred term	1. Activated partial thromboplastin time prolonged
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 18FEB2009 (2) - 02MAR2009 (14)
Duration of AE	1. 13
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. DOSE OF STUDY DRUG REDUCED
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540153004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540153004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/51/ASIAN/CHINA/YES
Medical history	Liver function test abnormal, Dermatomyositis, Pneumonia, Pulmonary hypertension, Rheumatoid arthritis, Right ventricular failure, Type 2 diabetes mellitus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DALTEPARIN SODIUM INJECTION, DIGAOXIN TABLETS, FUROSEMIDE, GASTER(FAMOTIDINE), LEVITRA, MIXED PROTAMINE ZINC RECOMBINANT HUMAN INSULIN INJECTION, MOBIC, MOXIFLOXACIN, POLYENEPHOSPHATIDYLCHOLINECAPSULES, POTASSIUM CHLORIDE SUSTAINED-RELEASE TABLETS, PREDNISONE, TAINUO (COMPOUNDPSEUDOEPHEDRINEHYDROCHLORIDECAPSULES), THYMOSIN FOR INJECTION, TORASEMIDE TABLETS, VITAMIN B6, VITAMIN C
Adverse Events (AE) Preferred term	1. Headache 2. Right ventricular failure 3. Dermatomyositis 4. Rheumatoid arthritis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/YES 3. SEVERE/NO/YES/YES 4. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 24FEB2009 (8) - 26FEB2009 (10) 2. 23MAR2009 (35) - 23APR2009 (66) 3. 28MAR2009 (40) - 23APR2009 (66) 4. 28MAR2009 (40) - 23APR2009 (66)
Duration of AE	1. 3 2. 32 3. 27 4. 27
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED PERMANENTLY 3. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY 4. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. DEATH 3. DEATH

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540153004

Parameter	Value
	4. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540153005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540153005/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/58/ASIAN/CHINA/YES
Medical history	Anaemia, Hypokalaemia, Hypoproteinaemia, Lung neoplasm malignant, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AVELOX, BENZYLPENICILLIN SODIUM, CEFUROXIME SODIUM FOR INJECTION, ERDOSTEINE, FUROSEMIDE, IRON PROTEIN SUCCINYLATE, LIPOVENOS, NETILMICIN SULFATE INJECTION, NOVAMIN, POTASSIUM CHLORIDE SUSTAINED-RELEASE TABLETS, POTASSIUM MAGNESIUM ASPARTATE ORAL SOLUTION, SOLUVITA, SPIRONOLACTONE, THYMOPETIDUM INJECTION, TORASEMIDE FOR INJECTION
Adverse Events (AE) Preferred term	1. Lung neoplasm malignant
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 18MAR2009 (28) - 18MAR2009 (28)
Duration of AE	1. 1
Dose on AE onset	1. 20 mg
Dose status on AE onset	1. .
Action taken	1. NONE
Outcome of event	1. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540153007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540153007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/43/ASIAN/CHINA/YES
Medical history	Hepatic function abnormal, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AVELOX, CLAVULANIC ACID+AMOXICILLIN, ENOXAPARIN, ESSENTIALE N [MALEATE], FAT-SOLUBLE VITAMIN INJECTION, FRAGMIN, FUROSEMIDE, GLUTATHIONE REDUCED, HYDROCHLOROTHIAZIDE, POLYENE PHOSPHATIDYLCHOLINE INJECTION, TONGXINLUO(TCM), VITAMIN B COMB (VITAMINB1 3MG,VITAMINB2 1.5MG,VITAMINB6 0.2MG), VITAMINC PILL, WARFARIN
Adverse Events (AE) Preferred term	1. Liver function test abnormal
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/YES/YES
Start/stop date of event with relative date	1. 04MAR2009 (1) - 02APR2009 (30)
Duration of AE	1. 30
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540153011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540153011/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/59/ASIAN/CHINA/YES
Medical history	Hepatic function abnormal, Lung infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLIN AND CLAVULANATE POTASSIUM, DIAMMONIUM GLYCYRRHIZINATE, DIAZEPAM, ENOXAPARIN, FUROSEMIDE, GLUTATHIONE, SILYMARIN, VITAMIN B COMPOUND, VITAMINC, WARFARIN
Adverse Events (AE) Preferred term	1. Burning sensation 2. Hepatic function abnormal
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 19JAN2010 (2) - 30JAN2010 (13) 2. 22JAN2010 (5) - 01FEB2010 (15)
Duration of AE	1. 12 2. 11
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. NONE 2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540163001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540163001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/74/ASIAN/CHINA/YES
Medical history	Depression, Hepatic cyst, Hepatic function abnormal, Hypertension, Menopause, Hepatic cancer metastatic, Varicose vein, Lung infection, Coronary artery disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	APAURIN, CALCIUM GLUCONATE, CIPRAM, ENOXAPARIN, GLUCUROLACTONE, GLUTHION, ISOSORBIDE MONONITRATE, MEROPENEM, MUCOSOLVAN, NEUTHIONE, NITROGLYCERIN, ROCEPHIN, SULBACTAM+CEFOPERAZONE, THERA-GARLICIN [PULMONARY INFECTION: ALLICIN], WARFARIN
Adverse Events (AE) Preferred term	1. Nausea 2. Abdominal discomfort 3. Metastases to lung 4. Metastases to liver 5. Petechiae 6. Drug eruption 7. Liver abscess 8. Thrombocytopenia 9. Rash 10. Thrombocytopenia 11. Hypokalaemia 12. Haemothorax 13. Hypovolaemic shock
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MODERATE/NO/YES/YES 5. MILD/YES/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. SEVERE/NO/NO/YES 11. MILD/NO/NO/NO 12. MODERATE/NO/NO/NO 13. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 29OCT2008 (2) - 30OCT2008 (3) 2. 29OCT2008 (2) - 01NOV2008 (5) 3. 12NOV2008 (16) - --------- (.) 4. 12NOV2008 (16) - --------- (.) 5. 15NOV2008 (19) - 20NOV2008 (24) 6. 15NOV2008 (19) - 20NOV2008 (24) 7. 23NOV2008 (27) - --------- (.) 8. 26NOV2008 (30) - 05DEC2008 (39) 9. 29NOV2008 (33) - 29NOV2008 (33)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540163001

Parameter	Value
	10. 06DEC2008 (40) - --------- (.)
	11. 09DEC2008 (43) - 12DEC2008 (46)
	12. 12DEC2008 (46) - --------- (.)
	13. 03JAN2009 (68) - 03JAN2009 (68)
Duration of AE	1. 2
	2. 4
	3. .
	4. .
	5. 6
	6. 6
	7. .
	8. 10
	9. 1
	10. .
	11. 4
	12. .
	13. 1
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Action taken	1. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540163001

Parameter	Value
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED
	6. STUDY DRUG DISCONTINUED AND RESTARTED
	7. REMEDIAL DRUG THERAPY
	8. STUDY DRUG DISCONTINUED PERMANENTLY
	9. REMEDIAL DRUG THERAPY
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. OTHER
	13. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. IMPROVED
	8. WORSENED
	9. RESOLVED
	10. UNCHANGED
	11. RESOLVED
	12. UNCHANGED
	13. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540163004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540163004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/83/ASIAN/CHINA/YES
Medical history	Asthma, Atrial fibrillation, Cerebral infarction, Cor pulmonale chronic, Chronic obstructive pulmonary disease, Diabetes mellitus, Hypertension, Hypertensive heart disease, Hyperuricaemia, Lobar pneumonia, Coronary artery disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ADLERIKA, ALLOPURINOL, AMBROXOL HYDROCHLORIDE FOR INJECTION, AMINOPHYLLINE, ANETHOL TRITHEINE, ANTISTERONE, APROVEL, ASPIRIN, ATROVENT, BENZBRONMARONE, CALCIUM GLUCONATE, CECLOR RELEASE TABLETS, CEFUROXIME-LIVZON, CHLORPHENAMINE MALEATE, CHLORPHENIRAMINE, CLARITYNE, COFETOL, COMPOUND GLYCYRRHIZA ORAL SOLUTION, DEXAMETHASONE SODIUM PHOSPHATE, DIAZEPAM, DIGOXIN, DIPROPHYLLINE, ELOSON, EXTENDED RELEASE NIFEDIPINE TABLETS, FORMOTEROL FUMARATE POWDER FOR INHALATION, FRAXIPARINE, FUROSEMIDE, FUROSEMIDE TABLETS, GEFARNATE TABLETS, GLUCOBAY, GLURENORM TABLET, GLYCEROL, GLYCEROL ENEMA, GLYCEROL ENEMAS, GLYCYRRHIZA COMPOUND, ISOSORBIDE DINITRATE INJECTION, ISOSORBIDE MONONITRATE, MAREN SOFT CAPLUSE, MAREN SOFT CAPSULES, MENTAL-PHENIC LOTION [ZINC OXIDE TO TREAT DRUG ERUPTION], MOTILIUM TABLET, MOXIFLOXACIN, MUCOSOLVAN, NEUTRAL INSULIN, POTASSIUM CITRATE, PREDNISONE ACETATE, PROMETHAZINE HYDROCHLORIDE, PULMICORT RESPULES, ROCEPHIN, SERETIDE, SINGULAIR, SODIUM GLUCURONATE, SPIRONOLACTONE TABLETS, THEOPHYLLINE SUSTAINED-RELEASE TABLETS, VC, VENTOLIN, VOTALIN EMULGEL, XIAOYANLIDAN TABLETS
Adverse Events (AE) Preferred term	1. Hypokalaemia 2. Ecchymosis 3. Epistaxis 4. Asthma 5. Cor pulmonale chronic 6. Hypokalaemia 7. Jaundice 8. Jaundice 9. Cholelithiasis 10. Drug eruption
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/YES/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 31MAR2009 (5) - 02APR2009 (7) 2. 13APR2009 (18) - 13APR2009 (18) 3. 16APR2009 (21) - 17APR2009 (22)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540163004

Parameter	Value
	4. 15JUL2009 (111) - 30JUL2009 (126)
	5. 15JUL2009 (111) - 30JUL2009 (126)
	6. 25JUL2009 (121) - 27JUL2009 (123)
	7. 01AUG2009 (128) - 02AUG2009 (129)
	8. 03AUG2009 (130) - 25AUG2009 (152)
	9. 06AUG2009 (133) - 25AUG2009 (152)
	10. 06AUG2009 (133) - 25AUG2009 (152)
Duration of AE	1. 3
	2. 1
	3. 2
	4. 16
	5. 16
	6. 3
	7. 2
	8. 23
	9. 20
	10. 20
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. I
	10. I
Action taken	1. NONE
	2. NONE
	3. STUDY DRUG DISCONTINUED AND RESTARTED
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540163004

Parameter	Value
	8. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	9. NONE
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. WORSENED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540163007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540163007/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/76/ASIAN/CHINA/YES
Medical history	Asthma, Cor pulmonale, Eczema, Hyperglycaemia, Hypertension, Stress ulcer, Cerebral infarction
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBROXOL, ATROVENT, AVELOX, CAPTOPRIL, CETIRIZINE, DIPROPHYLLINE, ELOSON, FAMOTIDINE, GLYCEROL ENEMA, IPRATROPIUM BROMIDE AEROSOL, ISOSORBIDE MONONITRATE, MEICILIN, METHYLPREDNISOLONE, NIFEDIPINE, NIFEDIPINE SUSTAINED-RELEASE TABLETS, NITROGLYCERIN, NOVOLIN N, NOVOLIN R, PULMICORT, SERETIDE, SINGULAIR, TETRAHYDROPALMATINE SULFATE, TULOBUTEROL, VENTOLIN, WYCAKON G
Adverse Events (AE) Preferred term	1. Hyperglycaemia 2. Asthma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/NO 2. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 24APR2009 (1) - 26APR2009 (3) 2. 13MAY2009 (20) - 19MAY2009 (26)
Duration of AE	1. 3 2. 7
Dose on AE onset	1. 15 mg 2. 15 mg
Dose status on AE onset	1. . 2. .
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540163009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540163009/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/ASIAN/CHINA/YES
Medical history	Arteriosclerosis, Cholecystitis, Cholelithiasis, Chronic obstructive pulmonary disease, Hyperlipidaemia, Hyponatraemia, Hysterectomy, Gastrooesophageal reflux disease, Rheumatoid arthritis, Pulmonary tuberculosis, Type 2 diabetes mellitus, Coronary artery disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACERTIL, AMINOPHYLLINE TABLETS, ATROVENT, CALCITRIOL, CALCIUM CARBONATE TABLETS, DIGOXIN, DIPROPHYLLINE, ENOXAPARIN, FUROSEMIDE, METHYLPREDNISOLONE TABLETS, MUCOSOLVAN, NOVOLIN R, SERETIDE, SPIRONOLACTONE, WARFARIN
Adverse Events (AE) Preferred term	1. Osteoporosis 2. Contusion 3. Cor pulmonale chronic
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/NO/YES 2. MILD/YES/NO/YES 3. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 12JAN2010 (5) - --------- (.) 2. 03JUL2010 (177) - 29JUL2010 (203) 3. 07JUL2010 (181) - 13AUG2010 (218)
Duration of AE	1. . 2. 27 3. 38
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540183002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540183002/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/63/ASIAN/CHINA/YES
Medical history	Cardiac disorder, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBROXOL HYDROCHLORIDE, BETALOC, CEFOTIAM, CEFUROXIME, DOPAMINE, ENOXAPARIN, FLUIMUCIL, GATIFLOXACIN, ISOSORBIDE MONONITRATE SUSTAINED RELEASE TABLETS, LIGUSTRAZINE, MANNATIDE [MANNATIDE IS THE INGRED., IT IS USE FOR HEALTHCARE TO ADD THE IMMUNIT, SHENMAI, SHUXUENING INJECTION, SHUXUETONG, THYMOPETIDUM, WARFARIN
Adverse Events (AE) Preferred term	1. Coronary artery disease
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 30MAR2009 (28) - 13APR2009 (42)
Duration of AE	1. 15
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540183006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540183006/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/55/ASIAN/CHINA/YES
Medical history	
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLIN/SULBACTAM, CEFOTIAM, ENOXAPARIN, EXTRACT OF GINKGO BILOBA LEAVES(CHINESE TRADITIONAL MEDICINE), NADROPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Alanine aminotransferase increased 2. Aspartate aminotransferase increased
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 24MAR2009 (6) - 23APR2009 (36) 2. 24MAR2009 (6) - 03APR2009 (16)
Duration of AE	1. 31 2. 11
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. NONE 2. NONE
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540183011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540183011/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/74/ASIAN/CHINA/YES
Medical history	Chronic obstructive pulmonary disease, Cor pulmonale
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBROXOL HYDROCHLORIDE, CEDILANID, CEFPIRAMIDE, CEFUROXIME, CIMETIDINE, DIFLUCAN, DOXOFYLLINE INJECTION, EPINEPHRINE, NAHCO3, NETILMICIN SULFATE, NIKETHAMIDE, NITROGLYCERIN, SHORTSCAPE FLEABANE HERB, SHUXUENING INJECTION [HERBAL PREPARATION. INDICATION IS PE], TIENAM, TORASEMIDE INJECTION, YIZUOYIN INJECTION [HERBAL PREPARATION FOR PULMONARY HEART DISEASE]
Adverse Events (AE) Preferred term	1. Cor pulmonale 2. Pulmonary embolism
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 30AUG2009 (81) - --------- (.) 2. 05SEP2009 (87) - 05SEP2009 (87)
Duration of AE	1. . 2. 1
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540183012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540183012/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/67/ASIAN/CHINA/YES
Medical history	Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBROXOL, CEFOPERZONE /TAZOBACTAM, CIMETIDINE, DOPAMINE, GATIFLOXACIN, PANTOPRAZOLE, XIYANPING (A TRADITIONAL CHINESE MEDICINE)
Adverse Events (AE) Preferred term	1. Upper gastrointestinal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 22JAN2010 (1) - 23JAN2010 (2)
Duration of AE	1. 2
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540193013

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540193013/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/80/ASIAN/CHINA/YES
Medical history	Atrial fibrillation, Bronchitis chronic, Cor pulmonale, Hepatic cyst, Intervertebral disc protrusion, Benign prostatic hyperplasia, Gallbladder polyp, Cardiac valve disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLCYSTEINE TABLET, AMBROXOL, AMBROXOL INJECTION, BENAZEPRIL, BUDESONIDE INJECTION, CELECOXIB CAPSULES, CHINESE MEDICINE (GAN CAO KOU FU YE), DOXOFYLLINE INJECTION, EPERISONE, IPRATROPIUM BROMIDE INJECTION, METHYLPREDNISOLONE INJECTION, MONTELUKAST TABLET, PIPERACILLIN AND TAZOBACTAM, SALBUTAMOL INJECTION, SALMETEROL XINAFOATE AND FLUTICASONE PROPIONATE POWDER FOR INHALATION, SALMETEROL/FLUTICASONE, SUSTAINED-RELEASE THEOPHYLLINE CAPSULES, TAZOCIN INJECTION
Adverse Events (AE) Preferred term	1. Bronchitis 2. Bronchitis 3. Melaena 4. Colon cancer 5. Intestinal fistula 6. Sepsis
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/NO 5. SEVERE/NO/YES/NO 6. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 15SEP2009 (12) - 28SEP2009 (25) 2. 07JAN2010 (126) - 26JAN2010 (145) 3. 19JAN2010 (138) - 25JAN2010 (144) 4. 25JAN2010 (144) - 25JAN2010 (144) 5. 31JAN2010 (150) - 03FEB2010 (153) 6. 01FEB2010 (151) - 03FEB2010 (153)
Duration of AE	1. 14 2. 20 3. 7 4. 1 5. 4 6. 3
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540193013

Parameter	Value
	3. . 4. F 5. F 6. F
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED PERMANENTLY 4. OTHER 5. REMEDIAL DRUG THERAPY,OTHER 6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED 4. RESOLVED 5. DEATH 6. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-540193013[1)]	FATAL MULTIPLE ORGAN DYSFUNCTION（PT：多臓器不全） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併発症（結腸癌）によるものであり、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540193024

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540193024/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/66/ASIAN/CHINA/YES
Medical history	Subcutaneous abscess, Appendicectomy, Appendicitis, Asthma, Cerebral infarction, Cholecystitis, Bronchitis chronic, Cor pulmonale, Haemorrhoids, Hepatic cyst, Hepatic function abnormal, Hypertension, Pulmonary hypertension, Deep vein thrombosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPROSTADIL, CIPROFLOXACIN, CLARITHROMYCIN SUSTAINED-RELEASE TABLETS, CONGRONG TONGBIAN KOUFUYE, HYDROCHLOROTHIAZIDE TABLETS, PENTOXYVERINE, POLYENE PHOSPHATIDYLCHOLINE CAPSULE, SERETIDE, SIMVASTATIN, SPIRONOLACTONE
Adverse Events (AE) Preferred term	1. Cor pulmonale acute 2. Constipation 3. Benign prostatic hyperplasia 4. Nasopharyngitis
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/NO 4. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 20MAY2010 (32) - 21JUN2010 (64) 2. 02JUN2010 (45) - 05JUN2010 (48) 3. 17JUN2010 (60) - --------- (.) 4. 20OCT2010 (185) - 30OCT2010 (195)
Duration of AE	1. 33 2. 4 3. . 4. 11
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. F 4. F
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540193024

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540193026

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540193026/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/78/ASIAN/CHINA/YES
Medical history	Atrial flutter, Cerebral infarction, Cholecystectomy, Coronary artery disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CINEPAZIDE MALEATE INJECTIO, LIPITOR
Adverse Events (AE) Preferred term	1. Gastric cancer
	2. Ischaemic stroke
	3. Occult blood positive
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES
	2. MODERATE/NO/YES/YES
	3. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --JUL2010 (.) - --------- (.)
	2. 15AUG2010 (26) - --------- (.)
	3. 07OCT2010 (79) - --------- (.)
Duration of AE	1. .
	2. .
	3. .
Dose on AE onset	1.
	2. 20 mg
	3. 20 mg
Dose status on AE onset	1.
	2. F
	3. F
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED PERMANENTLY
	3. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. IMPROVED
	3. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540193029

