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Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Number of subjects (%) with at least one adverse event		1078 (62.7%)	1080 (63.1%)	401 (23.3%)	394 (23.0%)
Blood and lymphatic system disorders	血液およびリンパ系障害	57 (3.3%)	45 (2.6%)	19 (1.1%)	10 (0.6%)
Anaemia	貧血	31 (1.8%)	25 (1.5%)	12 (0.7%)	6 (0.4%)
Anaemia haemolytic autoimmune	自己免疫性溶血性貧血	1 (<0.1%)	0		
Anaemia macrocytic	大球性貧血	1 (<0.1%)	0		
Autoimmune thrombocytopenia	自己免疫性血小板減少症	0	1 (<0.1%)		
Bone marrow failure	骨髄機能不全	1 (<0.1%)	0		
Deficiency anaemia	欠乏性貧血	1 (<0.1%)	0		
Febrile neutropenia	発熱性好中球減少症	1 (<0.1%)	1 (<0.1%)		
Haemorrhagic anaemia	出血性貧血	1 (<0.1%)	1 (<0.1%)		
Haemorrhagic diathesis	出血性素因	1 (<0.1%)	2 (0.1%)	1 (<0.1%)	2 (0.1%)
Hypercoagulation	凝固亢進	2 (0.1%)	2 (0.1%)		
Iron deficiency anaemia	鉄欠乏性貧血	3 (0.2%)	3 (0.2%)	2 (0.1%)	1 (<0.1%)
Leukocytosis	白血球増加症	0	3 (0.2%)		
Leukopenia	白血球減少症	2 (0.1%)	4 (0.2%)		
Lymphadenitis	リンパ節炎	1 (<0.1%)	1 (<0.1%)		
Lymphadenopathy	リンパ節症	3 (0.2%)	1 (<0.1%)		
Lymphadenopathy mediastinal	縦隔リンパ節腫脹	2 (0.1%)	1 (<0.1%)		
Microcytic anaemia	小球性貧血	1 (<0.1%)	0	1 (<0.1%)	0
Nephrogenic anaemia	腎性貧血	1 (<0.1%)	1 (<0.1%)		
Neutropenia	好中球減少症	1 (<0.1%)	0		
Pernicious anaemia	悪性貧血	1 (<0.1%)	0		
Polycythaemia	赤血球増加症	1 (<0.1%)	0	1 (<0.1%)	0
Splenomegaly	脾腫	1 (<0.1%)	0		
Spontaneous haematoma	特発性血腫	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Thrombocytopenia	血小板減少症	3 (0.2%)	3 (0.2%)	2 (0.1%)	1 (<0.1%)
Cardiac disorders	心臓障害	53 (3.1%)	47 (2.7%)	7 (0.4%)	1 (<0.1%)
Acute coronary syndrome	急性冠動脈症候群	1 (<0.1%)	0		
Acute myocardial infarction	急性心筋梗塞	4 (0.2%)	1 (<0.1%)		
Angina pectoris	狭心症	2 (0.1%)	2 (0.1%)		
Angina unstable	不安定狭心症	1 (<0.1%)	4 (0.2%)		
Aortic valve disease	大動脈弁疾患	0	1 (<0.1%)		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Aortic valve incompetence	大動脈弁閉鎖不全症	2 (0.1%)	0		
Arrhythmia	不整脈	1 (<0.1%)	0		
Atrial fibrillation	心房細動	4 (0.2%)	8 (0.5%)		
Atrial flutter	心房粗動	1 (<0.1%)	0		
Atrioventricular block	房室ブロック	0	2 (0.1%)		
Atrioventricular block second degree	第二度房室ブロック	1 (<0.1%)	0		
Bradycardia	徐脈	1 (<0.1%)	1 (<0.1%)		
Bundle branch block left	左脚ブロック	0	1 (<0.1%)		
Cardiac arrest	心停止	0	1 (<0.1%)		
Cardiac disorder	心障害	1 (<0.1%)	0		
Cardiac failure	心不全	3 (0.2%)	4 (0.2%)		
Cardiac failure chronic	慢性心不全	1 (<0.1%)	1 (<0.1%)		