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540193029/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/80/ASIAN/CHINA/YES
Medical history	Bronchiectasis, Herpes zoster, Hypertension, Pulmonary hypertension, Candidiasis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPINE BESYLATE TABLETS, ATROVENT, ENOXAPARIN, FLUIMUCIL, ISOSORBIDE MONONITRATE TABLETS, METHYCOBAL, NADROPARIN, NEXIUM, PULMICORT RESPULES, VENTOLIN, WARFARIN
Adverse Events (AE) Preferred term	1. Cerebral haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 21NOV2010 (39) - 26NOV2010 (44)
Duration of AE	1. 6
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY
Outcome of event	1. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号：11702-540193029

死亡に至るまでの経過

被験者は80歳、アジア人女性。2010年10月12日、肺塞栓症と診断され、2010年10月14日にエノキサパリン（110mg）／用量調節ワルファリンの投与を開始した。

2010年11月21日、被験者は脳出血（出血：脳出血）を発現した。本事象により被験者は死亡に至ったため重篤とされた。本事象により被験者の治験は中止された。治験責任（分担）医師は、本事象の重症度は高度で、治験薬との因果関係は「あり」と判断した。被験者は高血圧の病歴を有していた。被験者は突然意識を消失した。2010年11月21日、本事象により治験薬の投与は中止された。本事象に対する治療は行われなかった。2010年11月26日、本事象により被験者は死亡に至った。死体検案書未入手のため、剖検結果は不明である。

CIACは、脳出血（出血：脳出血）を「重大な出血事象」とし、死亡原因を出血と判定した。

Laboratory Parameter	Normal Range	Date	Result
Hemoglobin	Local: 12.0-16.0 g/dL	09 Oct 2010	13.1 g/dL
Platelets	Local: 100-300 giga/L	09 Oct 2010	128 giga/L
PICT Seconds	Central: 24.80-36.40 S	14 Oct 2010	**60.00 S (H)**
Prothrombin Time (PT)	Central: 11.80-15.50 S	14 Oct 2010	**16.20 S (H)**
PT Ratio	Central: 0.70-1.20 %	14 Oct 2010	**0.65 % (L)**
PT, INR	Central: 0.9-1.2	14 Oct 2010	**1.4 (H)**

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540203003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540203003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/65/ASIAN/CHINA/YES
Medical history	Chronic obstructive pulmonary disease, Cor pulmonale, Goitre, Benign prostatic hyperplasia, Lung infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	10% FRUCTOSE INJECTION, AODIYA---ISOSORBIDEMONONITRATEFORINJECTION, AOXIKANG, BACQURE, CEDILANID, CIPROBAY, CLARITYNE, CREATINEPHOSPHATESODIUMFORINJECTION, DOXOFYLLINE, DUPHALAC [LACTULOSE], ENOXAPARIN, FURSEMIDE, IMIPENEM AND CILASTATIN SODIUM FOR INJECTION, MEDROL, METHYLPREDNISOLONE, MOTILIUM, MUCOSOLVAN INJECTION, PROSCAR, PULMICORT RESPULES, SINGULAIR, TALCID, WARFARIN
Adverse Events (AE) Preferred term	1. Cor pulmonale 2. Chronic obstructive pulmonary disease 3. Pneumonia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 31JUL2009 (3) - --------- (.) 2. 04AUG2009 (7) - --------- (.) 3. 01SEP2009 (35) - 01SEP2009 (35)
Duration of AE	1. . 2. . 3. 1
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED 2. UNCHANGED 3. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540223015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540223015/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/71/ASIAN/CHINA/YES
Medical history	Bronchitis chronic, Intervertebral disc protrusion
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACETYLCYSTEINE CAPSULES, AMBROXOL HYDROCHLORIDE INJECTION, ATROVENT, BAIHE GUJIN KOUFUYE, CEFDINIR CAPSULES, CEFUROXIME SODIUM FOR INJECTION, CLINDAMYCIN PALMITATE HYDROCHLORIDE, DOXOFYLLINE GLUCOSE LNJECTION, FUFANG XIANZHULI YE (TCM), LEVAMLODIPINE BESYLATETABLETS, MOTILIUM, MOXIFLOXACIN HYDROCHLORIDE AND SODIUM CHLORIDE INJECTION, PRAVASTATIN, SALMETEROL XINAFOATE AND FLUTICASONE PROPIONATE POWDER FOR INHALATI, TRIMEBUTINE MALEATE TABLETS
Adverse Events (AE) Preferred term	1. Hyperlipidaemia 2. Hepatic steatosis 3. Hypertension 4. Dyspepsia 5. Chronic obstructive pulmonary disease
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 19MAY2010 (1) - --------- (.) 2. 20MAY2010 (2) - --------- (.) 3. 20MAY2010 (2) - --------- (.) 4. 20MAY2010 (2) - 01JUN2010 (14) 5. 15NOV2010 (181) - 27NOV2010 (193)
Duration of AE	1. . 2. . 3. . 4. 13 5. 13
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. . 5. F
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540223015

Parameter	Value
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED
	2. INSUFFICIENT FOLLOW-UP
	3. IMPROVED
	4. RESOLVED
	5. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540243004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540243004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/30/ASIAN/CHINA/YES
Medical history	Hepatitis B
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASMETON, CEFOPERAZONE SODIUM AND SULBACTAM SODIUM FOR INJECTION, COMPOUND GLYCYRRHIZIM TABLETS, COMPOUND GLYCYRRHIZIN INJECTION, DIAMMONIUM GLYCYRRIHIZINATE, ENOXAPARIN, ESSENTIALE INJECTION, ESSENTIALE TABLETS, FAMOTIDINE, GLYCERINE ENEMA, KETOTIFEN FUMARATE TABLETS, LACTULOSE ORAL SOLUTION, MOXIFLOXACIN HYDROCHLORIDE TABLETS
Adverse Events (AE) Preferred term	1. Constipation 2. Alanine aminotransferase increased 3. Aspartate aminotransferase increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 22OCT2010 (2) - 22OCT2010 (2) 2. 25OCT2010 (5) - 10NOV2010 (21) 3. 25OCT2010 (5) - 10NOV2010 (21)
Duration of AE	1. 1 2. 17 3. 17
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg
Dose status on AE onset	1. . 2. . 3. .
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540243005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540243005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/39/ASIAN/CHINA/YES
Medical history	
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACARBOSE TABLETS, ENOXAPARIN, WARFARIN
Adverse Events (AE) Preferred term	1. Type 2 diabetes mellitus 2. Alanine aminotransferase increased 3. Gingival bleeding
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 29NOV2010 (9) - --------- (.) 2. 03DEC2010 (13) - 13JAN2011 (54) 3. 21MAR2011 (121) - 21MAR2011 (121)
Duration of AE	1. . 2. 42 3. 1
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. NONE
Outcome of event	1. IMPROVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540253002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540253002/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/50/ASIAN/CHINA/YES
Medical history	Hypocalcaemia, Hypokalaemia, Menopause, Pneumonia, Bundle branch block right
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPRAZOLAM TABLET, ALPRAZOLAM TABLETS, AMBROXOL HYDROCHLORIDE, AMINOPHYLLINE INJECTION, ANTISTERONE, ATORVASTATIN CALCIUM, BAYER ASPIRIN, CEFUROXIME, CEFUROXIME SODIUM FOR INJECTION, CLOPIDOGREL SULFATE TABLETS, CRAVIT, DAN HONG INJECTION, DEXAMETHASONE, DIGOXIN TABLET, DILTIAZEM HYDROCHLORIDE, ENOXAPARIN, ENOXAPARIN SODIUM, EXTRACT OF HORSE CHESTNUT SEEDS, FUMARATE BISOPROLOL TABLETS, FUROSEMIDE, FUROSEMIDE INJECTION, HYDROCHLOROTHIAZIDE, IRBESARTAN TABLETS, ISOSORBIDE MONONITRATE, LEVOFLOXACIN HYDROCHLORIDE INJECTION, LEVOFLOXACIN TABLET, PIPERACILLIN AND SULBACTAM, SPIRONOLACTONE, THEOPHYLLINE, THEOPHYLLINESUSTAINED-RELEASETABLETS, TORASEMIDE, TRIMETAZIDINE, WARFARIN, WEN XIN KE LI
Adverse Events (AE) Preferred term	1. Acute myocardial infarction 2. Pneumonia 3. Pneumonia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 26JUL2010 (74) - --------- (.) 2. 26JUL2010 (74) - 03AUG2010 (82) 3. 13AUG2010 (92) - 27AUG2010 (106)
Duration of AE	1. . 2. 9 3. 15
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED 2. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540253002

Parameter	Value
	3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540253005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/540253005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/64/ASIAN/CHINA/YES
Medical history	Bronchiectasis, Pyrexia, Respiratory failure
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBROXOL HYDROCHLORIDE, AMINOPHYLLINE, AZITHROMYCIN, CLINDAMYCIN PHOSPHATE INJECTION, COMPOUND GLYCYRRHIZA ORAL SOLUTION, ENOXAPARIN, IBUPROFEN, METRONIDAZOLE, PIPERACILLIN SODIUM AND TAZOBACTAM SODIUM FOR INJECTION, PIPERACILLIN-TAZOBACTAM, POTASSIUM CHLORIDE, SHEN QI FU ZHENG, THEOPHYLLINE SUSTAINED-RELEASE TABLETS, TORASEMIDE, VANCOMYCIN, WARFARIN
Adverse Events (AE) Preferred term	1. Lung abscess 2. Bronchiectasis 3. Hypokalaemia 4. Lung abscess
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/YES 4. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 17JUL2010 (2) - 24JUL2010 (9) 2. 17JUL2010 (2) - --------- (.) 3. 18JUL2010 (3) - --------- (.) 4. 25JUL2010 (10) - --------- (.)
Duration of AE	1. 8 2. . 3. . 4. .
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. WORSENED 2. INSUFFICIENT FOLLOW-UP 3. INSUFFICIENT FOLLOW-UP

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 540253005

Parameter	Value
	4. INSUFFICIENT FOLLOW-UP

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 550043035

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/550043035/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/28/ASIAN/INDONESIA/YES
Medical history	Haemolytic anaemia, Thrombocytopenia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BISOLVON SYRUP, CLAVAMOX, CODIPRONT EXPECTORANT, FOLIC ACID, HEMOBION, LEVOCIN, MAAGTRAL SYRUP, MEDROL, NEXIUM, ORADEXON, PLADOGREL
Adverse Events (AE) Preferred term	1. Haemolytic anaemia 2. Bronchitis 3. Bronchitis 4. Oedema peripheral
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/NO/NO 4. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 25JAN2010 (3) - 24MAY2010 (122) 2. 27JAN2010 (5) - 18FEB2010 (27) 3. 10MAY2010 (108) - 14MAY2010 (112) 4. 22MAY2010 (120) - --------- (.)
Duration of AE	1. 120 2. 23 3. 5 4. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 20 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. F 4. F
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 550043035

Parameter	Value
	4. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 560043001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/560043001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/73/ASIAN/KOREA (SOUTH)/YES
Medical history	Asthma, Benign prostatic hyperplasia, Chest pain, Gastric cancer, Haemorrhoids, Hypertension, Spinal column stenosis, Sputum discoloured, Stab wound, Bone pain
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMBROXOL, ATROVENT UDV, ENOXAPARIN, HEPARIN, NORVASC, UNFRACTIONATED HEPARIN, VENTOLIN NEBULES, WARFARIN
Adverse Events (AE) Preferred term	1. Haemoptysis 2. Conjunctival haemorrhage 3. Chest pain 4. Nausea 5. Dizziness 6. Gingival bleeding
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/YES/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/NO 5. MODERATE/NO/NO/NO 6. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 24OCT2008 (23) - 24OCT2008 (23) 2. 11DEC2008 (71) - 19DEC2008 (79) 3. 02JAN2009 (93) - 14JAN2009 (105) 4. 12JAN2009 (103) - 28JAN2009 (119) 5. 13JAN2009 (104) - 15JAN2009 (106) 6. 30JAN2009 (121) - 30JAN2009 (121)
Duration of AE	1. 1 2. 9 3. 13 4. 17 5. 3 6. 1
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 560043001

Parameter	Value
	6.
Action taken	1. NONE
	2. STUDY DRUG DISCONTINUED AND RESTARTED
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 560043003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/560043003/No study medication
Sex/Age/Race/Country/Safety population	MALE/28/ASIAN/KOREA (SOUTH)/NO
Medical history	Pain in extremity, Food allergy, Pharyngitis, Seasonal allergy, Solar urticaria, Oedema peripheral, Urine analysis abnormal, Upper limb fracture, Pleural effusion, Haematochezia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	
Adverse Events (AE) Preferred term	1. Acute myeloid leukaemia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 16DEC2008 (.) - --------- (.)
Duration of AE	1. .
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. OTHER
Outcome of event	1. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 570023002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/570023002/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/57/WHITE/LITHUANIA/YES
Medical history	Obstructive airways disorder, Inguinal hernia, Menopause, Pneumonia, Gastric ulcer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXICILLINI, AMPICILINI, AMPICILLIN, BUDEZONIDE ET FORMATEROL, CEFUROXIME, CIPROFLOXACIN, DEXAMETHASONE, ENOXAPARIN, FUROSEMIDI, FUROZEMIDE, HEPARINE, IBUPROFEN, IRON, ISOSORBIDE DINITRATE, OMEPRAZOLE, OXYGEN THERAPY, POTASSIUM CHLORIDE 7.45%, RANITIDINI, SALBUTAMOL, SALMETEROL ET FLUTICASONE, SOL. SODIUM CGHLORIDE 0.9 %, TIOTROPIUM BROMIDE, WARFARIN
Adverse Events (AE) Preferred term	1. Chronic obstructive pulmonary disease 2. Chronic obstructive pulmonary disease 3. Myocardial ischaemia 4. Angina pectoris 5. Chronic obstructive pulmonary disease 6. Oedema peripheral 7. Toothache 8. Iron deficiency anaemia 9. Chronic obstructive pulmonary disease 10. Oedema peripheral
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/YES/YES 3. MILD/NO/YES/YES 4. MILD/NO/YES/YES 5. MODERATE/NO/YES/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/YES/YES 10. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 02DEC2010 (77) - 13DEC2010 (88) 2. 17APR2011 (213) - 21APR2011 (217) 3. 18APR2011 (214) - --------- (.) 4. 18APR2011 (214) - --------- (.) 5. 18MAY2011 (244) - 30MAY2011 (256) 6. 18MAY2011 (244) - 20MAY2011 (246) 7. 22MAY2011 (248) - 27MAY2011 (253) 8. 30MAY2011 (256) - --------- (.) 9. 30JUN2011 (287) - 08JUL2011 (295) 10. 30JUN2011 (287) - --------- (.)
Duration of AE	1. 12 2. 5 3. .

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 570023002

Parameter	Value
	4. .
	5. 13
	6. 3
	7. 6
	8. .
	9. 9
	10. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY,OTHER
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY,OTHER
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. UNCHANGED
	4. UNCHANGED
	5. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 570023002

Parameter	Value
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED
	10. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 570023005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/570023005/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/50/WHITE/LITHUANIA/YES
Medical history	Lung neoplasm malignant, Pneumonia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMPICILLIN/ SULBACTAM, ANALGIN, CEFUROXIME, DEXAMETHASONE, FENTAYL, FULSED, FUROZEMIDE, FUROZEMIDI, IBUPROFEN, MECHANICAL VENTILATION, METRANIDAZOLE, MORPHINI , OMEPRAZOLE, OXYGEN THERAPY, POTASSIUM CHLORIDE 7.45%, RANITIDINI, SOL. SDIUM CHLORIDE 0.9%, TRAMADOL
Adverse Events (AE) Preferred term	1. Pneumonia 2. Dyspepsia 3. Pneumonia 4. Lung neoplasm malignant 5. Dyspnoea 6. Pneumonia 7. Dyspnoea
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/YES/YES 4. SEVERE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. SEVERE/NO/YES/YES 7. SEVERE/NO/NO/YES
Start/stop date of event with relative date	1. 14DEC2010 (14) - 03JAN2011 (34) 2. 22DEC2010 (22) - 17JAN2011 (48) 3. 25JAN2011 (56) - 07FEB2011 (69) 4. 03FEB2011 (65) - --------- (.) 5. 05FEB2011 (67) - 06MAR2011 (96) 6. 06MAR2011 (96) - 24MAR2011 (114) 7. 06MAR2011 (96) - --------- (.)
Duration of AE	1. 21 2. 27 3. 14 4. . 5. 30 6. 19 7. .
Dose on AE onset	1. 15 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 570023005

Parameter	Value
	7. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. WORSENED
	6. DEATH
	7. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580023021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/580023021/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/78/WHITE/SWITZERLAND/YES
Medical history	Anaemia, Joint swelling, Back pain, Depression, Hiatus hernia, Infection, Neuropathy peripheral, Night sweats, Oesophageal candidiasis, Osteoarthritis, Pneumonia, Raynaud's phenomenon, Tinnitus, Weight decreased, Osteoarthritis, Systemic inflammatory response syndrome
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACIDUM FOLICUM, BENERVA, CALCIUM 1000 FF, CO-AMOXI-MEPHA, DAFALGAN, DALTEPARIN, DIFLUCAN, DULCOLAX [BISACODYLUM], FERINJECT, FLUCONAZOL MEPHA, LYRICA, MOVICOL, NEXIUM, NOVALGIN, NOVALGIN PRN, PANTOPRAZOLUM, REMERON, ROCEPHIN, SPIRICORT, SYMBICORT 200/6
Adverse Events (AE) Preferred term	1. Oesophageal candidiasis 2. Haemoglobin decreased 3. C-reactive protein increased 4. Cough 5. Oedema peripheral 6. Chronic obstructive pulmonary disease 7. Osteoarthritis 8. Osteoarthritis 9. Constipation
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/YES/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/NO/YES/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 13JAN2011 (4) - 30JAN2011 (21) 2. 17JAN2011 (8) - 28JAN2011 (19) 3. 21JAN2011 (12) - 28JAN2011 (19) 4. 21JAN2011 (12) - 07FEB2011 (29) 5. 21JAN2011 (12) - 07FEB2011 (29) 6. 24JAN2011 (15) - --------- (.) 7. 20MAY2011 (131) - 01JUN2011 (143) 8. 01JUN2011 (143) - 18JUN2011 (160) 9. 18JUN2011 (160) - 03AUG2011 (206)
Duration of AE	1. 18 2. 12 3. 8 4. 18 5. 18

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580023021

Parameter	Value
	6. .
	7. 13
	8. 18
	9. 47
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. I
	2. I
	3. I
	4. I
	5. I
	6. I
	7. .
	8. .
	9. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED AND RESTARTED
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY,OTHER
	7. REMEDIAL DRUG THERAPY,OTHER
	8. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. IMPROVED
	7. WORSENED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580023021

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580023022

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/580023022/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/79/WHITE/SWITZERLAND/YES
Medical history	Faecal incontinence, Leg amputation, Gastrooesophageal reflux disease, Vitamin D deficiency, Decreased appetite, Pneumonia, Prostate cancer
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ATROVENT, BIOFLORIN, CALCIMAGAN, CO AMOXI MEPHA, ENOXAPARIN, FLAGYL, KONAKION, NEXIUM, PANTOZOL, PASPERTIN, ROCEPHIN, VENTOLIN, ZOLADEX, ZOLPIDEM
Adverse Events (AE) Preferred term	1. Gastrointestinal haemorrhage 2. Pyrexia
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 27JAN2011 (8) - 15FEB2011 (27) 2. 30JAN2011 (11) - 03FEB2011 (15)
Duration of AE	1. 20 2. 5
Dose on AE onset	1. 2.
Dose status on AE onset	1. 2.
Action taken	1. DOSE OF STUDY DRUG REDUCED,REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580023023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/580023023/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/79/WHITE/SWITZERLAND/YES
Medical history	Temporal arteritis, Hypertension, Haemorrhagic cyst
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATACAND [CANDESARTAN CILEXETIL ALONE], CALCIMAGON D3, PANADOL, PANTOZOL, SPIRICORT
Adverse Events (AE) Preferred term	1. Pulmonary venous thrombosis 2. Foot fracture 3. Syncope 4. Anaemia 5. Aortic dissection
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/YES/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 17JUN2011 (136) - 19JUN2011 (138) 2. 17JUN2011 (136) - 30JUN2011 (149) 3. 17JUN2011 (136) - 17JUN2011 (136) 4. 19JUN2011 (138) - 22SEP2011 (233) 5. 19JUN2011 (138) - 30JUN2011 (149)
Duration of AE	1. 3 2. 14 3. 1 4. 96 5. 12
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. F 5. F
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER 2. NONE 3. REMEDIAL DRUG THERAPY 4. OTHER 5. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580023023

Parameter	Value
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas erjli 21MAR2013 11:35

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-580023023[2)]	PULMONARY VEIN THROMBOSIS（PT：肺静脈血栓症） 治験担当医はリバーロキサバンと報告事象との関連性があると判断した。弊社は、リバーロキサバンが関与した医学的証拠がないことから、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580043002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/580043002/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/61/WHITE/SWITZERLAND/YES
Medical history	Bronchopneumonia, Diabetes mellitus, Pneumothorax, Postmenopause, Pleural effusion, Lung neoplasm
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, AMOXICILLINUMAUGMENTIN), BELOC ZOK, BROMAZEPAM (LEXOTANIL), BRUFEN(IBUPROFENE), BULBOID (GLYCERINE), DAFALGAN(PARACETAMOL), DEXAMETHASONE, DILZEM(DILTIAZEMI HYDROCHLORIDUM.), ENOXAPARIN, ENOXAPARIN 1.0 MG/KG TWICE DAILY, ENOXAPARIN, 1.0 MG/KG TWICE DAILY, FRAXIFORTE(NADROPARINE), GEMCITABINE, GEMCITABINE (GEMZAR), GLIMEPIRIDUM.(AMARYL), IMPORTAL(LACTITOLUM MONOHYDRICUM.), KONAKION(PHYTOMENADIONUM), LIQUEMINE, MORPHINE, MST [MORPHINE SULFATE], MST(MORPHINE), NABELBINE, NABELNINE, NEXIUM(ESOMEPRAZOLE), PANADOL, PASPERTIN(METOCLOPRAMIDI HYDROCHLORIDUM.), PRONTOLAX (BISACODYLUM), ZOFRAN(ONDANSETRONUM)
Adverse Events (AE) Preferred term	1. Pneumothorax 2. Nausea 3. Constipation 4. Atrial fibrillation 5. International normalised ratio fluctuation 6. Metastatic neoplasm
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MODERATE/YES/NO/YES 6. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 29APR2008 (134) - --------- (.) 2. 20JUN2008 (186) - 10JUL2008 (206) 3. 20JUN2008 (186) - 22JUL2008 (218) 4. 26JUN2008 (192) - --------- (.) 5. 29JUN2008 (195) - 30JUN2008 (196) 6. 22JUL2008 (218) - 26JUL2008 (222)
Duration of AE	1. . 2. 21 3. 33 4. . 5. 2 6. 5
Dose on AE onset	1. 2. 3. 4. 5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580043002

Parameter	Value
	6.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580043003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/580043003/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/72/WHITE/SWITZERLAND/YES
Medical history	Atrial fibrillation, Breast cancer, Bronchopneumonia, Cardiac failure, Breast cancer metastatic, Pleural effusion, Post-traumatic epilepsy, Benign prostatic hyperplasia, Septic shock, Alcoholism, Osteoarthritis, Nasal neoplasm, Tonsillar neoplasm
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, ACIDUM ACETYLSALICYLICUM, AROMASIN, CHLORHYDRATE DE TRAMADOL.(TRAMAL), CHONDROITIN SULFATE SODIUM (STRUCTUM), DILTIAZEMI HYDROCHLORIDUM, ENOXAPARIN, FINASTERIDUM.(PROSCAR), FUROSEMIDE, KCL, LEVETIRACETAM(KEPPRA), MALÉATE D'ÉNALAPRIL.(EPRIL), METOPROLOL FUMARATE, METOPROLOL SUCCINATE (BELOC), PHENOBARBITALUM(LUMINAL), PHENOBARBITALUM.(LUMINAL), SODIUM PICOSULFATE (LAXOBERON), THIAMINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE (BENERVA), TORASEMIDUM.
Adverse Events (AE) Preferred term	1. Partial seizures 2. Traumatic haematoma 3. Onychalgia 4. Hypokalaemia 5. Constipation 6. Cardiac failure 7. Atrial fibrillation 8. Metastasis 9. Chest pain 10. General physical health deterioration 11. Constipation 12. Chest pain 13. General physical health deterioration
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/NO 7. MODERATE/NO/YES/NO 8. MODERATE/NO/NO/NO 9. MODERATE/NO/NO/NO 10. MODERATE/NO/YES/NO 11. MILD/NO/NO/NO 12. MILD/NO/NO/NO 13. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --APR2008 (.) - --------- (.) 2. 17JAN2008 (2) - 21JAN2008 (6) 3. 17JAN2008 (2) - 18JAN2008 (3)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580043003

Parameter	Value
	4. 18JAN2008 (3) - 21JAN2008 (6)
	5. 21JAN2008 (6) - 25JAN2008 (10)
	6. 04FEB2008 (20) - --------- (.)
	7. 04FEB2008 (20) - --------- (.)
	8. 16FEB2008 (32) - --------- (.)
	9. 06AUG2008 (204) - 13AUG2008 (211)
	10. 01OCT2008 (260) - 20OCT2008 (279)
	11. 01OCT2008 (260) - --------- (.)
	12. 10OCT2008 (269) - --------- (.)
	13. 21OCT2008 (280) - --------- (.)
Duration of AE	1. .
	2. 5
	3. 2
	4. 4
	5. 5
	6. .
	7. .
	8. .
	9. 8
	10. 20
	11. .
	12. .
	13. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580043003

Parameter	Value
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Action taken	1. NONE
	2. OTHER
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY,OTHER
	7. REMEDIAL DRUG THERAPY
	8. OTHER
	9. REMEDIAL DRUG THERAPY,OTHER
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY,OTHER
	13. NONE
Outcome of event	1. IMPROVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. IMPROVED
	7. IMPROVED
	8. UNCHANGED
	9. RESOLVED
	10. IMPROVED
	11. INSUFFICIENT FOLLOW-UP
	12. INSUFFICIENT FOLLOW-UP

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580043003

Parameter	Value
	13. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580043010

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/580043010/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/68/WHITE/SWITZERLAND/YES
Medical history	Skin cancer, Hypercholesterolaemia, Hypertension, Prostatic specific antigen increased, Phlebectomy, Myocardial ischaemia, Osteoarthritis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRINE, ASPIRINE CARDIO, BUSCOPAN(SCOPOLAMINE), BUSCOPAN(SCOPOLAMINI BUTYLBROMIDUM, CRESTOR(ROSUVASTATINE), DAFALGAN(PARACETAMOL), DORMICUM(MIDAZOLAM), GLUCOSAMINE/CHONDROITIN, LEXOTANIL(BROMAZEPAM), LIQUEMINE, NEXIUM, NEXIUM(ESOMEPRAZOLE), OMED, PERFALGAN(PARACETAMOL), PLAVIX, SORTIS(ATORVASTATINUM), TORADOL(KETOROLAC), TORECAN(THIETHYLPERAZINUM, TRAMAL(CHLORHYDRATE DE TRAMADOL)
Adverse Events (AE) Preferred term	1. Muscle spasms 2. Abdominal discomfort 3. Abdominal pain 4. Cholecystitis 5. Pancreatitis 6. Hepatic enzyme increased 7. Insomnia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MODERATE/YES/YES/YES 5. MILD/NO/NO/YES 6. MODERATE/YES/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --OCT2008 (.) - --OCT2008 (.) 2. 11MAY2008 (34) - 13MAY2008 (36) 3. 04JUN2008 (58) - 06JUN2008 (60) 4. 06JUN2008 (60) - 13JUN2008 (67) 5. 06JUN2008 (60) - 13JUN2008 (67) 6. 06JUN2008 (60) - 04AUG2008 (119) 7. 11JUN2008 (65) - 11JUN2008 (65)
Duration of AE	1. . 2. 3 3. 3 4. 8 5. 8 6. 60 7. 1
Dose on AE onset	1. 2. 20 mg 3. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580043010

Parameter	Value
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. I
Action taken	1. OTHER
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	5. NONE
	6. OTHER
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. WORSENED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-580043010[2)]	CHOLECYSTITIS（PT：胆嚢炎） 治験担当医はリバーロキサバンと報告事象との関連性があると判断した。弊社は、投与中に回復し、本剤の関与を示す情報がないことから、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580043015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/580043015/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/65/WHITE/SWITZERLAND/YES
Medical history	Bundle branch block left, Sleep apnoea syndrome, Tooth extraction
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMIODARONE(AMIODARONE), ASPIRINE, BELOC ZOK, CORDARONE(AMIODARONE HYDROCHLORICUM), FRAXIFORTE(NADROPARINUM CALCICUM), KCL, LOPRESOR, LOPRESOR (METOPROLOL), METO ZEROK
Adverse Events (AE) Preferred term	1. Atrial fibrillation 2. Hypokalaemia
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 20JAN2009 (127) - 29APR2009 (226) 2. 20JAN2009 (127) - 21JAN2009 (128)
Duration of AE	1. 100 2. 2
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. .
Action taken	1. REMEDIAL DRUG THERAPY,OTHER 2. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580043022

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/580043022/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/69/WHITE/SWITZERLAND/YES
Medical history	Arrhythmia, Insomnia, Benign prostatic hyperplasia, Alcohol use
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, BECOZYME FORTE, BECOZYME FORTE(THIAMINI NITRAS B1, RIBOFLAVINUM B2, PYRIDOXINI, BELOC ZOK, BENERVA, BENERVA (THIAMINE HYDROCHLORIDE), BRUFEN, CLEXANE, DAFALGAN, DOSPIR, ENOXAPARIN, EPRIL, LASIX, LOPRESOR, NEXIUM, PRADIF, TOPLEXIL SYRUP (OXOMEMAZINUM), TOREM, TRASICOR, ZOLPIDEM (ZOLPIDEMI TARTRAS)
Adverse Events (AE) Preferred term	1. Influenza like illness 2. Myalgia 3. Cardiac failure
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. --JUL2009 (.) - 08JUL2009 (37) 2. --NOV2009 (.) - --------- (.) 3. 22NOV2009 (174) - 02DEC2009 (184)
Duration of AE	1. . 2. . 3. 11
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED 2. IMPROVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580043027

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/580043027/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/69/WHITE/SWITZERLAND/YES
Medical history	Back pain, Cervix carcinoma, Glaucoma, Hypercholesterolaemia, Insomnia, Menopause, Osteoporosis, Intra-abdominal haemangioma, Vertebral wedging
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACIDE FOLIQUE, CALCIMAGON D3(COLECALCIFEROL+CALCIUM), COLPOTROPHINE(PROMESTRIENUM), CONDROSULF, DORMICUM, EZETROL, FENTANYL, FERINJECT, FERINJECT (FER SOUS FORME DE, FERINJECT(FER SOUS FORME DE CARBOXYMALTOSE FERRIQUE., FOCETRIA, HEPARINE, MAGNESIOCARD, MUTAGRIP, NEXIUM, NUTROF TOTAL(VITAMINE C 120 MG, VITAMINE E 10 MG, ZINC 15 MG,...., PARACETAMOL(DAFALGAN), SELIPRAM(PRAVASTATIN), SINTROM, ZOLPIDEM
Adverse Events (AE) Preferred term	1. Gastrointestinal haemorrhage 2. Insomnia 3. Anaemia 4. Vulvovaginal dryness 5. Muscle spasms 6. Occult blood positive
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES 2. MILD/NO/NO/YES 3. MODERATE/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/YES/NO/YES
Start/stop date of event with relative date	1. 26AUG2009 (22) - 14DEC2009 (132) 2. 26AUG2009 (22) - 31AUG2009 (27) 3. 26AUG2009 (22) - --------- (.) 4. 31OCT2009 (88) - --------- (.) 5. 25APR2010 (264) - --------- (.) 6. 26APR2010 (265) - 22JUL2010 (352)
Duration of AE	1. 111 2. 6 3. . 4. . 5. . 6. 88
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580043027

Parameter	Value
	2. .
	3. .
	4. .
	5. .
	6. .
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. IMPROVED
	4. IMPROVED
	5. IMPROVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580043028

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/580043028/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/74/WHITE/SWITZERLAND/YES
Medical history	Diabetes mellitus, Glaucoma, Polymyalgia rheumatica, Rectal ulcer haemorrhage, Cognitive disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTOMEL, AZOPT, CALCIMAGON, DAFALGAN, ENOXAPARIN, FOLVITE, JANUVIA, K+, KAMILLOSAN, MAGNESIOCARD, METFIN, MG5 LONGORAL, MYCOLOG, NOVORAPID, OMEPRAZOLE, PREDNISONE, SEPTIVON [CETRIMONIUM CHLORIDE, TRICLOCARBAN], VITARUBIN, XEFO
Adverse Events (AE) Preferred term	1. Balanoposthitis 2. Hypokalaemia 3. Genital erythema 4. Dyspnoea 5. Hypokalaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/YES/YES 5. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --NOV2009 (.) - 10JAN2010 (139) 2. 26AUG2009 (2) - 27AUG2009 (3) 3. 11SEP2009 (18) - 13SEP2009 (20) 4. 27SEP2009 (34) - 28SEP2009 (35) 5. 09DEC2009 (107) - 09DEC2009 (107)
Duration of AE	1. . 2. 2 3. 3 4. 2 5. 1
Dose on AE onset	1. 2. 15 mg 3. 15 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. . 5. I
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. NONE 4. OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580043028

Parameter	Value
	5. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580123007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/580123007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/79/WHITE/SWITZERLAND/YES
Medical history	Agitation, Osteoarthritis, Atrial fibrillation, Hypercholesterolaemia, Pneumonia, Supraventricular extrasystoles, Ventricular extrasystoles, Hysterosalpingo-oophorectomy, Pubis fracture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	(SACCHAROMYCES BOULARDII LYOPHILISIERT)PERENTEROL, ACENOCOUMAROL, AMIDARONE, ARTHROTON, CIPROXIN, CLEXANE, CONCOR, CONCOR (BISOPROLOLI FUMARAS), CRANBERRY CONCENTRATE, DAFALGAN, ENOXAPARIN, GUAIFENESIN (RESYL), KLACID, LANZOPRAZOL, LEXOTANIL, METO ZEROC, METO ZEROK, MULTAQ, NOVALGIN, ORTHO GYNEST, PERFALGAN, POTASSIUM, TEMESTA, TIBERAL, VITALUX
Adverse Events (AE) Preferred term	1. Diarrhoea 2. Atrial flutter 3. Urosepsis 4. Hypokalaemia 5. Cystitis 6. Cystitis 7. Wound haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --OCT2010 (.) - --OCT2010 (.) 2. 14SEP2010 (5) - 22SEP2010 (13) 3. 10OCT2010 (31) - 15OCT2010 (36) 4. 10OCT2010 (31) - 14DEC2010 (96) 5. 07DEC2010 (89) - 12DEC2010 (94) 6. 30DEC2010 (112) - 03JAN2011 (116) 7. 03FEB2011 (147) - 03FEB2011 (147)
Duration of AE	1. . 2. 9 3. 6 4. 66 5. 6 6. 5 7. 1
Dose on AE onset	1. 2. 3. 4.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580123007

Parameter	Value
	5.
	6.
	7.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580183001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/580183001/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/42/WHITE/SWITZERLAND/YES
Medical history	Back pain, Obesity, Reduced bladder capacity
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACENOCOUMAROL, BRUFEN, CATTALERG, CEVAZETTE, CLARITHROMYCIN, CLEXANE, DAFALGAN, ENOXAPARIN, EXCIPIAL [EXCIPIAL NOS], NEXIUM, OMNEPRAZOL, PRIMPERAN, SPASMEX
Adverse Events (AE) Preferred term	1. Nausea 2. Drug intolerance 3. Chills 4. Headache 5. Pruritus 6. Paraesthesia 7. Pain in extremity 8. Chest pain 9. Vaginal haemorrhage 10. Vomiting 11. Panic reaction 12. Tinnitus 13. Renal pain 14. Loss of libido 15. Submaxillary gland enlargement 16. Asthenia 17. Leukocytosis 18. Eosinophilia 19. Scotoma 20. Myalgia 21. Polyuria 22. Oropharyngeal blistering 23. Pollakiuria 24. Polydipsia 25. Upper respiratory tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/YES/YES/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/YES/NO/YES 6. MILD/YES/NO/YES 7. MODERATE/YES/NO/YES 8. MODERATE/YES/NO/YES 9. MODERATE/YES/NO/YES 10. MILD/YES/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580183001

Parameter	Value
	11. MODERATE/NO/NO/YES
	12. MILD/YES/NO/YES
	13. MILD/NO/NO/YES
	14. MILD/YES/NO/YES
	15. MILD/YES/NO/YES
	16. MILD/YES/NO/YES
	17. MODERATE/YES/NO/YES
	18. MODERATE/YES/NO/YES
	19. MODERATE/YES/NO/YES
	20. MILD/NO/NO/YES
	21. MILD/NO/NO/YES
	22. MILD/YES/NO/YES
	23. MILD/NO/NO/YES
	24. MILD/NO/NO/YES
	25. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 12MAR2010 (4) - --------- (.)
	2. 12MAR2010 (4) - 14JUN2010 (98)
	3. 20MAR2010 (12) - 20MAR2010 (12)
	4. 21MAR2010 (13) - --------- (.)
	5. 22MAR2010 (14) - 07JUN2010 (91)
	6. 25MAR2010 (17) - 07JUN2010 (91)
	7. 25MAR2010 (17) - 01APR2010 (24)
	8. 06APR2010 (29) - 12APR2010 (35)
	9. 09APR2010 (32) - 08JUN2010 (92)
	10. 10APR2010 (33) - --------- (.)
	11. 16APR2010 (39) - 19APR2010 (42)
	12. 19APR2010 (42) - --------- (.)
	13. 19APR2010 (42) - 08JUL2010 (122)
	14. 19APR2010 (42) - --------- (.)
	15. 21APR2010 (44) - --------- (.)
	16. 05MAY2010 (58) - --------- (.)
	17. 10MAY2010 (63) - --------- (.)
	18. 10MAY2010 (63) - --------- (.)
	19. 16MAY2010 (69) - 16MAY2010 (69)
	20. 17MAY2010 (70) - --------- (.)
	21. 17MAY2010 (70) - 08JUL2010 (122)
	22. 17MAY2010 (70) - --------- (.)
	23. 17MAY2010 (70) - 08JUL2010 (122)
	24. 17MAY2010 (70) - 08JUL2010 (122)
	25. 27MAY2010 (80) - --------- (.)
Duration of AE	1. .
	2. 95

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580183001

Parameter	Value
	3. 1
	4. .
	5. 78
	6. 75
	7. 8
	8. 7
	9. 61
	10. .
	11. 4
	12. .
	13. 81
	14. .
	15. .
	16. .
	17. .
	18. .
	19. 1
	20. .
	21. 53
	22. .
	23. 53
	24. 53
	25. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580183001