Cardiac failure congestive	うっ血性心不全	0	2 (0.1%)		
Coronary artery disease	冠動脈疾患	0	1 (<0.1%)		
Cyanosis	チアノーゼ	1 (<0.1%)	3 (0.2%)	1 (<0.1%)	0
Diastolic dysfunction	拡張機能障害	1 (<0.1%)	0	1 (<0.1%)	0
Hypertensive heart disease	高血圧性心疾患	0	1 (<0.1%)		
Left ventricular hypertrophy	左室肥大	1 (<0.1%)	2 (0.1%)		
Mitral valve incompetence	僧帽弁閉鎖不全症	1 (<0.1%)	3 (0.2%)		
Mitral valve prolapse	僧帽弁逸脱	0	1 (<0.1%)		
Myocardial infarction	心筋梗塞	0	1 (<0.1%)		
Myocardial ischaemia	心筋虚血	0	2 (0.1%)		
Palpitations	動悸	15 (0.9%)	5 (0.3%)	2 (0.1%)	1 (<0.1%)
Pericardial cyst	心膜嚢胞	1 (<0.1%)	0		
Pericarditis	心膜炎	1 (<0.1%)	0		
Right ventricular failure	右室不全	1 (<0.1%)	0		
Sick sinus syndrome	洞不全症候群	0	1 (<0.1%)		
Sinoatrial block	洞房ブロック	0	1 (<0.1%)		
Sinus arrhythmia	洞性不整脈	0	2 (0.1%)		
Sinus tachycardia	洞性頻脈	1 (<0.1%)	0		
Supraventricular tachycardia	上室性頻脈	0	1 (<0.1%)		
Tachyarrhythmia	頻脈性不整脈	1 (<0.1%)	0		
Tachycardia	頻脈	9 (0.5%)	5 (0.3%)	3 (0.2%)	0

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Tricuspid valve incompetence	三尖弁閉鎖不全症	0	1 (<0.1%)		
Ventricular extrasystoles	心室性期外収縮	1 (<0.1%)	0		
Ventricular tachycardia	心室性頻脈	0	1 (<0.1%)		
Congenital, familial and genetic disorders	先天性、家族性および遺伝性障害	19 (1.1%)	15 (0.9%)		
Adenomatous polyposis coli	大腸腺腫性ポリポーシス	0	1 (<0.1%)		
Antithrombin III deficiency	アンチトロンビンＩＩＩ欠乏症	2 (0.1%)	0		
Congenital cystic kidney disease	先天性嚢胞性腎疾患	1 (<0.1%)	1 (<0.1%)		
Congenital urethral anomaly	先天性尿道異常	1 (<0.1%)	0		
Dolichocolon	過長結腸	1 (<0.1%)	0		
Dysplastic naevus syndrome	異形成母斑症候群	1 (<0.1%)	0		
Factor II mutation	第ＩＩ因子突然変異	3 (0.2%)	2 (0.1%)		
Factor V Leiden mutation	第Ⅴ因子ライデン変異	8 (0.5%)	8 (0.5%)		
Gene mutation	遺伝子突然変異	2 (0.1%)	3 (0.2%)		
Hip dysplasia	股関節形成不全	0	1 (<0.1%)		
Mixed hyperlipidaemia	混合型高脂血症	1 (<0.1%)	0		
Phimosis	包茎	0	1 (<0.1%)		
Ear and labyrinth disorders	耳および迷路障害	24 (1.4%)	22 (1.3%)	6 (0.3%)	2 (0.1%)
Deafness	難聴	1 (<0.1%)	0		
Deafness neurosensory	感音性難聴	1 (<0.1%)	0	1 (<0.1%)	0
Deafness unilateral	片耳難聴	0	1 (<0.1%)		
Ear discomfort	耳不快感	2 (0.1%)	1 (<0.1%)		
Ear haemorrhage	耳出血	2 (0.1%)	4 (0.2%)	1 (<0.1%)	2 (0.1%)
Ear pain	耳痛	2 (0.1%)	2 (0.1%)	1 (<0.1%)	0
External ear inflammation	外耳の炎症	0	1 (<0.1%)		
Hearing impaired	聴覚障害	1 (<0.1%)	0	1 (<0.1%)	0
Hypoacusis	聴力低下	1 (<0.1%)	1 (<0.1%)		
Tinnitus	耳鳴	3 (0.2%)	2 (0.1%)		
Vertigo	回転性めまい	14 (0.8%)	10 (0.6%)	3 (0.2%)	0
Vertigo labyrinthine	迷路性回転性めまい	0	1 (<0.1%)		