Parameter	Value
	20.
	21.
	22.
	23.
	24.
	25.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED PERMANENTLY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. NONE
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580183001

Parameter	Value
	12. NONE
	13. NONE
	14. NONE
	15. NONE
	16. REMEDIAL DRUG THERAPY
	17. NONE
	18. NONE
	19. NONE
	20. REMEDIAL DRUG THERAPY
	21. NONE
	22. NONE
	23. NONE
	24. NONE
	25. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. IMPROVED
	11. RESOLVED
	12. IMPROVED
	13. RESOLVED
	14. UNCHANGED
	15. UNCHANGED
	16. UNCHANGED
	17. IMPROVED
	18. IMPROVED
	19. RESOLVED
	20. UNCHANGED
	21. RESOLVED
	22. UNCHANGED
	23. RESOLVED
	24. RESOLVED

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 580183001

Parameter	Value
	25. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-580183001[1)]	SINTROM INTOLERANCE（PT：薬物不耐性） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、併用被疑薬のアセノクマロールによるものであり、エノキサパリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 590023004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/590023004/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/69/WHITE/FINLAND/YES
Medical history	Ankylosing spondylitis, Diaphragmatic hernia, Hypertension, Hysterectomy, Insomnia, Lymphoma, Obesity, Constipation, Myalgia, Dyspepsia, Fibromyalgia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMLODIPIN, ARCOXIA, GAVISCON, IMOVANE, KLORTRIPTYL MITE, LACTULOSE, MEDROL, PANADOL, SOMAC
Adverse Events (AE) Preferred term	1. Nausea 2. Haemorrhoidal haemorrhage 3. Rectal haemorrhage 4. Haemorrhoidal haemorrhage 5. Anaemia 6. Anaemia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MILD/YES/YES/YES 6. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. --APR2010 (.) - --APR2010 (.) 2. 21JAN2010 (9) - 26JAN2010 (14) 3. 10MAR2010 (57) - 10MAR2010 (57) 4. 01APR2010 (79) - --APR2010 (.) 5. 19MAY2010 (127) - 04JUN2010 (143) 6. 07JUL2010 (176) - 09AUG2010 (209)
Duration of AE	1. . 2. 6 3. 1 4. . 5. 17 6. 34
Dose on AE onset	1. 2. 15 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. . 5. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 590023004

Parameter	Value
	6. .
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-590023004[3), 3)]	POSITIVE FECAL OCCULT BLOOD TEST（PT：便潜血陽性） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、リバーロキサバンの抗凝固作用により出血リスクが高まったこと及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。また、既往症（リンパ腫）による可能性も考えられる。 STOOL BLOOD SAMPLE POSITIVE（PT：便潜血陽性） 治験担当医は報告事象との因果関係評価を行っていない。弊社は、リバーロキサバンの抗凝固作用により出血リスクが高まったこと及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。また、既往症（リンパ腫）による可能性も考えられる。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 590023005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/590023005/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/65/WHITE/FINLAND/YES
Medical history	Osteoarthritis, Eczema, Insomnia, Sterilisation, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, KALCIPOS-D, LANTZOPRATZOL, PARACETAMOL, PRIMASPAN, SELEXID, SIMVASTATIN, WARFARIN, ZOPINOX
Adverse Events (AE) Preferred term	1. Chest pain 2. Urinary tract infection 3. Epistaxis 4. Gingival bleeding 5. Chest pain 6. Dyspepsia 7. Urinary tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 20JAN2010 (7) - 21JAN2010 (8) 2. 16FEB2010 (34) - 26FEB2010 (44) 3. 17FEB2010 (35) - 17FEB2010 (35) 4. 15APR2010 (92) - 15MAY2010 (122) 5. 15JUN2010 (153) - 17JUN2010 (155) 6. 20SEP2010 (250) - 04FEB2011 (387) 7. 14OCT2010 (274) - 17NOV2010 (308)
Duration of AE	1. 2 2. 11 3. 1 4. 31 5. 3 6. 138 7. 35
Dose on AE onset	1. 2. 3. 4. 5. 6. 7.
Dose status on AE onset	1.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 590023005

Parameter	Value
	2.
	3.
	4.
	5.
	6.
	7.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 610013001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/610013001/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/80/ASIAN/TAIWAN/YES
Medical history	Asthma, Bronchitis chronic, Constipation, Cough, Duodenal ulcer, Gastric ulcer, Haemorrhoids, Insomnia, Functional gastrointestinal disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BAMBEC, GASCON, MEDICON, MGO, MUCOSOLVAN, NACID, REGROW, ROHYPNOL, SERETIDE EVOHALER, VENTOLIN
Adverse Events (AE) Preferred term	1. Small cell lung cancer stage unspecified
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 16AUG2009 (27) - --------- (.)
Duration of AE	1. .
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. F
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 610013004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/610013004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/41/ASIAN/TAIWAN/YES
Medical history	Bronchitis, Cough, Eczema, Lung neoplasm malignant, Nausea, Pleural effusion, Rash follicular, Tinea pedis, Vomiting
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTEIN EFFERVESCENT, ADALAT, APRESOLINE, ATIVAN, ATROVENT, ATROVENT NEBULIZER, AVASTIN, BRICANYL, BRICANYL SOLUTION, CAPOTEN, CODEINE, COMBIVENT UDV, COMPOUND GLYCYRRHIZA MIXTURE, CRAVIT, DANZEN, DEPAIN, DIOVAN, DIPHENHYDRAMINE HYDROCHLORIDE, DIPHENHYDRAMINI, DORISON, DORMICUM, DOXABEN, DULCOLAX [BISACODYL], FENTANYL HPQ, FLUITRAN, GEMZAR, HARNALIDGE D, INTEBAN CREAM, KCL 20MEQ+NS 500 ML, MEGEST, MGO, MORPHINE, MUCOSOLVAN, MYCOSTATIN, NINCORT ORAL, NORVASC, PREDONINE, PROCTOSEDYL SUPPOSITORY [CINCHOCAINE HCL,HYDROCORT], RASITOL, REGROW, RINDERON, SALINE, SALINE INJECTION, SLOW-K, SOLU-MEDROL, TAITA NO. 5, TAXOTERE, TAZOCIN, TINTEN, TOPAAL, TOPAAL CHEWABLE, TRAMAL, TRANSAMIN, ULTRACET, VENTOLIN INHALER, ZITHROMAX
Adverse Events (AE) Preferred term	1. Lung neoplasm malignant 2. Lobar pneumonia 3. Hypertension 4. Mouth ulceration 5. Diarrhoea 6. Dyspnoea 7. Pneumonia 8. Oedema peripheral 9. Muscular weakness 10. Listeriosis 11. Decreased appetite 12. Headache 13. Lung neoplasm malignant
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MODERATE/NO/YES/YES 8. MODERATE/NO/YES/YES 9. MODERATE/NO/YES/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MILD/NO/NO/YES 13. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 07OCT2009 (26) - 20OCT2009 (39)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 610013004

Parameter	Value
	2. 24NOV2009 (74) - 07DEC2009 (87)
	3. 28NOV2009 (78) - --------- (.)
	4. 29NOV2009 (79) - --------- (.)
	5. 12MAR2010 (182) - 22MAR2010 (192)
	6. 17MAR2010 (187) - 20MAR2010 (190)
	7. 17MAR2010 (187) - 20MAR2010 (190)
	8. 26APR2010 (227) - 11MAY2010 (242)
	9. 26APR2010 (227) - 11MAY2010 (242)
	10. 27APR2010 (228) - 10MAY2010 (241)
	11. 19MAY2010 (250) - --------- (.)
	12. 19MAY2010 (250) - --------- (.)
	13. 30MAY2010 (261) - 30MAY2010 (261)
Duration of AE	1. 14
	2. 14
	3. .
	4. .
	5. 11
	6. 4
	7. 4
	8. 16
	9. 16
	10. 14
	11. .
	12. .
	13. 1
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 610013004

Parameter	Value
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. NONE
	13. NONE
Outcome of event	1. IMPROVED
	2. RESOLVED
	3. IMPROVED
	4. INSUFFICIENT FOLLOW-UP
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. INSUFFICIENT FOLLOW-UP
	12. INSUFFICIENT FOLLOW-UP

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 610013004

Parameter	Value
	13. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 610013005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/610013005/No study medication
Sex/Age/Race/Country/Safety population	FEMALE/84/ASIAN/TAIWAN/NO
Medical history	Arteriosclerosis, Constipation, Depression, Gastric ulcer, Gastrooesophageal reflux disease, Hypertension, Lung neoplasm malignant, Peptic ulcer, Knee arthroplasty, Postmenopause, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	
Adverse Events (AE) Preferred term	1. Oral candidiasis 2. Haemoptysis 3. Pneumonia 4. Insomnia 5. Dermatitis diaper 6. Delirium 7. Non-small cell lung cancer 8. Malignant pleural effusion 9. Lymphangiosis carcinomatosa
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/NO 2. MODERATE/NO/NO/NO 3. MODERATE/NO/NO/NO 4. MILD/NO/NO/NO 5. MILD/NO/NO/NO 6. MODERATE/NO/NO/NO 7. SEVERE/NO/YES/NO 8. MODERATE/NO/YES/NO 9. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 06MAR2010 (.) - 09MAR2010 (.) 2. 09MAR2010 (.) - 09MAR2010 (.) 3. 15MAR2010 (.) - --------- (.) 4. 16MAR2010 (.) - --------- (.) 5. 08MAR2010 (.) - --------- (.) 6. 20MAR2010 (.) - --------- (.) 7. 27FEB2010 (.) - 20MAR2010 (.) 8. 27FEB2010 (.) - 20MAR2010 (.) 9. 27FEB2010 (.) - 20MAR2010 (.)
Duration of AE	1. 4 2. 1 3. . 4. . 5. . 6. . 7. 22 8. 22 9. 22

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 610013005

Parameter	Value
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
	2. REMEDIAL DRUG THERAPY,OTHER
	3. REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY,OTHER
	5. REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY,OTHER
	7. OTHER
	8. OTHER
	9. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. INSUFFICIENT FOLLOW-UP
	4. INSUFFICIENT FOLLOW-UP
	5. INSUFFICIENT FOLLOW-UP
	6. INSUFFICIENT FOLLOW-UP
	7. DEATH
	8. DEATH

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 610013005

Parameter	Value
	9. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 650023003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/650023003/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/33/ASIAN/HONGKONG/YES
Medical history	Asthma, Depression, Insomnia, Migraine
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALPRAZOLAM, AUGMENTIN, DOLOGESIC [DEXTROPROPOXYPHENE NAPSILATE,PARACETAMOL], LASIX, PANADOL, PANTOLOC, PEPCIDINE, STILNOX, SYMBICORT, SYR. MORPHINE, SYR.KCL, SYR.MORPHINE, TAZOSIN, TOLVON, TRAMADOL, VENTOLIN, ZOLOFT
Adverse Events (AE) Preferred term	1. Pyrexia 2. Vaginal haemorrhage 3. Haemoptysis 4. Cellulitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/YES/NO
Start/stop date of event with relative date	1. 14MAR2010 (2) - 18MAR2010 (6) 2. 14MAR2010 (2) - 18MAR2010 (6) 3. 17MAR2010 (5) - 18MAR2010 (6) 4. 30SEP2010 (202) - 20OCT2010 (222)
Duration of AE	1. 5 2. 5 3. 2 4. 21
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. F
Action taken	1. REMEDIAL DRUG THERAPY 2. NONE 3. NONE 4. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 650023003

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 660013012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/660013012/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/44/ASIAN/MALAYSIA/YES
Medical history	Anaemia, Transfusion, Epistaxis, Menorrhagia, Platelet transfusion, Evans syndrome
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AZITHROMYCIN, CALAMINE 2% SULPHUR, CALCIUM LACTATE, CALCIUM LACTATE 0.3G, CLEXANE, FERROUS FUMARATE, FOLIC ACID, IV HYDROCORTISONE, IV RANITIDINE, IV TAZOSCIN, PREDNISOLONE, PRENISOLONE, PROVERA, SAFERON, TAB AZITHROMYCIN, TAB RANITIDINE, TRANEXAMIC ACID
Adverse Events (AE) Preferred term	1. Acne 2. Pyrexia 3. Cough 4. Menorrhagia 5. Menorrhagia 6. Menorrhagia
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/YES/YES/YES 5. MODERATE/YES/YES/YES 6. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 22AUG2010 (26) - 20MAR2011 (236) 2. 20OCT2010 (85) - 22OCT2010 (87) 3. 20OCT2010 (85) - 22OCT2010 (87) 4. 02JAN2011 (159) - 11JAN2011 (168) 5. 20MAR2011 (236) - 24MAR2011 (240) 6. 30MAY2011 (307) - 19JUN2011 (327)
Duration of AE	1. 211 2. 3 3. 3 4. 10 5. 5 6. 21
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 660013012

Parameter	Value
	5. .
	6. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 670013005

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/670013005/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/72/ASIAN/PHILIPPINES/YES
Medical history	Arteriosclerosis, Cardiomegaly, Cor pulmonale, Oedema peripheral, Gastritis, Hypertension, Pulmonary tuberculosis, Liver function test abnormal, Tricuspid valve incompetence, Postmenopause, Dyslipidaemia, Venous insufficiency
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CENTRUM, DAFLON [DIOSMIN + HESPERIDIN], DILTIAZEM, DORNER, FLUIMUCIL, FUROSEMIDE, LANOXIN, LASIX, LEVOPRONT, METOPROLOL, MOSEGOR VITA, OMEPRAZOLE, OMEPRON, SIMVASTATIN, VASTAREL
Adverse Events (AE) Preferred term	1. Chest pain 2. Cough 3. Ecchymosis 4. Hepatic congestion 5. Epistaxis 6. Haemoptysis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/YES/YES/YES
Start/stop date of event with relative date	1. 29MAY2008 (37) - 03JUN2008 (42) 2. 02JUN2008 (41) - 25JUN2008 (64) 3. 11JUN2008 (50) - 04JUL2008 (73) 4. 24SEP2008 (155) - --------- (.) 5. 12APR2009 (355) - 12APR2009 (355) 6. 12APR2009 (355) - 12APR2009 (355)
Duration of AE	1. 6 2. 24 3. 24 4. . 5. 1 6. 1
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. . 2. . 3. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 670013005

Parameter	Value
	4. .
	5. .
	6. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. OTHER
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 670013015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/670013015/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/47/ASIAN/PHILIPPINES/YES
Medical history	Metastases to bone, Lung carcinoma cell type unspecified stage III, Fracture, Pleural effusion, Road traffic accident, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTONE [SPIRINOLACTONE], ALDAZIDE, ASCORBIC ACID, BARIUM SULFATE, BUSCOPAN, CASTOR OIL, CEFTAZIDIME, CENTRUM, CIPROFLOXACIN, CLEXANE, DAFLON [DIOSMIN + HESPERIDIN], DOLCET, DOMPERIDONE, ENOXAPARIN, FLUIMUCIL, FRESH FROZEN PLASMA, FUROSEMIDE, HYDROCORTISONE, LILAC, LORATADINE, LUNG CARE PLUS [VITAMIN C 65MG, VITAMIN D 5MG, PANTOTHENIC ACID 5MG, CALCIUM 100, MORIAMIN FORTE [5-OXYANTHRANILIC ACID,CA PANTOTHENAT,FOLIC ACID,I-ISOLEUCIN,I-AC, PANKREOFLAT [DIMETHICONE 80MG, PACREATIN 170MG], POLYNERV [POLYNERV INGREDIENTS VIT B1 500MG, VIT B6 250MG, VIT B12 1MG], POLYNERVE [VITAMIN SUPPLEMENT: VIT B1 VIT B6, VIT B12], SIMVASTATIN, TRAMADOL HCL, VITAMIN K, WARFARIN
Adverse Events (AE) Preferred term	1. Haematoma 2. Haematoma 3. Ascites 4. Cough 5. Metastases to lung 6. Hepatic cirrhosis 7. Metastases to liver 8. Abdominal pain 9. Hypoaesthesia 10. Muscle fatigue 11. Pleural effusion 12. Acute respiratory failure
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/YES/YES 4. MILD/NO/NO/YES 5. SEVERE/NO/NO/YES 6. MILD/NO/NO/YES 7. SEVERE/NO/YES/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/YES/YES 12. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 05FEB2009 (4) - 17FEB2009 (16) 2. 06FEB2009 (5) - 17FEB2009 (16) 3. 28MAR2009 (55) - --------- (.) 4. 03MAY2009 (91) - 13MAY2009 (101)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 670013015

Parameter	Value
	5. 02JUN2009 (121) - --------- (.)
	6. 02JUN2009 (121) - --------- (.)
	7. 02JUN2009 (121) - --------- (.)
	8. 10JUN2009 (129) - --------- (.)
	9. 16JUN2009 (135) - --------- (.)
	10. 16JUN2009 (135) - --------- (.)
	11. 11SEP2009 (222) - 20SEP2009 (231)
	12. 18SEP2009 (229) - 20SEP2009 (231)
Duration of AE	1. 13
	2. 12
	3. .
	4. 11
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. 10
	12. 3
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 670013015

Parameter	Value
	11.
	12.
Action taken	1. NONE
	2. NONE
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. NONE
	7. OTHER
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	12. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. IMPROVED
	4. RESOLVED
	5. UNCHANGED
	6. UNCHANGED
	7. UNCHANGED
	8. UNCHANGED
	9. UNCHANGED
	10. UNCHANGED
	11. IMPROVED
	12. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 670013021

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/670013021/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/83/ASIAN/PHILIPPINES/YES
Medical history	Aortic arteriosclerosis, Diabetes mellitus, Hypertension, Peripheral artery aneurysm, Myocardial fibrosis, Pneumonia, Pulmonary tuberculosis, Tricuspid valve incompetence, Mitral valve sclerosis, Deficiency anaemia, Emphysema
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMVASC, ANSIMAR, ASCORBIC ACID, BENAZIPRIL, FERROUS SULFATE, FLUIMUCIL, GLIMEPIRIDE, HYTRIN, LACTULOSE, LEVOFLOXACIN, OMEPRAZOLE, PIPERACILLIN-TAZOBACTAM, QUADTAB, SIMVASTATIN
Adverse Events (AE) Preferred term	1. Constipation 2. Cerebrovascular accident 3. Cardio-respiratory arrest
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/YES/YES/YES 3. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 28AUG2009 (1) - --------- (.) 2. 02SEP2009 (6) - --------- (.) 3. 03SEP2009 (7) - 03SEP2009 (7)
Duration of AE	1. . 2. . 3. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg
Dose status on AE onset	1. . 2. . 3. F
Action taken	1. REMEDIAL DRUG THERAPY 2. STUDY DRUG DISCONTINUED PERMANENTLY 3. NONE
Outcome of event	1. UNCHANGED 2. UNCHANGED 3. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-670013021[2)]	SUSPECTED STROKE（PT：脳血管発作） 治験担当医はリバーロキサバンと報告事象との関連性はあると判断した。弊社は、虚血性である可能性が高く薬効欠如とも考えられ、また原疾患（肺塞栓症）及び合併症（高血圧、糖尿病）による影響とも考えられることから、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 670013022

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/670013022/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/58/ASIAN/PHILIPPINES/YES
Medical history	Gouty arthritis, Haemoptysis, Hypertension, Oedema peripheral, Congestive cardiomyopathy, Pulmonary arterial hypertension, Congenital coronary artery malformation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ARCOXIA, CEFUROXIME, CELEBREX, CO-AMOXICLAV, COLCHICINE, DILZEM, DOLCET, ENOXAPARIN, ERDOSTEINE, FERN C, LANOXIN, PARACETAMOL, SILDENAFIL, SOLU-CORTEF, TRAMADOL, WARFARIN
Adverse Events (AE) Preferred term	1. Gouty arthritis 2. Muscle strain 3. Productive cough 4. Conjunctival haemorrhage 5. Hepatic steatosis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/NO 5. MILD/NO/YES/NO
Start/stop date of event with relative date	1. 16NOV2010 (5) - 21NOV2010 (10) 2. 07DEC2010 (26) - 13DEC2010 (32) 3. 09MAR2011 (118) - 13MAR2011 (122) 4. 21MAY2011 (191) - 24MAY2011 (194) 5. 17JUN2011 (218) - --------- (.)
Duration of AE	1. 6 2. 7 3. 5 4. 4 5. .
Dose on AE onset	1. 2. 3. 4. 5.
Dose status on AE onset	1. 2. 3. 4. 5.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 670013022

Parameter	Value
Outcome of event	5. NONE 1. RESOLVED 2. RESOLVED 3. RESOLVED 4. RESOLVED 5. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 670013023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/670013023/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/37/ASIAN/PHILIPPINES/YES
Medical history	Haemoptysis, Lower respiratory tract infection, Pulmonary infarction, Ventricular septal defect, Eisenmenger's syndrome, Pulmonary arterial hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALDACTONE [SPIRINOLACTONE], ALLOPURINOL, CIPROFLOXACIN, DOLCET, DUAVENT, FLUIMUCIL, FUROSEMIDE, HYDROCHLOROTHIAZIDE, KALIUM DURULE, LANOXIN, LEVOFLOXACIN, OMEPRAZOLE, PLASIL, SILDENAFIL, SINECOD TABLET
Adverse Events (AE) Preferred term	1. Hypokalaemia 2. Menorrhagia 3. Hypokalaemia 4. Pneumonia 5. Eisenmenger's syndrome 6. Arthritis 7. Hyperuricaemia 8. Upper respiratory tract infection 9. Upper respiratory tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/YES/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 26FEB2011 (4) - 28FEB2011 (6) 2. 28FEB2011 (6) - 01MAR2011 (7) 3. 05MAR2011 (11) - 07MAR2011 (13) 4. 19MAR2011 (25) - --------- (.) 5. 28MAR2011 (34) - 06JUN2011 (104) 6. 06MAY2011 (73) - 18MAY2011 (85) 7. 10MAY2011 (77) - 12AUG2011 (171) 8. 10AUG2011 (169) - 19AUG2011 (178) 9. 07SEP2011 (197) - --------- (.)
Duration of AE	1. 3 2. 2 3. 3 4. . 5. 71 6. 13 7. 95

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 670013023

Parameter	Value
	8. 10
	9. .
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. IMPROVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 670013023

Parameter	Value
	9. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 680023011

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/680023011/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/67/ASIAN/SINGAPORE/YES
Medical history	Pyrexia, Hyperlipidaemia, Hypertension, Hypoalbuminaemia, Scoliosis, Spinal column stenosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AQUEOUS CREAM [LIQUID PARAFFIN], ATENOLOL, AUGMENTIN, BENZYAMINE [LOZENGES FOR LARYNGITIS], CALCIUM/VIT D, CELEBREX, CLEXANE, CODEINE, ENOXAPARIN, FRUSEMIDE, HYDROCHLOROTHIAZIDE, HYDROXYZINE, LOVASTATIN, MAGNESIUM TRISILICATE, NIFEDIPINE, NORMAL SALINE, OMEPRAZOLE, PARACETAMOL, PIRITON, POTASSIUM CHLORIDE, STEMETIL, TRAMADOL, WARFARIN
Adverse Events (AE) Preferred term	1. Oedema peripheral 2. Cellulitis 3. Pollakiuria 4. Sciatica 5. Dyspnoea exertional 6. Laryngitis 7. Rhinorrhoea 8. Headache 9. Renal mass 10. Contusion 11. Dizziness 12. Abdominal pain upper 13. Hyponatraemia 14. Pruritus 15. Dry skin 16. Purpura 17. Contusion 18. Contusion 19. Contusion 20. Contusion 21. Scoliosis 22. Spinal column stenosis 23. Scoliosis 24. Spinal column stenosis 25. Hypoaesthesia 26. Pain in extremity
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 680023011

Parameter	Value
	8. MILD/NO/NO/YES
	9. MILD/NO/NO/YES
	10. MILD/NO/NO/YES
	11. MILD/NO/NO/YES
	12. MILD/NO/NO/YES
	13. MILD/NO/NO/YES
	14. MILD/NO/NO/YES
	15. MILD/NO/NO/YES
	16. MILD/YES/NO/YES
	17. MILD/YES/NO/YES
	18. MILD/YES/NO/YES
	19. MILD/YES/NO/YES
	20. MILD/YES/NO/YES
	21. SEVERE/NO/YES/YES
	22. SEVERE/NO/YES/YES
	23. MILD/NO/NO/YES
	24. MILD/NO/NO/YES
	25. MILD/NO/NO/YES
	26. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --JUL2008 (.) - --------- (.)
	2. --AUG2008 (.) - 26AUG2008 (69)
	3. --AUG2008 (.) - --------- (.)
	4. --SEP2008 (.) - --------- (.)
	5. --OCT2008 (.) - 14OCT2008 (118)
	6. --OCT2008 (.) - 14OCT2008 (118)
	7. --AUG2008 (.) - --------- (.)
	8. 19JUN2008 (1) - 19JUN2008 (1)
	9. 20JUN2008 (2) - --------- (.)
	10. 21JUN2008 (3) - 23JUN2008 (5)
	11. 21JUN2008 (3) - 27JUN2008 (9)
	12. 22JUN2008 (4) - 22JUN2008 (4)
	13. 24JUN2008 (6) - 29JUN2008 (11)
	14. 28JUN2008 (10) - --JUL2008 (.)
	15. 28JUN2008 (10) - --JUL2008 (.)
	16. 19AUG2008 (62) - --AUG2008 (.)
	17. 01SEP2008 (75) - 02OCT2008 (106)
	18. 01SEP2008 (75) - 02OCT2008 (106)
	19. 01SEP2008 (75) - 02OCT2008 (106)
	20. 01SEP2008 (75) - 02OCT2008 (106)
	21. 19NOV2008 (154) - 20NOV2008 (155)
	22. 19NOV2008 (154) - 20NOV2008 (155)
	23. 21NOV2008 (156) - --------- (.)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 680023011

Parameter	Value
	24. 21NOV2008 (156) - --------- (.)
	25. 02DEC2008 (167) - 29DEC2008 (194)
	26. 15DEC2008 (180) - 14JAN2009 (210)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. 1
	9. .
	10. 3
	11. 7
	12. 1
	13. 6
	14. .
	15. .
	16. .
	17. 32
	18. 32
	19. 32
	20. 32
	21. 2
	22. 2
	23. .
	24. .
	25. 28
	26. 31
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 680023011

Parameter	Value
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 680023011

Parameter	Value
	4. REMEDIAL DRUG THERAPY
	5. OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. REMEDIAL DRUG THERAPY
	16. NONE
	17. NONE
	18. NONE
	19. NONE
	20. NONE
	21. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	22. STUDY DRUG DISCONTINUED AND RESTARTED,OTHER
	23. NONE
	24. NONE
	25. NONE
	26. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. UNCHANGED
	4. UNCHANGED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. RESOLVED
	16. RESOLVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 680023011

Parameter	Value
	20. RESOLVED
	21. RESOLVED
	22. RESOLVED
	23. UNCHANGED
	24. UNCHANGED
	25. RESOLVED
	26. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700023007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/80/WHITE/NEW ZEALAND/YES
Medical history	Cellulitis, Constipation, Fluid retention, Osteoarthritis, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CODEINE PHOSPHATE, COLOXYL WITH SENNA, ENERLYTE [GLUCOSE+POTASS. CHLORIDE+SODIUM ACID CITRATE+SODIUM CHLORIDE,DIARRHOEA, ENOXAPARIN, FLUCLOXACILLIN, FRUMIL, FRUSEMIDE, HEPARIN, LACTULOSE, M-ESLON, MORPHINE, ONDANSETRON, PARACETAMOL, PENICILLIN, SEVREDOL, TRAMADOL, WARFARIN
Adverse Events (AE) Preferred term	1. Cellulitis 2. Cardiac failure 3. Cellulitis 4. Diarrhoea
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 10SEP2007 (8) - 17SEP2007 (15) 2. 10SEP2007 (8) - 10SEP2007 (8) 3. 17SEP2007 (15) - 05OCT2007 (33) 4. 29SEP2007 (27) - 19OCT2007 (47)
Duration of AE	1. 8 2. 1 3. 19 4. 21
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY 2. NONE 3. REMEDIAL DRUG THERAPY 4. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023007

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023015

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700023015/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/60/WHITE/NEW ZEALAND/YES
Medical history	Body mass index increased, Chest pain, Disorientation, Diplopia, Hepatic cyst, Osteoarthritis, Arthralgia, Vertigo, Food intolerance
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	DEER VELVET CAPSULES, IBUPROFEN, PANADOL, TRAMADOL, VOLTAREN
Adverse Events (AE) Preferred term	1. Dizziness 2. Groin pain 3. Occult blood positive 4. Influenza 5. Lower gastrointestinal haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/YES/NO/YES 4. MODERATE/NO/NO/NO 5. MILD/YES/NO/NO
Start/stop date of event with relative date	1. 25JUL2008 (22) - --------- (.) 2. 17FEB2009 (229) - --------- (.) 3. 20MAY2009 (321) - 23MAY2009 (324) 4. 20JUL2009 (382) - 04AUG2009 (397) 5. 25JUL2009 (387) - 25JUL2009 (387)
Duration of AE	1. . 2. . 3. 4 4. 16 5. 1
Dose on AE onset	1. 20 mg 2. 20 mg 3. 20 mg 4. 20 mg 5. 20 mg
Dose status on AE onset	1. . 2. . 3. . 4. F 5. F
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY 3. NONE 4. REMEDIAL DRUG THERAPY 5. NONE
Outcome of event	1. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023015

Parameter	Value
	2. IMPROVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023030

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700023030/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/78/WHITE/NEW ZEALAND/YES
Medical history	Chest pain, Gastrooesophageal reflux disease, Haemorrhoids, Hypercholesterolaemia, Hypertension, Osteoporosis, Pubis fracture, Hip arthroplasty, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACCURETIC, ASPIRIN, BEZAFIBRILATE, CAL D FORTE, CALCIUM CARBONATE, DEPRIM, ENOXAPARIN, FELODIPINE, FOSAMAX, GTN SPRAY, IBUPROFEN, METOPROLOL, MORPHINE, OMEPREZOLE, PARACETAMOL, SEVEREDOL, WARFARIN
Adverse Events (AE) Preferred term	1. Pleuritic pain 2. Limb injury 3. Limb injury 4. Haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 31AUG2009 (4) - 02SEP2009 (6) 2. 07OCT2009 (41) - 12DEC2009 (107) 3. 09DEC2009 (104) - 20FEB2010 (177) 4. 28JAN2010 (154) - 01MAR2010 (186)
Duration of AE	1. 3 2. 67 3. 74 4. 33
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. NONE 4. OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023030

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023031

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700023031/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/34/WHITE/NEW ZEALAND/YES
Medical history	Pelvic fracture, Haemothorax, Arthralgia, Pulmonary embolism, Perirenal haematoma, Splenic rupture, Traumatic liver injury
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXYCILLIN, AUGMENTIN, BENZYLPENICILLIN, CEPHAZOLIN, CLEXANE, DEXAMETHASONE, DEXTROSE SALINE WITH 20 MMOL KCL, DICLOFENAC, FENTANYL, FLUCLOXACILLIN, MIDAZOLAM, MORPHINE, NORMAL SALINE, ONDANSETRON, OPTREX DRY EYE DROPS, PARACETAMOL, PARECOXIB, PLASMALYTE, PROPOFOL, SEVREDOL, TETANUS VACCINATION, TRAMADOL
Adverse Events (AE) Preferred term	1. Eyelid skin dryness 2. Headache 3. Contusion 4. Impetigo 5. Laceration 6. Wound infection 7. Wound infection 8. Contusion 9. Headache
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MODERATE/NO/YES/YES 8. MILD/YES/NO/YES 9. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 14SEP2009 (4) - 30SEP2009 (20) 2. 21OCT2009 (41) - 28OCT2009 (48) 3. 28NOV2009 (79) - 03DEC2009 (84) 4. 16FEB2010 (159) - 15MAR2010 (186) 5. 30MAR2010 (201) - 12MAY2010 (244) 6. 07APR2010 (209) - 17APR2010 (219) 7. 23APR2010 (225) - 12MAY2010 (244) 8. 15AUG2010 (339) - 27SEP2010 (382) 9. 26AUG2010 (350) - 02SEP2010 (357)
Duration of AE	1. 17 2. 8 3. 6 4. 28 5. 44

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023031

Parameter	Value
	6. 11
	7. 20
	8. 44
	9. 8
Dose on AE onset	1. 15 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. NONE
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023031

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023033

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700023033/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/NEW ZEALAND/YES
Medical history	Arthritis, Cholecystectomy, Bladder neck suspension, Gastritis, Hypertension, Hysterectomy, Muscular weakness, Spinal laminectomy, Hip arthroplasty, Urinary incontinence, Sinus operation, Chondroplasty
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, ATIVAN, BENDROFLUAZIDE, BISACODYL SUPPOSITORY, BOTOX, CENTRUM, CODEINE, CODINE PHOSPHATE, COLGOUT, DIURIN, ENOXAPARIN, FENTANYL, FISH OIL, FLORA RESTORE, GAVISON, GENTAMYCIN, GLUCOSAMINE/CONDROITON, GLYCERIN SUPPOSITORY, GLYCERYL TRINITRATE, ISOSORBIDE MONONITRATE, LACTULOSE, LAXSOL, LOSEC, M-ESLON, MAGNESIUM, METOCLOPRAMIDE, MIDAZOLAM, MORPHINE, NORFLOXACIN, NUTRALIFE HERBAL DIURETIC, ONDANSETRON, PARACETAMOL, PLASMALYTE, PREDNISONE, PROPOFOL, RANITIDINE, SEVEREDOL, SEVREDOL, SIMVASTATIN, SPIROTONE, STEMITIL, VESICARE, WARFARIN
Adverse Events (AE) Preferred term	1. Anxiety 2. Localised infection 3. Epistaxis 4. Oedema peripheral 5. Gout 6. Urinary tract infection 7. Pulmonary oedema 8. Nausea 9. Abdominal pain upper 10. Nausea 11. Constipation 12. Constipation 13. Muscular weakness 14. Nausea 15. Cardiac failure congestive 16. Cystitis 17. Cystitis 18. International normalised ratio increased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MODERATE/NO/YES/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023033

Parameter	Value
	12. MILD/NO/NO/YES
	13. MODERATE/NO/YES/YES
	14. MILD/NO/NO/YES
	15. MILD/NO/NO/YES
	16. MILD/NO/NO/YES
	17. MILD/NO/NO/YES
	18. MILD/YES/NO/YES
Start/stop date of event with relative date	1. --OCT2009 (.) - --------- (.)
	2. --JUL2010 (.) - --------- (.)
	3. 06OCT2009 (12) - 06OCT2009 (12)
	4. 01NOV2009 (38) - --------- (.)
	5. 03NOV2009 (40) - --------- (.)
	6. 05NOV2009 (42) - 08NOV2009 (45)
	7. 16DEC2009 (83) - 24DEC2009 (91)
	8. 10JAN2010 (108) - 12JAN2010 (110)
	9. 17MAR2010 (174) - --------- (.)
	10. 17MAR2010 (174) - 17MAR2010 (174)
	11. 18MAR2010 (175) - 18MAR2010 (175)
	12. 12APR2010 (200) - 16APR2010 (204)
	13. 13APR2010 (201) - 26APR2010 (214)
	14. 14APR2010 (202) - 15APR2010 (203)
	15. 19APR2010 (207) - --------- (.)
	16. 24APR2010 (212) - 30APR2010 (218)
	17. 21MAY2010 (239) - --------- (.)
	18. 10JUN2010 (259) - 14JUN2010 (263)
Duration of AE	1. .
	2. .
	3. 1
	4. .
	5. .
	6. 4
	7. 9
	8. 3
	9. .
	10. 1
	11. 1
	12. 5
	13. 14
	14. 2
	15. .
	16. 7
	17. .

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023033

Parameter	Value
	18. 5
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023033

Parameter	Value
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. REMEDIAL DRUG THERAPY
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. NONE
	16. REMEDIAL DRUG THERAPY
	17. REMEDIAL DRUG THERAPY
	18. DOSE OF STUDY DRUG REDUCED
Outcome of event	1. UNCHANGED
	2. UNCHANGED
	3. RESOLVED
	4. IMPROVED
	5. IMPROVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. UNCHANGED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. RESOLVED
	14. RESOLVED
	15. UNCHANGED
	16. RESOLVED
	17. UNCHANGED
	18. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023036

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700023036/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/66/WHITE/NEW ZEALAND/YES
Medical history	Breast cancer, Renal failure chronic, Diabetes mellitus, Gout, Hypertension, Obesity, Postmenopause, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CEFACLOR, CEFUROXIME, CHAKRA AND AURA LOTION NOS, CLEXANE, CODEINE PHOSPHATE, DICLOFENAC, ENALAPRIL, ENOXAPARIN, FEMARA, GELOFUSION, GENTAMYCIN, GIK INFUSION, GLIPAZIDE, METFORMIN, METOPROLOL SR, NITROFURANTOIN, NORMAL SALINE, PARACETAMOL, PREDNISONE, SIMVASTATIN, WARFARIN
Adverse Events (AE) Preferred term	1. Pruritus 2. Urinary tract infection 3. Diarrhoea 4. Asthenia 5. Liver function test abnormal 6. Hypotension 7. Hyperglycaemia 8. Dehydration 9. International normalised ratio decreased 10. Headache 11. Gout 12. Gait disturbance 13. Muscular weakness
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. SEVERE/NO/YES/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/NO/YES 12. MILD/NO/NO/YES 13. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 09JUN2010 (7) - 23JUN2010 (21) 2. 06AUG2010 (65) - 19AUG2010 (78) 3. 08AUG2010 (67) - 10AUG2010 (69) 4. 09AUG2010 (68) - 11AUG2010 (70) 5. 10AUG2010 (69) - 19AUG2010 (78) 6. 10AUG2010 (69) - 12AUG2010 (71) 7. 10AUG2010 (69) - 11AUG2010 (70)

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023036

Parameter	Value
	8. 10AUG2010 (69) - 13AUG2010 (72)
	9. 10AUG2010 (69) - 12AUG2010 (71)
	10. 13AUG2010 (72) - 13AUG2010 (72)
	11. 23SEP2010 (113) - 23NOV2010 (174)
	12. 18OCT2010 (138) - --------- (.)
	13. 28OCT2010 (148) - --------- (.)
Duration of AE	1. 15
	2. 14
	3. 3
	4. 3
	5. 10
	6. 3
	7. 2
	8. 4
	9. 3
	10. 1
	11. 62
	12. .
	13. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700023036

Parameter	Value
	11.
	12.
	13.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY,OTHER
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. REMEDIAL DRUG THERAPY
	12. NONE
	13. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED
	13. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700033004/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/67/WHITE/NEW ZEALAND/YES
Medical history	Seasonal allergy, Presyncope, Meniscus removal
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ATENOLOL, BETALOC, CARTIA [ACETYLSALICYLIC ACID], ENOXAPARIN, GTN SPRAY, ISOSORBIDE MONONITRATE, OXYGEN, PANADOL [PARACETAMOL ALONE: 500MG PER TABLET], SIMVASTATIN, WARFARIN
Adverse Events (AE) Preferred term	1. Chest pain 2. Angina pectoris 3. Hyperlipidaemia 4. Headache
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 26OCT2007 (11) - 25NOV2007 (41) 2. 26NOV2007 (42) - 31JUL2008 (290) 3. 26NOV2007 (42) - --------- (.) 4. 20DEC2007 (66) - 07MAY2008 (205)
Duration of AE	1. 31 2. 249 3. . 4. 140
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY,OTHER 3. REMEDIAL DRUG THERAPY 4. OTHER
Outcome of event	1. WORSENED 2. RESOLVED 3. IMPROVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033004

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033006

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700033006/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/69/WHITE/NEW ZEALAND/YES
Medical history	Arthritis, Asthma, Bronchiectasis, Cholecystectomy, Cholecystitis, Gastrooesophageal reflux disease, Irritable bowel syndrome, Osteoporosis, Vulvovaginal candidiasis, Sinusitis, Talipes, Uterine prolapse repair, Varicose vein, Postmenopause
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALENDRONATE, AUGMENTIN, BRUFEN, BRUFEN SR, BUCCASTEM, BUSCOPAN, CALCIFEROL, CODRAL COLD & FLU DAY CASPULES, CODRAL COLD & FLU NIGHT CAPSULES, DIFFLAM THROAT LOZENGE (BENZYDAMINE 3 MG + CETYLPYRIDINIUM CHLORIDE 1.33 MG), ENOXAPARIN, LOSEC, MAXOLON, OMEPRAZOLE (LOSEC), PANADEINE, PANADOL, PARADEX, SODIUM CHLORIDE 0.9%, SODIUM CHLORIDE 0.9% WITH KCL 20 MMOL, TILCOTIL, VITAMIN C TABLET, WARFARIN, ZOPI CLONE, ZOPICLONE, ZOPLICONE
Adverse Events (AE) Preferred term	1. Pain in extremity 2. Contusion 3. Gastroenteritis 4. Pain in extremity 5. Sinusitis 6. Vomiting 7. Upper respiratory tract infection 8. Wound haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MODERATE/NO/YES/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 17JAN2008 (10) - 30JAN2008 (23) 2. 24MAR2008 (77) - 22JAN2009 (381) 3. 22APR2008 (106) - 26APR2008 (110) 4. 07MAY2008 (121) - 05SEP2008 (242) 5. 16JUL2008 (191) - 21JUL2008 (196) 6. 31JUL2008 (206) - 01AUG2008 (207) 7. 21OCT2008 (288) - 16NOV2008 (314) 8. 26JAN2009 (385) - --------- (.)
Duration of AE	1. 14 2. 305 3. 5 4. 122 5. 6 6. 2

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033006

Parameter	Value
	7. 27
	8. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. OTHER
	2. NONE
	3. REMEDIAL DRUG THERAPY,OTHER
	4. DOSE OF STUDY DRUG REDUCED
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033006

Parameter	Value
	8. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033025

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700033025/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/68/WHITE/NEW ZEALAND/YES
Medical history	Basal cell carcinoma, Contusion, Depression, Hypertension, Local swelling, Local swelling, Obesity, Osteoarthritis, Rectal polyp, Rhinitis, Sinus headache, Sleep apnoea syndrome, Varicose vein, Postmenopause, Sinus operation, Cataract operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACCUPRIL, ASPIRIN EC, CODEINE PHOSPHATE, DICLOFENAC, ENOXAPARIN, FLU VACCINE, GASTROLYTE, GLUCOSAMINE COMPLEX, IBUPROFEN, MAXOLON, OTRIVINE NASAL SPRAY, PARACETAMOL, STEMETIL PRN, THOMPSON'S GLUCOSAMINE, WARFARIN, ZYRTEC (CETIRIZINE HYDROCHLORIDE)
Adverse Events (AE) Preferred term	1. Contusion 2. Contusion 3. Musculoskeletal pain 4. Pain in extremity 5. Chest pain 6. Dizziness 7. Headache 8. Hypertension 9. Subdural haematoma
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. SEVERE/YES/YES/YES
Start/stop date of event with relative date	1. 06MAR2009 (2) - 08APR2009 (35) 2. 09MAR2009 (5) - 12APR2009 (39) 3. 23APR2009 (50) - 01MAY2009 (58) 4. 23APR2009 (50) - 01MAY2009 (58) 5. 29APR2009 (56) - 29APR2009 (56) 6. 29APR2009 (56) - 29APR2009 (56) 7. 29APR2009 (56) - 29APR2009 (56) 8. 15MAY2009 (72) - 13JUL2009 (131) 9. 12JUL2009 (130) - --------- (.)
Duration of AE	1. 34 2. 35 3. 9 4. 9 5. 1

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033025

Parameter	Value
	6. 1
	7. 1
	8. 60
	9. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. OTHER
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033025

Parameter	Value
	9. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033035

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700033035/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/53/WHITE/NEW ZEALAND/YES
Medical history	Asthma, Atelectasis, Bronchitis, Hiatus hernia, Pleural effusion, Pleurisy, Pulmonary infarction, Dyslipidaemia, Varicose vein operation, Spinal operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BRICANYL/TERBUTALINE PRN, CHONDROITIN, DICLOFENAC, ENOXAPARIN, FISH OIL, GLUCOSAMINE, MORPHINE PRN, OMEPRAZOLE, PARACETAMOL PRN, PULMICORT/BUDESONIDE, SEVREDOL PRN, SIMVASTATIN, TRAMADOL, WARFARIN, ZOPICLONE PRN
Adverse Events (AE) Preferred term	1. Haemoptysis 2. Pleurisy 3. Haematospermia 4. Cough
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/YES/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 09JUL2009 (4) - 25JUL2009 (20) 2. 11JUL2009 (6) - 28JUL2009 (23) 3. 11SEP2009 (68) - 11SEP2009 (68) 4. 06OCT2009 (93) - --------- (.)
Duration of AE	1. 17 2. 18 3. 1 4. .
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. OTHER 3. NONE 4. OTHER
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033035

Parameter	Value
	4. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033038

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700033038/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/74/WHITE/NEW ZEALAND/YES
Medical history	Skin neoplasm excision, Lentigo maligna stage unspecified, Inguinal hernia repair, Herpes zoster
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, ENOXAPARIN, PARACETAMOL, PARACETAMOL PRN, VITAMIN C, WARFARIN
Adverse Events (AE) Preferred term	1. Prostatic specific antigen increased 2. Accidental overdose 3. Contusion 4. Nasopharyngitis 5. Basal cell carcinoma 6. Prostate cancer
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/YES/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/YES/YES
Start/stop date of event with relative date	1. 13OCT2009 (7) - --------- (.) 2. 15OCT2009 (9) - 15OCT2009 (9) 3. 17OCT2009 (11) - 27OCT2009 (21) 4. 25NOV2009 (50) - 16DEC2009 (71) 5. 26JAN2010 (112) - 26JAN2010 (112) 6. 29JAN2010 (115) - --------- (.)
Duration of AE	1. . 2. 1 3. 11 4. 22 5. 1 6. .
Dose on AE onset	1. 2. 3. 4. 5. 6.
Dose status on AE onset	1. 2. 3. 4. 5. 6.
Action taken	1. OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033038

Parameter	Value
	2. STUDY DRUG DISCONTINUED AND RESTARTED
	3. NONE
	4. REMEDIAL DRUG THERAPY
	5. OTHER
	6. OTHER
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033040

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700033040/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/60/ASIAN/NEW ZEALAND/YES
Medical history	Tendon operation, Heart sounds abnormal, Hypertension, Inguinal hernia repair, Thrombocytopenia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	BENDROFLUAZIDE, RENITEC
Adverse Events (AE) Preferred term	1. Pulmonary arterial pressure increased 2. Lower respiratory tract infection
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. SEVERE/NO/YES/NO
Start/stop date of event with relative date	1. 01DEC2009 (47) - --------- (.) 2. 02NOV2010 (383) - 09NOV2010 (390)
Duration of AE	1. . 2. 8
Dose on AE onset	1. 20 mg 2. 20 mg
Dose status on AE onset	1. . 2. F
Action taken	1. OTHER 2. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. IMPROVED 2. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033042

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700033042/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/73/WHITE/NEW ZEALAND/YES
Medical history	Angina pectoris, Cellulitis, Retinal vein occlusion, Constipation, Hypertension, Intervertebral disc operation, Myocardial infarction, Osteoarthritis, Skin ulcer, Spinal decompression, Thrombophlebitis superficial, Type 2 diabetes mellitus, Colitis ulcerative, Postmenopause, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACTRAPID, AQUEOUS CREAM [EMULSIFYING WAX,PARAFFIN, LIQUID,WHITE SOFT PARAFFIN], ATRACURIUM BOLUS, BETALOC CR, CARTIA, CEFOXITIN, CILAZAPRIL, CLONIDINE, COLOXYL WITH SENNA PRN, CYCLIZINE, DEXAMETHASONE, DIASIP, DURIDE, DURIDE CR, FENTANYL, FERROGRADUMET (FERROUS SULPHATE), FLUCLOXACILLIN, FORTISIP, FRUSEMIDE, GLIPIZIDE, GLYCOPYRROLATE, GTN, HEPARIN, HYDROXYCOBALAMIN (NEO-B12), IMODIUM, KLEAN-PREP, LACTULOSE PRN, LEMNIS FATTY CREAM HC, LIPITOR, LOSEC, MAXALON, METARAMINOL, METFORMIN, METOPROLOL, METOPROLOL CR, METRONIDAZOLE, MIDAZOLAM, MORPHINE, NEOSTIGMINE, ONDANSETRON, PARACETAMOL, PARACETAMOL PRN, PLASMALYTE, PROPOFOL, SALAZOPYRIN, SEVREDOL, SLOW K, TRAMADOL
Adverse Events (AE) Preferred term	1. Haemorrhoidal haemorrhage 2. Lethargy 3. Enteritis 4. Diabetes mellitus inadequate control 5. Iron deficiency anaemia 6. Vitamin B12 deficiency 7. Tumour haemorrhage 8. Colon cancer 9. Angina unstable 10. Blood potassium decreased
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MILD/NO/NO/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/YES/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 03DEC2009 (2) - 18FEB2010 (79) 2. 04DEC2009 (3) - 08JUN2010 (189) 3. 01JAN2010 (31) - 04JAN2010 (34) 4. 12JAN2010 (42) - 22JUN2010 (203) 5. 21JAN2010 (51) - --------- (.) 6. 28JAN2010 (58) - 08MAR2010 (97) 7. 19FEB2010 (80) - 15APR2010 (135)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033042

Parameter	Value
	8. 19FEB2010 (80) - 15APR2010 (135)
	9. 22APR2010 (142) - --------- (.)
	10. 22APR2010 (142) - 24APR2010 (144)
Duration of AE	1. 78
	2. 187
	3. 4
	4. 162
	5. .
	6. 40
	7. 56
	8. 56
	9. .
	10. 3
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. I
	10. I
Action taken	1. OTHER
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY,OTHER
	8. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	9. REMEDIAL DRUG THERAPY,OTHER

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033042

Parameter	Value
	10. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. IMPROVED
	10. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033047

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700033047/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/26/WHITE/NEW ZEALAND/YES
Medical history	Homocystinuria, Myopia, Pulmonary embolism, Pulmonary infarction, Peripheral arterial occlusive disease
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, AUGMENTIN, BETAINE, CLEXANE, CODEINE PRN, CODRAL COLD & FLU TABLETS PRN, COLDREX COLD & FLU TABLETS [GUAIPHENESIN, PARACETAMOL, PHENYLEPHRINE], FENTANYL, FOLIC ACID, HEPARIN, L-CYSTINE, LIGNOCAINE 1%, LINCTUS GEE, MALTODEXTRIN, MIDAZOLAM, SEVREDOL, XMET
Adverse Events (AE) Preferred term	1. Pleuritic pain 2. Lower respiratory tract infection 3. Pleural effusion 4. Nasopharyngitis 5. Upper respiratory tract infection 6. Nasopharyngitis 7. Wound haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/NO/YES 2. SEVERE/NO/NO/YES 3. SEVERE/NO/YES/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/YES/NO/YES
Start/stop date of event with relative date	1. 28OCT2010 (17) - 06DEC2010 (56) 2. 29OCT2010 (18) - 06DEC2010 (56) 3. 29OCT2010 (18) - 06DEC2010 (56) 4. 22DEC2010 (72) - 26DEC2010 (76) 5. 10FEB2011 (122) - 26FEB2011 (138) 6. 04APR2011 (175) - 07APR2011 (178) 7. 07JUN2011 (239) - 07JUN2011 (239)
Duration of AE	1. 40 2. 39 3. 39 4. 5 5. 17 6. 4 7. 1
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 20 mg 5. 20 mg 6. 20 mg

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033047

Parameter	Value
	7. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. OTHER
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033049

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700033049/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/36/WHITE/NEW ZEALAND/YES
Medical history	Haematoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, CODEINE PHOSPHATE PRN, DULCOLAX SUPPOSITORY PRN [BISACODYL], ENOXAPARIN, FLUCLOXACILLIN, LAXSOL, PARACETAMOL, PARACETAMOL PRN, TRAMADOL, WARFARIN
Adverse Events (AE) Preferred term	1. Haemoptysis 2. Chest pain 3. Constipation 4. Nasopharyngitis
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. MODERATE/NO/YES/YES 3. MODERATE/NO/NO/YES 4. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 19NOV2010 (4) - 21NOV2010 (6) 2. 12DEC2010 (27) - 23DEC2010 (38) 3. 23JAN2011 (69) - 05FEB2011 (82) 4. 04MAR2011 (109) - 18APR2011 (154)
Duration of AE	1. 3 2. 12 3. 14 4. 46
Dose on AE onset	1. 2. 3. 4.
Dose status on AE onset	1. 2. 3. 4.
Action taken	1. NONE 2. REMEDIAL DRUG THERAPY,OTHER 3. REMEDIAL DRUG THERAPY 4. NONE
Outcome of event	1. RESOLVED 2. RESOLVED 3. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700033049

Parameter	Value
	4. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700043002/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/69/WHITE/NEW ZEALAND/YES
Medical history	Cerebrovascular accident, Gastroenteritis, Gastrooesophageal reflux disease, Haemoglobin decreased, Hypercholesterolaemia, Hypertension, Hysterectomy, Overweight, Drug hypersensitivity, Urinary tract infection, Renal impairment, Shoulder operation
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CALAMINE LOTION, INDAPAMIDE, LORATIDINE, METOPROLOL, OMEPRAZOLE, OXYGEN, SIMVASTATIN
Adverse Events (AE) Preferred term	1. Urticaria
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/YES/YES
Start/stop date of event with relative date	1. 21SEP2007 (4) - 03OCT2007 (16)
Duration of AE	1. 13
Dose on AE onset	1. 15 mg
Dose status on AE onset	1. .
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043004

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700043004/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/57/ASIAN/NEW ZEALAND/YES
Medical history	Adrenal adenoma, Angina pectoris, Aortic aneurysm repair, Gastrooesophageal reflux disease, Headache, Helicobacter infection, Hepatic steatosis, Hypertension, Myocardial ischaemia, Spinal osteoarthritis, Rheumatoid arthritis, Acute myocardial infarction
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, FELODIPINE, FRUSEMIDE, GTN SPRAY, HYDROXYCHLOROQUINE SULPHATE, LIPITOR, METOPROLOL, PARACETAMOL, PREDNISONE, SOMAC
Adverse Events (AE) Preferred term	1. Diarrhoea 2. Oropharyngeal pain 3. Feeling of body temperature change 4. Haemorrhoidal haemorrhage 5. Dyspnoea 6. Oedema 7. Angina pectoris 8. Diarrhoea 9. Productive cough
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/YES/YES 8. MODERATE/NO/NO/NO 9. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 18DEC2007 (20) - 20DEC2007 (22) 2. 07JAN2008 (40) - 23JAN2008 (56) 3. 07JAN2008 (40) - 23JAN2008 (56) 4. 22MAR2008 (115) - 25MAR2008 (118) 5. 05MAY2008 (159) - --------- (.) 6. 27MAY2008 (181) - --------- (.) 7. 27MAY2008 (181) - 30MAY2008 (184) 8. 16JUN2008 (201) - 20JUN2008 (205) 9. 16JUN2008 (201) - --------- (.)
Duration of AE	1. 3 2. 17 3. 17 4. 4 5. . 6. . 7. 4

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043004

Parameter	Value
	8. 5
	9. .
Dose on AE onset	1. 15 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. F
	9. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. OTHER
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. UNCHANGED
	6. IMPROVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043004

Parameter	Value
	9. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043007

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700043007/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/48/WHITE/NEW ZEALAND/YES
Medical history	Lung disorder, Emphysema, Gastrooesophageal reflux disease, Alcoholic, Hypercholesterolaemia, Tobacco poisoning
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, ENOXAPARIN, OMEPRAZOLE, PARACETAMOL, ROBOTASYN [DEXTROMETHORPHAN HYDROBROMIDE], SIMVASTATIN, VENTOLIN INHALOR, WARFARIN
Adverse Events (AE) Preferred term	1. Non-cardiac chest pain 2. Haemoptysis 3. Nasopharyngitis 4. Post-tussive vomiting 5. Epistaxis 6. Loss of consciousness 7. Haemorrhage intracranial 8. Loss of consciousness 9. Tension headache 10. Abdominal pain lower 11. Loss of consciousness 12. Convulsion
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/YES/NO/YES 3. MODERATE/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/YES/NO/YES 6. MILD/YES/NO/YES 7. MILD/YES/YES/YES 8. MILD/NO/YES/YES 9. MODERATE/YES/YES/YES 10. MILD/NO/NO/YES 11. MODERATE/NO/YES/YES 12. MODERATE/NO/YES/YES
Start/stop date of event with relative date	1. 29APR2008 (50) - 29APR2008 (50) 2. 10JUL2008 (122) - 12AUG2008 (155) 3. 10JUL2008 (122) - --NOV2008 (.) 4. 10JUL2008 (122) - 18AUG2008 (161) 5. 17JUL2008 (129) - 17JUL2008 (129) 6. 21OCT2008 (225) - 21OCT2008 (225) 7. 28OCT2008 (232) - 31OCT2008 (235) 8. 28OCT2008 (232) - 29OCT2008 (233) 9. 28OCT2008 (232) - 31OCT2008 (235) 10. 30NOV2008 (265) - 06JAN2009 (302) 11. 17FEB2009 (344) - 18FEB2009 (345)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043007

Parameter	Value
	12. 17FEB2009 (344) - 18FEB2009 (345)
Duration of AE	1. 1
	2. 34
	3. .
	4. 40
	5. 1
	6. 1
	7. 4
	8. 2
	9. 4
	10. 38
	11. 2
	12. 2
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. NONE
	2. NONE
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043007

Parameter	Value
	6. NONE
	7. NONE
	8. OTHER
	9. REMEDIAL DRUG THERAPY,OTHER
	10. NONE
	11. NONE
	12. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-700043007[2)]	ONE SIDED HEADACHE - PROBABLY TENSION HEADACHE（PT：緊張性頭痛） 治験担当医はと報告事象との関連性があると判断した。弊社は、その後の検査により頭蓋内出血が確認されなったため、ワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。

1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043009

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700043009/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/59/ASIAN/NEW ZEALAND/YES
Medical history	Tendon operation, Body mass index increased, Cervix carcinoma, Cervix carcinoma, Hypertension, Hysterectomy, Laparotomy, Thrombectomy, Varicose vein, Seasonal allergy, Gastrointestinal disorder
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ASPIRIN, AUGMENTIN, CILAZAPRIL, CLOPIDOGREL, ENOXAPARIN, FENTENYL, GEES LINCTUS, GTN NITROLINGUAL SPRAY, HEPARIN, ISOSORBIDE MONONITRATE, LIGNOCAINE 1%, LIPEX, LORACLEAR, METOPROLOL CR, MIDAZOLAM, PARACETAMOL, SLOW K, TIROFIBAN, WARFARIN
Adverse Events (AE) Preferred term	1. Musculoskeletal discomfort 2. Rash 3. Oedema peripheral 4. Abdominal discomfort 5. Influenza 6. Cough 7. Nasopharyngitis 8. Fatigue 9. Chest pain 10. Acute myocardial infarction 11. Chest pain 12. Coronary artery dissection 13. Seasonal allergy
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MODERATE/NO/NO/YES 9. MODERATE/NO/NO/YES 10. MODERATE/NO/YES/YES 11. MODERATE/NO/YES/YES 12. MODERATE/NO/YES/YES 13. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 03JUN2008 (5) - --------- (.) 2. 04JUN2008 (6) - 12JUN2008 (14) 3. 05JUN2008 (7) - 10JUN2008 (12) 4. 10JUN2008 (12) - 23JUN2008 (25) 5. 16JUN2008 (18) - 23JUN2008 (25) 6. 16JUN2008 (18) - 23JUN2008 (25) 7. 28JUL2008 (60) - --AUG2008 (.)

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043009

Parameter	Value
	8. 29JUL2008 (61) - --------- (.)
	9. 30JUL2008 (62) - 31JUL2008 (63)
	10. 20AUG2008 (83) - 27AUG2008 (90)
	11. 20AUG2008 (83) - 27AUG2008 (90)
	12. 20AUG2008 (83) - 27AUG2008 (90)
	13. 09NOV2008 (164) - --------- (.)
Duration of AE	1. .
	2. 9
	3. 6
	4. 14
	5. 8
	6. 8
	7. .
	8. .
	9. 2
	10. 8
	11. 8
	12. 8
	13. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043009

Parameter	Value
	11.
	12.
	13.
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. NONE
	10. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	11. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	12. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	13. NONE
Outcome of event	1. IMPROVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. UNCHANGED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED
	13. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043012

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700043012/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/36/WHITE/NEW ZEALAND/YES
Medical history	Cardiolipin antibody positive, Thrombophlebitis superficial, Wrist fracture, Antiphospholipid antibodies positive, Cutaneous lupus erythematosus
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CODEINE PHOSPHATE, DICLOFENAC, FLUCLOXACILLIN, LACTULOSE, MORPHINE, NUROFEN, OMEPRASOLE, PARACETAMOL, SEVREDOL, THALIDOMIDE
Adverse Events (AE) Preferred term	1. Arthropod bite 2. Blister 3. Blister 4. Blister 5. Fall 6. Musculoskeletal chest pain 7. Loss of consciousness 8. Haemoptysis 9. Influenza 10. Cough 11. Joint swelling 12. Skin ulcer 13. Cellulitis 14. Arthralgia 15. Joint dislocation 16. Conjunctival haemorrhage
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/YES/NO/YES 4. MILD/YES/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MILD/YES/NO/YES 9. MODERATE/NO/NO/YES 10. MILD/NO/NO/YES 11. MILD/NO/NO/YES 12. MODERATE/NO/YES/YES 13. MODERATE/NO/NO/YES 14. MODERATE/NO/NO/YES 15. MODERATE/NO/NO/NO 16. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --OCT2009 (.) - --OCT2009 (.) 2. 04NOV2008 (6) - 17NOV2008 (19) 3. 05NOV2008 (7) - 17NOV2008 (19)

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043012

Parameter	Value
	4. 12NOV2008 (14) - 17NOV2008 (19)
	5. 26JAN2009 (89) - 26JAN2009 (89)
	6. 26JAN2009 (89) - 09FEB2009 (103)
	7. 26JAN2009 (89) - 26JAN2009 (89)
	8. 05AUG2009 (280) - 07AUG2009 (282)
	9. 05AUG2009 (280) - 19AUG2009 (294)
	10. 05AUG2009 (280) - 10AUG2009 (285)
	11. 07SEP2009 (313) - 09SEP2009 (315)
	12. 15OCT2009 (351) - --------- (.)
	13. 15OCT2009 (351) - --------- (.)
	14. 15OCT2009 (351) - --------- (.)
	15. 16NOV2009 (383) - 16NOV2009 (383)
	16. 17NOV2009 (384) - --------- (.)
Duration of AE	1. .
	2. 14
	3. 13
	4. 6
	5. 1
	6. 15
	7. 1
	8. 3
	9. 15
	10. 6
	11. 3
	12. .
	13. .
	14. .
	15. 1
	16. .
Dose on AE onset	1.
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043012

Parameter	Value
	14. 20 mg
	15. 20 mg
	16. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
	10. .
	11. .
	12. .
	13. .
	14. .
	15. F
	16. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. REMEDIAL DRUG THERAPY
	7. NONE
	8. NONE
	9. REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. REMEDIAL DRUG THERAPY
	14. REMEDIAL DRUG THERAPY
	15. NONE
	16. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043012

Parameter	Value
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. IMPROVED
	13. IMPROVED
	14. IMPROVED
	15. RESOLVED
	16. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043017

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700043017/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/48/WHITE/NEW ZEALAND/YES
Medical history	Asthma, Body mass index increased, Gastrooesophageal reflux disease, Humerus fracture, Joint dislocation, Migraine, Orchidectomy, Radius fracture, Ulna fracture, Ligament rupture, Ligament rupture, Ligament rupture
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AUGMENTIN, CALAMINE LOTION, CHARCOAL TABS, CLEXANE, CODEINE PHOSPHATE, COLCHICHINE, DEPOMEDROL, ENOXAPARIN, FRUSEMIDE, HYDROCORTISONE, MYLANTA [ALUMINIUM HYDROXIDE; MAGNESIUM HYDROXIDE; SIMETHICONE], OMEPRAZOLE, PARACETAMOL, VENTOLIN INHALER, WARFARIN, ZYRTEC [CETIRIZINE HYDROCHLORIDE]
Adverse Events (AE) Preferred term	1. Pyrexia 2. Dyspepsia 3. Drug hypersensitivity 4. Post-tussive vomiting 5. Heat rash 6. Musculoskeletal chest pain 7. Gout 8. Arthralgia 9. Oedema 10. Oedema peripheral 11. Dermatitis allergic 12. Skin discolouration 13. Alanine aminotransferase increased 14. Aspartate aminotransferase increased 15. Neutropenia 16. Varicose vein 17. Musculoskeletal chest pain 18. Night sweats 19. Dyspnoea 20. Breast mass 21. International normalised ratio increased 22. Diarrhoea 23. International normalised ratio increased 24. Wound haemorrhage 25. Melaena 26. Muscle strain
Intensity/ Relationship to study drug /SAE/TE	1. MILD/NO/NO/YES 2. MILD/YES/NO/YES 3. SEVERE/YES/NO/YES 4. MODERATE/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/YES/YES/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043017

Parameter	Value
	8. MODERATE/YES/NO/YES
	9. MODERATE/YES/NO/YES
	10. MODERATE/YES/NO/YES
	11. MODERATE/YES/NO/YES
	12. MODERATE/NO/NO/YES
	13. MILD/YES/NO/YES
	14. MILD/YES/NO/YES
	15. MILD/NO/NO/YES
	16. MILD/NO/NO/YES
	17. MILD/YES/NO/YES
	18. MODERATE/YES/NO/YES
	19. MODERATE/YES/NO/YES
	20. MILD/YES/NO/YES
	21. MILD/YES/NO/YES
	22. MILD/YES/NO/YES
	23. MILD/YES/NO/YES
	24. MILD/NO/NO/YES
	25. MILD/YES/NO/YES
	26. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --NOV2009 (.) - 10DEC2009 (247)
	2. 08APR2009 (1) - 20APR2009 (13)
	3. 15APR2009 (8) - 28APR2009 (21)
	4. 19APR2009 (12) - 19APR2009 (12)
	5. 30APR2009 (23) - 15MAY2009 (38)
	6. 10JUL2009 (94) - 10JUL2009 (94)
	7. 13AUG2009 (128) - --------- (.)
	8. 13AUG2009 (128) - 17AUG2009 (132)
	9. 13AUG2009 (128) - 01DEC2009 (238)
	10. 13AUG2009 (128) - 17AUG2009 (132)
	11. 14AUG2009 (129) - 29AUG2009 (144)
	12. 01SEP2009 (147) - --------- (.)
	13. 10SEP2009 (156) - --------- (.)
	14. 10SEP2009 (156) - 01OCT2009 (177)
	15. 21SEP2009 (167) - 16FEB2010 (315)
	16. 30SEP2009 (176) - --------- (.)
	17. 20OCT2009 (196) - 04NOV2009 (211)
	18. 20OCT2009 (196) - 01FEB2010 (300)
	19. 20OCT2009 (196) - 01JAN2010 (269)
	20. 01NOV2009 (208) - --------- (.)
	21. 30DEC2009 (267) - 07JAN2010 (275)
	22. 01JAN2010 (269) - --------- (.)
	23. 21JAN2010 (289) - 25JAN2010 (293)

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043017

Parameter	Value
	24. 03FEB2010 (302) - 10FEB2010 (309)
	25. 28FEB2010 (327) - 12MAR2010 (339)
	26. 28FEB2010 (327) - --------- (.)
Duration of AE	1. .
	2. 13
	3. 14
	4. 1
	5. 16
	6. 1
	7. .
	8. 5
	9. 111
	10. 5
	11. 16
	12. .
	13. .
	14. 22
	15. 149
	16. .
	17. 16
	18. 105
	19. 74
	20. .
	21. 9
	22. .
	23. 5
	24. 8
	25. 13
	26. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043017

Parameter	Value
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
	21.
	22.
	23.
	24.
	25.
	26.
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043017

Parameter	Value
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	8. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	9. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	10. REMEDIAL DRUG THERAPY
	11. NONE
	12. NONE
	13. OTHER
	14. OTHER
	15. OTHER
	16. NONE
	17. OTHER
	18. OTHER
	19. OTHER
	20. REMEDIAL DRUG THERAPY
	21. DOSE OF STUDY DRUG REDUCED,OTHER
	22. NONE
	23. DOSE OF STUDY DRUG REDUCED,OTHER
	24. NONE
	25. OTHER
	26. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. IMPROVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. UNCHANGED
	13. IMPROVED
	14. RESOLVED
	15. RESOLVED
	16. IMPROVED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043017

Parameter	Value
	20. IMPROVED
	21. RESOLVED
	22. UNCHANGED
	23. RESOLVED
	24. RESOLVED
	25. RESOLVED
	26. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-700043017[2)]	GOUT（BILATERAL ANKLE PAIN AND LEG SWELLING）（PT：痛風） 治験担当医はワルファリンと報告事象との関連性があると判断した。弊社は、併発症と考え、ワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043030

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700043030/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/54/WHITE/NEW ZEALAND/YES
Medical history	Asthma, Back pain, Bronchopneumonia, Constipation, Dengue fever, Gastrooesophageal reflux disease, Headache, Hypothyroidism, Pyelonephritis, Vomiting, Postmenopause, Bone cyst excision
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CALCIUM CARBONATE, CEFACLOR, CEFUROXIME, CODEINE PHOSPHATE, DICLOFENAC, LACTULOSE, LAXOL, LEVOTHYROXINE, METOCLOPROMIDE, MICROLAX ENEMA [NA CITRATE, NA LAURYL SULFOACETATE, SORBIC ACID, SORBITOL, WATER, OMEPRAZOLE, ONDASETRON, PARACETAMOL, SALBUTAMOL, TRAMADOL
Adverse Events (AE) Preferred term	1. Injection site haematoma 2. Hepatic steatosis 3. Cholelithiasis 4. Diarrhoea 5. Convulsion 6. Nausea
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES 4. MILD/YES/NO/YES 5. MODERATE/NO/YES/NO 6. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. 17MAR2010 (1) - 23MAR2010 (7) 2. 18MAR2010 (2) - --------- (.) 3. 18MAR2010 (2) - --------- (.) 4. 23MAR2010 (7) - 24MAR2010 (8) 5. 20APR2010 (35) - 22APR2010 (37) 6. 20APR2010 (35) - --------- (.)
Duration of AE	1. 7 2. . 3. . 4. 2 5. 3 6. .
Dose on AE onset	1. 15 mg 2. 15 mg 3. 15 mg 4. 15 mg 5. 15 mg 6. 15 mg
Dose status on AE onset	1. . 2. . 3. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043030

Parameter	Value
	4. .
	5. F
	6. F
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. UNCHANGED
	3. UNCHANGED
	4. RESOLVED
	5. RESOLVED
	6. IMPROVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043038

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700043038/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/44/WHITE/NEW ZEALAND/YES
Medical history	Anxiety, Depression, Gastrooesophageal reflux disease, Alcoholic, Blood iron decreased, Palpitations, Tension headache, Haemorrhoidal haemorrhage, Dyslipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, CODEINE, CYCLIZINE, DICLOFENAC, ENOXAPARIN, FENTANYL, HEALTHERIES BRAND IRON TABLETS, LEXAPRO, LORAZEPAM, LOSEC, MAXOLON, MIDAZOLAM, MORPHINE ELIXIR, MYLANTA [ALUMINIUM HYDROXIDE, MAGNESIUM HYDROXIDE, SIMETHICONE], NORMAL SALINE, PARACETOMOL, SERTRALINE, SEVREDOL, VENLAFAXINE, WARFARIN, ZOPICLONE
Adverse Events (AE) Preferred term	1. Insomnia 2. Dyspnoea at rest 3. Tendon pain 4. Myofascial pain syndrome 5. Gastrooesophageal reflux disease 6. Pain in extremity 7. Musculoskeletal pain 8. Gastritis 9. Back pain 10. Cough 11. Gastritis 12. Musculoskeletal pain
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MILD/NO/NO/YES 5. MODERATE/YES/NO/YES 6. MILD/NO/NO/YES 7. MODERATE/NO/NO/YES 8. MODERATE/YES/YES/YES 9. MILD/NO/NO/YES 10. MILD/NO/NO/YES 11. MODERATE/YES/NO/YES 12. MILD/NO/NO/NO
Start/stop date of event with relative date	1. --DEC2010 (.) - 14MAR2011 (112) 2. --MAR2011 (.) - 02MAY2011 (161) 3. --AUG2011 (.) - 19SEP2011 (301) 4. --AUG2011 (.) - 19SEP2011 (301) 5. 24NOV2010 (2) - --JAN2011 (.) 6. 24DEC2010 (32) - --JAN2011 (.) 7. 24DEC2010 (32) - 19JAN2011 (58) 8. 16JAN2011 (55) - 24JAN2011 (63)

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043038

Parameter	Value
	9. 14MAR2011 (112) - --APR2011 (.)
	10. 28MAR2011 (126) - 02MAY2011 (161)
	11. 10MAY2011 (169) - --JUL2011 (.)
	12. 15SEP2011 (297) - 16SEP2011 (298)
Duration of AE	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. 27
	8. 9
	9. .
	10. 36
	11. .
	12. 2
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043038

Parameter	Value
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. REMEDIAL DRUG THERAPY,OTHER
	8. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	9. NONE
	10. NONE
	11. REMEDIAL DRUG THERAPY
	12. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. RESOLVED
	12. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-700043038[2)]	GASTRITIS（PT：胃炎） 治験担当医はエノキサパリン及びワルファリンと報告事象との関連性があると判断した。弊社は、既往症（アルコール過量摂取及び胃食道逆流）によるものであり、エノキサパリン及びワルファリンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043039

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700043039/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/66/WHITE/NEW ZEALAND/YES
Medical history	Hypothyroidism, Bundle branch block left, Lung consolidation, Postmenopause, Respiratory tract infection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	AMOXYCILLIN, CALCIUM CARBONATE, CEFUROXIME, DOMPERIDONE, GLUCOSAMINE COMBINED WITH OMEGA3, INFLUENZA INJECTION, METHYLPREDNISOLONE, MORPHINE, ONDANSETRON, OXYCONTON, OXYNORM, PARACETOMOL, RESERVATROL, ROXITHROMYCIN, THYROXINE, WARFARIN
Adverse Events (AE) Preferred term	1. Muscle spasms 2. Pulmonary infarction 3. Dry eye 4. Contusion 5. Emotional distress 6. Fatigue
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES 2. SEVERE/YES/YES/YES 3. MILD/YES/NO/YES 4. MILD/YES/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES
Start/stop date of event with relative date	1. --APR2011 (.) - --JUN2011 (.) 2. 10DEC2010 (1) - 11DEC2010 (2) 3. 21DEC2010 (12) - 18MAR2011 (99) 4. 10MAR2011 (91) - --APR2011 (.) 5. 10JUN2011 (183) - 31AUG2011 (265) 6. 10JUN2011 (183) - 31AUG2011 (265)
Duration of AE	1. . 2. 2 3. 88 4. . 5. 83 6. 83
Dose on AE onset	1. 2. 15 mg 3. 15 mg 4. 20 mg 5. 20 mg 6. 20 mg
Dose status on AE onset	1. 2. . 3. . 4. .

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700043039

Parameter	Value
	5. .
	6. .
Action taken	1. NONE
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. NONE
	5. NONE
	6. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-700043039[2)]	PULMONARY INFARCTION（PT：肺梗塞） 治験担当医はリバーロキサバンと報告事象との関連性があると判断した。弊社は、原疾患（肺塞栓症）、合併症（感染）及び既往のアスベストス曝露によるものであり、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700053037

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700053037/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/55/WHITE/NEW ZEALAND/YES
Medical history	Femoral neck fracture, Femoral neck fracture, Lipoma
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	CLEXANE, ENOXAPARIN, EPIRUBICIN, PARACETAMOL, WARFARIN
Adverse Events (AE) Preferred term	1. Nausea
	2. Haemoptysis
	3. Conjunctival haemorrhage
	4. Conjunctival haemorrhage
	5. Ocular hyperaemia
	6. Bladder cancer
	7. Haematuria
	8. Haematuria
Intensity/ Relationship to study drug /SAE/TE	1. MILD/YES/NO/YES
	2. MILD/NO/NO/YES
	3. MILD/YES/NO/YES
	4. MILD/YES/NO/YES
	5. MILD/YES/NO/YES
	6. SEVERE/NO/YES/YES
	7. MODERATE/NO/NO/YES
	8. MODERATE/YES/NO/YES
Start/stop date of event with relative date	1. 13MAY2010 (4) - 16MAY2010 (7)
	2. 14MAY2010 (5) - 16MAY2010 (7)
	3. 22MAY2010 (13) - 23MAY2010 (14)
	4. 01JUN2010 (23) - 04JUN2010 (26)
	5. 30JUL2010 (82) - 06AUG2010 (89)
	6. 19SEP2010 (133) - 22OCT2010 (166)
	7. 19SEP2010 (133) - 21SEP2010 (135)
	8. 22OCT2010 (166) - 06NOV2010 (181)
Duration of AE	1. 4
	2. 3
	3. 2
	4. 4
	5. 8
	6. 34
	7. 3
	8. 16
Dose on AE onset	1.
	2.
	3.
	4.
	5.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700053037

Parameter	Value
	6.
	7.
	8.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. NONE
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY,OTHER
	7. OTHER
	8. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700053038

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700053038/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/67/WHITE/NEW ZEALAND/YES
Medical history	Atrial fibrillation, Rotator cuff syndrome, Depression, Endometriosis, Myocardial ischaemia, Hysterectomy, Dyslipidaemia, Intestinal resection, Intestinal resection
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	A-SCABIES [PERMETHRIN, HYDROXYBENZOATES AND TRICLOSAN], ASPRIN, AUGMENTIN, CEFUROXIME, CITALOPRAM, CLEXANE, CODEINE, CODEINE PHOSPHATE, CYCLINE, DEXTROSE/SALINE, DURO-TUSS, ENOXAPARIN, FENTANYL, FRESH FROZEN PLASMA, GELOFUSION, GENTAMICIN, HARTMANN, IBUPROFEN, KCL, LACTOSE, LAXSOL, LIPEX, LOSEC, METOCLOPRAMIDE, METROCLORPRAMIDE, METRONIDAZOLE, MGSO4, MICROLAX [SODIUM CITRATE,SODIUM LAURYL SULFOACETATE, SORBIC ACID,SORBITOL], MORPHINE ELIXIR, NILSTAT, NITROLINGAL SPRAY, ONDANSETRON, OXYCONTIN, OXYNORM, PARACETOMOL, SOLTALOL, TRAMADOL, TRAMODOL, WARFARIN
Adverse Events (AE) Preferred term	1. Contusion 2. Decreased appetite 3. Cough 4. Arthralgia 5. Upper respiratory tract infection 6. Large intestine perforation 7. Operative haemorrhage 8. Drug eruption 9. Contusion 10. Contusion 11. Dyspnoea 12. Heart rate irregular 13. Chest pain 14. Dizziness 15. Dyspnoea 16. Heart rate irregular 17. Vomiting 18. Diverticulum 19. Rectal haemorrhage 20. Constipation
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/YES/NO/YES 2. MILD/YES/NO/YES 3. MILD/NO/NO/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. SEVERE/NO/YES/YES 7. MODERATE/YES/NO/YES 8. SEVERE/NO/NO/YES 9. SEVERE/NO/NO/YES

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700053038

Parameter	Value
	10. MODERATE/NO/NO/YES
	11. MILD/NO/NO/YES
	12. MILD/NO/NO/YES
	13. MODERATE/NO/NO/YES
	14. MILD/NO/NO/YES
	15. MODERATE/NO/NO/YES
	16. MODERATE/NO/NO/YES
	17. MODERATE/NO/NO/YES
	18. MILD/NO/NO/YES
	19. MILD/YES/NO/YES
	20. MODERATE/NO/NO/YES
Start/stop date of event with relative date	1. 24MAY2010 (1) - 20AUG2010 (89)
	2. 25MAY2010 (2) - --NOV2010 (.)
	3. 30MAY2010 (7) - 01JUN2010 (9)
	4. 02JUN2010 (10) - 16JUN2010 (24)
	5. 14JUL2010 (52) - 01AUG2010 (70)
	6. 16AUG2010 (85) - 25AUG2010 (94)
	7. 17AUG2010 (86) - 17AUG2010 (86)
	8. 18AUG2010 (87) - 22SEP2010 (122)
	9. 27AUG2010 (96) - 22SEP2010 (122)
	10. 12OCT2010 (142) - 28OCT2010 (158)
	11. 25NOV2010 (186) - 17FEB2011 (270)
	12. 17DEC2010 (208) - 17FEB2011 (270)
	13. 17DEC2010 (208) - --------- (.)
	14. 20JAN2011 (242) - --------- (.)
	15. 17FEB2011 (270) - --------- (.)
	16. 17FEB2011 (270) - --------- (.)
	17. 12APR2011 (324) - 12APR2011 (324)
	18. 03MAY2011 (345) - --------- (.)
	19. 10MAY2011 (352) - --------- (.)
	20. 10MAY2011 (352) - --------- (.)
Duration of AE	1. 89
	2. .
	3. 3
	4. 15
	5. 19
	6. 10
	7. 1
	8. 36
	9. 27
	10. 17
	11. 85

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700053038

Parameter	Value
	12. 63
	13. .
	14. .
	15. .
	16. .
	17. 1
	18. .
	19. .
	20. .
Dose on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.
	14.
	15.
	16.
	17.
	18.
	19.
	20.
Dose status on AE onset	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.
	9.
	10.
	11.
	12.
	13.

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700053038

Parameter	Value
	14.
	15.
	16.
	17.
	18.
	19.
	20.
Action taken	1. NONE
	2. NONE
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	7. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	8. NONE
	9. NONE
	10. NONE
	11. NONE
	12. NONE
	13. NONE
	14. NONE
	15. NONE
	16. OTHER
	17. NONE
	18. NONE
	19. REMEDIAL DRUG THERAPY
	20. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED
	10. RESOLVED
	11. WORSENED
	12. WORSENED
	13. UNCHANGED
	14. UNCHANGED
	15. UNCHANGED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700053038

Parameter	Value
	16. UNCHANGED
	17. RESOLVED
	18. UNCHANGED
	19. UNCHANGED
	20. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700053039

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/700053039/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/71/WHITE/NEW ZEALAND/YES
Medical history	Adrenal adenoma, Diverticulitis, Hypercholesterolaemia, Hypertension, Hysterectomy, Renal impairment, Insomnia, Spinal osteoarthritis, Osteoarthritis, Polymyalgia rheumatica, Post herpetic neuralgia, Hip arthroplasty, Hip arthroplasty, Type 2 diabetes mellitus, Urge incontinence
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACCUPRIL, ACCURETIC, AMITRYPTILINE, ASPRIN, AUGMENTIN, CARDIZEM, CEFACLOR, CELIPROLOL, CELIPROLOL HCL, CHOLECALCIFEROL, CITRALOPRAM, CLONAZEPAM, CODEINE PHOSPHATE, ENOXAPARIN, FUROSEMIDE, HUMALOG, HUMALOG MI X25, INSULIN LANTIS, NITOLINGUAL PUMPSPRAY, NORFLEX, NORTRYPTYLINE, PANADOL, PARACETAMOL, PARACODE, PREDISONE, PREDNISONE, RIVAROXABAN - HOSPTIAL STOCK, SIMVASTATIN, SPIRONOLACTONE, SPRONOLACTONE, TRAMOL, TREMAZEPAM
Adverse Events (AE) Preferred term	1. Depression 2. Contusion 3. Contusion 4. Injection site haematoma 5. Fluid retention 6. Stasis dermatitis 7. Dyspnoea 8. Cellulitis 9. Chest pain 10. Presyncope 11. Lethargy 12. Arthralgia 13. Peroneal nerve palsy 14. Upper respiratory tract infection 15. Muscular weakness 16. Diabetic neuropathy 17. Contusion 18. Fall 19. Muscle spasms 20. Cellulitis 21. Hypertonic bladder
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MILD/YES/NO/YES 3. MILD/YES/NO/YES 4. MILD/YES/NO/YES 5. MODERATE/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. SEVERE/NO/YES/YES 9. SEVERE/NO/YES/YES

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700053039

Parameter	Value
	10. MILD/NO/NO/YES
	11. SEVERE/NO/NO/YES
	12. MODERATE/NO/NO/YES
	13. MODERATE/NO/NO/YES
	14. MILD/NO/NO/YES
	15. SEVERE/NO/YES/YES
	16. SEVERE/NO/NO/YES
	17. MODERATE/YES/NO/YES
	18. MODERATE/NO/NO/YES
	19. MODERATE/NO/NO/YES
	20. MODERATE/NO/NO/NO
	21. MODERATE/NO/NO/NO
Start/stop date of event with relative date	1. --DEC2010 (.) - --------- (.)
	2. 16JUN2010 (21) - 30JUN2010 (35)
	3. 12JUL2010 (47) - 26JUL2010 (61)
	4. 12JUL2010 (47) - --------- (.)
	5. 19AUG2010 (85) - --------- (.)
	6. 13SEP2010 (110) - 27SEP2010 (124)
	7. 23SEP2010 (120) - 23OCT2010 (150)
	8. 27SEP2010 (124) - 25NOV2010 (183)
	9. 01OCT2010 (128) - 04OCT2010 (131)
	10. 11NOV2010 (169) - --DEC2010 (.)
	11. 07DEC2010 (195) - --------- (.)
	12. 15JAN2011 (234) - --------- (.)
	13. 15JAN2011 (234) - --------- (.)
	14. 14MAR2011 (292) - 14APR2011 (323)
	15. 30MAR2011 (308) - --------- (.)
	16. 30MAR2011 (308) - --------- (.)
	17. 13APR2011 (322) - 04MAY2011 (343)
	18. 13APR2011 (322) - 15APR2011 (324)
	19. 06MAY2011 (345) - 01JUN2011 (371)
	20. 25MAY2011 (364) - 03JUN2011 (373)
	21. 26MAY2011 (365) - --------- (.)
Duration of AE	1. .
	2. 15
	3. 15
	4. .
	5. .
	6. 15
	7. 31
	8. 60
	9. 4

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700053039

Parameter	Value
	10. .
	11. .
	12. .
	13. .
	14. 32
	15. .
	16. .
	17. 22
	18. 3
	19. 27
	20. 10
	21. .
Dose on AE onset	1.
	2. 15 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
	10. 20 mg
	11. 20 mg
	12. 20 mg
	13. 20 mg
	14. 20 mg
	15. 20 mg
	16. 20 mg
	17. 20 mg
	18. 20 mg
	19. 20 mg
	20. 20 mg
	21. 20 mg
Dose status on AE onset	1.
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700053039

Parameter	Value
	10. .
	11. .
	12. .
	13. .
	14. .
	15. .
	16. .
	17. .
	18. .
	19. .
	20. F
	21. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. NONE
	3. NONE
	4. NONE
	5. REMEDIAL DRUG THERAPY
	6. NONE
	7. NONE
	8. REMEDIAL DRUG THERAPY
	9. REMEDIAL DRUG THERAPY,OTHER
	10. NONE
	11. NONE
	12. REMEDIAL DRUG THERAPY
	13. NONE
	14. REMEDIAL DRUG THERAPY
	15. NONE
	16. NONE
	17. NONE
	18. NONE
	19. REMEDIAL DRUG THERAPY
	20. DOSE OF STUDY DRUG REDUCED
	21. REMEDIAL DRUG THERAPY
Outcome of event	1. UNCHANGED
	2. RESOLVED
	3. RESOLVED
	4. UNCHANGED
	5. UNCHANGED
	6. WORSENED
	7. RESOLVED
	8. RESOLVED
	9. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 700053039

Parameter	Value
	10. RESOLVED
	11. UNCHANGED
	12. UNCHANGED
	13. UNCHANGED
	14. RESOLVED
	15. UNCHANGED
	16. UNCHANGED
	17. RESOLVED
	18. RESOLVED
	19. RESOLVED
	20. RESOLVED
	21. UNCHANGED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 710023020

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/710023020/Rivaroxaban
Sex/Age/Race/Country/Safety population	FEMALE/79/ASIAN/THAILAND/YES
Medical history	Central nervous system lymphoma, Diabetes mellitus, Femoral neck fracture, Hypertension, Menopause, Osteoporosis, Vertebrobasilar insufficiency, Hyperlipidaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ACYCLOVIR, AMITRYPTYLINE, AMLODIPINE, ATARAX, CACIUM CARBONATE, CEFIPIME, CEFTRIAXONE, DEXAMETHASONE, DILANTIN, ERTAPENAM, FILGRASTIM, FOLIC ACID, FOSFOMYCIN, GLUCO-OPH, KEPPRA, LEUCOVORIN, LORAZEPAM, LUMIGAN, METHOTREXATE, METRONIDAZOLE, ONDANSETRON, PRENISOLONE CREAM, PREVACID, TOBRAMYCIN, VITAMIN B1-6-12, ZYRTEC
Adverse Events (AE) Preferred term	1. Urinary tract infection 2. Pneumonia bacterial 3. Muscular weakness 4. Diverticular perforation 5. Drug hypersensitivity 6. Conjunctivitis 7. Convulsion 8. Altered state of consciousness 9. Sepsis
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. MODERATE/NO/NO/YES 3. MODERATE/NO/YES/YES 4. MODERATE/NO/NO/YES 5. MODERATE/NO/NO/YES 6. MODERATE/NO/NO/YES 7. SEVERE/NO/NO/YES 8. SEVERE/NO/YES/YES 9. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 29APR2010 (29) - 15MAY2010 (45) 2. 21MAY2010 (51) - 02JUN2010 (63) 3. 11JUN2010 (72) - 18JUL2010 (109) 4. 16JUN2010 (77) - 05AUG2010 (127) 5. 02JUL2010 (93) - 10JUL2010 (101) 6. 06JUL2010 (97) - 06AUG2010 (128) 7. 07JUL2010 (98) - --------- (.) 8. 05AUG2010 (127) - 08AUG2010 (130) 9. 15AUG2010 (137) - 24SEP2010 (177)
Duration of AE	1. 17 2. 13 3. 38 4. 51 5. 9

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 710023020

Parameter	Value
	6. 32
	7. .
	8. 4
	9. 41
Dose on AE onset	1. 20 mg
	2. 20 mg
	3. 20 mg
	4. 20 mg
	5. 20 mg
	6. 20 mg
	7. 20 mg
	8. 20 mg
	9. 20 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. .
	6. .
	7. .
	8. .
	9. .
Action taken	1. REMEDIAL DRUG THERAPY
	2. REMEDIAL DRUG THERAPY
	3. REMEDIAL DRUG THERAPY
	4. STUDY DRUG DISCONTINUED AND RESTARTED,REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY,OTHER
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. REMEDIAL DRUG THERAPY
	9. NONE
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. UNCHANGED
	8. RESOLVED

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 710023020

Parameter	Value
	9. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 710023023

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/710023023/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	FEMALE/83/ASIAN/THAILAND/YES
Medical history	Colon cancer, Glaucoma, Hyperlipidaemia, Hypertension, Myocardial ischaemia
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	APROVEL, ASPIRIN, ENOXAPARIN, EZETROL, FARLUTAL, INDAMPAMIDE, ISORDIL, LIPITOR, VASTAREL MR, WARFARIN
Adverse Events (AE) Preferred term	1. Colon cancer metastatic
Intensity/ Relationship to study drug /SAE/TE	1. SEVERE/NO/YES/YES
Start/stop date of event with relative date	1. 03DEC2010 (106) - 01FEB2011 (166)
Duration of AE	1. 61
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY
Outcome of event	1. DEATH

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas　erjli　21MAR2013 11:35

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 710053002

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/710053002/Enoxaparin/VKA
Sex/Age/Race/Country/Safety population	MALE/70/WHITE/THAILAND/YES
Medical history	Insomnia, Deep vein thrombosis
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ENOXAPARIN, MOBIC, POLYTANOL, SENNOSIDES A$B {SENOKNOT}, TRAMOL, TRYPTANOL, VILERM CREAM, WARFARIN
Adverse Events (AE) Preferred term	1. Pulmonary infarction 2. Tension headache 3. Oral herpes
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/YES 2. MILD/NO/NO/YES 3. MILD/NO/NO/YES
Start/stop date of event with relative date	1. 03OCT2010 (3) - --------- (.) 2. 25OCT2010 (25) - 24NOV2010 (55) 3. 23MAY2011 (235) - 02JUN2011 (245)
Duration of AE	1. . 2. 31 3. 11
Dose on AE onset	1. 2. 3.
Dose status on AE onset	1. 2. 3.
Action taken	1. REMEDIAL DRUG THERAPY 2. REMEDIAL DRUG THERAPY 3. REMEDIAL DRUG THERAPY
Outcome of event	1. IMPROVED 2. RESOLVED 3. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-8.sas erjli 21MAR2013 11:35

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 710053003

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/710053003/Rivaroxaban
Sex/Age/Race/Country/Safety population	MALE/78/ASIAN/THAILAND/YES
Medical history	
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	ALTEPLASE, CARDEPINE, DOMICUM, FLUIMUCIL, HEPARIN, MIRACID, OMEPRAZOLE, SENOKOT, UNFRACTIONATED HEPARIN
Adverse Events (AE) Preferred term	1. Constipation 2. Post procedural haemorrhage 3. Respiratory failure 4. Hypertension 5. Mouth ulceration 6. Pharyngitis 7. Rhinitis allergic 8. Dyspnoea 9. Cough
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/NO/YES 2. SEVERE/NO/YES/YES 3. SEVERE/YES/YES/YES 4. MODERATE/NO/NO/YES 5. MILD/NO/NO/YES 6. MILD/NO/NO/YES 7. MILD/NO/NO/YES 8. MILD/NO/NO/YES 9. MILD/NO/NO/NO
Start/stop date of event with relative date	1. 05OCT2010 (1) - 22OCT2010 (18) 2. 07OCT2010 (3) - 09OCT2010 (5) 3. 07OCT2010 (3) - 22OCT2010 (18) 4. 07OCT2010 (3) - 08OCT2010 (4) 5. 08OCT2010 (4) - 09OCT2010 (5) 6. 09OCT2010 (5) - 18OCT2010 (14) 7. 09OCT2010 (5) - 13OCT2010 (9) 8. 09OCT2010 (5) - 09OCT2010 (5) 9. 12OCT2010 (8) - 22OCT2010 (18)
Duration of AE	1. 18 2. 3 3. 16 4. 2 5. 2 6. 10 7. 5 8. 1 9. 11

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 710053003

Parameter	Value
Dose on AE onset	1. 15 mg
	2. 15 mg
	3. 15 mg
	4. 15 mg
	5. 15 mg
	6. 15 mg
	7. 15 mg
	8. 15 mg
	9. 15 mg
Dose status on AE onset	1. .
	2. .
	3. .
	4. .
	5. F
	6. F
	7. F
	8. F
	9. F
Action taken	1. REMEDIAL DRUG THERAPY
	2. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	3. STUDY DRUG DISCONTINUED PERMANENTLY,REMEDIAL DRUG THERAPY,OTHER
	4. REMEDIAL DRUG THERAPY
	5. REMEDIAL DRUG THERAPY
	6. REMEDIAL DRUG THERAPY
	7. REMEDIAL DRUG THERAPY
	8. NONE
	9. REMEDIAL DRUG THERAPY
Outcome of event	1. RESOLVED
	2. RESOLVED
	3. RESOLVED
	4. RESOLVED
	5. RESOLVED
	6. RESOLVED
	7. RESOLVED
	8. RESOLVED

付表 2.7.6.2- 2 重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 710053003

Parameter	Value
	9. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is after treatment phase,F will be listed.
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被験者番号	因果関係判定根拠に関する治験依頼者の見解
11702-710053003[4), 2)]	ORAL MUCOSAL BLEEDING DUE TO TRAUMATIC TRACHEAL INTUBATION（PT：外傷性出血） 治験担当医は、因果関係を否定できると判断した。弊社は、リバーロキサバンの抗凝固作用及び報告事象発現との時間的関連性から、因果関係は否定できないと考える。 RESPIRATORY FAILURE（PT：呼吸不全） 治験担当医はリバーロキサバンと報告事象との関連性があると判断した。弊社は、原疾患（肺塞栓症）の悪化によるものであり、リバーロキサバンとの因果関係は否定できると考える。

因果関係判定に関して、治験担当医師、Bayer HealthCare 社及びバイエル薬品の見解が異なるパターンを被験者番号 の右上に以下の番号を付与した。
1）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
2）治験担当医師が「関連あり」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連なし」の場合
3）治験担当医師の評価は得られておらず、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
4）治験担当医師が「関連なし」、Bayer HealthCare 社及びバイエル薬品（両者を弊社とする）が「関連あり」の場合
5）治験担当医師及びバイエル薬品（弊社）が「関連あり」、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」の場合
6）治験担当医師の評価は得られておらず、Bayer HealthCare 社（ドイツ安全性部門）が「関連なし」、バイエル薬品（弊社）が「関連あり」の場合

付表 2.7.6.2- 2　重篤な有害事象の叙述（試験 11702-PE、無作為割り付け例）（続き）

Subject ID: 760023001

Parameter	Value
Study number/ Subject ID/ Treatment group	11702/760023001/No study medication
Sex/Age/Race/Country/Safety population	MALE/73/WHITE/LATVIA/NO
Medical history	Arteriosclerosis, Atrial fibrillation, Hypertension
Concomitant Medication ATC subclass (WHO-DD version 3q2005)	
Adverse Events (AE) Preferred term	1. Ischaemic stroke
Intensity/ Relationship to study drug /SAE/TE	1. MODERATE/NO/YES/NO
Start/stop date of event with relative date	1. 23SEP2010 (.) - 23OCT2010 (.)
Duration of AE	1. 31
Dose on AE onset	1.
Dose status on AE onset	1.
Action taken	1. REMEDIAL DRUG THERAPY,OTHER
Outcome of event	1. RESOLVED

All AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is(onset day of AE minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase,F will be listed.
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