Endocrine disorders	内分泌障害	4 (0.2%)	9 (0.5%)		
Basedow's disease	バセドウ病	1 (<0.1%)	0		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Cushingoid	クッシング様	0	1 (<0.1%)		
Goitre	甲状腺腫	2 (0.1%)	2 (0.1%)		
Hyperthyroidism	甲状腺機能亢進症	0	2 (0.1%)		
Hypothyroidism	甲状腺機能低下症	1 (<0.1%)	4 (0.2%)		
Eye disorders	眼障害	40 (2.3%)	39 (2.3%)	14 (0.8%)	19 (1.1%)
Asthenopia	眼精疲労	1 (<0.1%)	0		
Blepharochalasis	眼瞼皮膚弛緩症	0	1 (<0.1%)		
Cataract	白内障	4 (0.2%)	3 (0.2%)		
Cataract cortical	皮質白内障	1 (<0.1%)	0		
Conjunctival haemorrhage	結膜出血	12 (0.7%)	21 (1.2%)	9 (0.5%)	14 (0.8%)
Conjunctivitis	結膜炎	4 (0.2%)	2 (0.1%)		
Diabetic retinopathy	糖尿病性網膜症	2 (0.1%)	1 (<0.1%)		
Dry eye	眼乾燥	1 (<0.1%)	1 (<0.1%)		
Entropion	眼瞼内反	0	1 (<0.1%)		
Eye haemorrhage	眼出血	2 (0.1%)	3 (0.2%)	2 (0.1%)	3 (0.2%)
Eye inflammation	眼の炎症	1 (<0.1%)	0		
Eye movement disorder	眼運動障害	1 (<0.1%)	0		
Eye pain	眼痛	1 (<0.1%)	0		
Eye pruritus	眼そう痒症	1 (<0.1%)	0		
Hypermetropia	遠視	1 (<0.1%)	0		
Hyphaema	前房出血	1 (<0.1%)	0	1 (<0.1%)	0
Keratoconjunctivitis sicca	乾性角結膜炎	0	1 (<0.1%)		
Lacrimal haemorrhage	涙器出血	0	1 (<0.1%)		
Macular hole	黄斑円孔	1 (<0.1%)	0		
Maculopathy	黄斑症	1 (<0.1%)	0		
Ocular hyperaemia	眼充血	0	3 (0.2%)	0	2 (0.1%)
Retinal detachment	網膜剥離	1 (<0.1%)	0		
Retinal exudates	網膜滲出物	1 (<0.1%)	0	1 (<0.1%)	0
Retinopathy	網膜症	1 (<0.1%)	0		
Vision blurred	霧視	3 (0.2%)	1 (<0.1%)	1 (<0.1%)	0
Visual impairment	視力障害	1 (<0.1%)	1 (<0.1%)		
Vitreous detachment	硝子体剥離	1 (<0.1%)	0	1 (<0.1%)	0
Vitreous haemorrhage	硝子体出血	0	1 (<0.1%)		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Gastrointestinal disorders	胃腸障害	337 (19.6%)	295 (17.2%)	118 (6.9%)	87 (5.1%)
Abdominal discomfort	腹部不快感	14 (0.8%)	8 (0.5%)	4 (0.2%)	1 (<0.1%)
Abdominal distension	腹部膨満	5 (0.3%)	5 (0.3%)	2 (0.1%)	0
Abdominal pain	腹痛	24 (1.4%)	15 (0.9%)	2 (0.1%)	0
Abdominal pain lower	下腹部痛	6 (0.3%)	1 (<0.1%)	1 (<0.1%)	0
Abdominal pain upper	上腹部痛	18 (1.0%)	9 (0.5%)	3 (0.2%)	1 (<0.1%)
Abdominal wall cyst	腹壁嚢胞	1 (<0.1%)	0		
Abdominal wall haematoma	腹壁血腫	1 (<0.1%)	1 (<0.1%)		
Aerophagia	空気嚥下	0	1 (<0.1%)		
Anal haemorrhage	肛門出血	0	1 (<0.1%)	0	1 (<0.1%)
Anal skin tags	肛門皮膚垂	0	1 (<0.1%)		
Ascites	腹水	3 (0.2%)	2 (0.1%)		
Barrett's oesophagus	バレット食道	1 (<0.1%)	0		
Chapped lips	口唇のひび割れ	1 (<0.1%)	0		
Coeliac artery stenosis	腹腔動脈狭窄	0	1 (<0.1%)		
Coeliac disease	セリアック病	1 (<0.1%)	0		
Colitis	大腸炎	0	1 (<0.1%)		
Colitis ulcerative	潰瘍性大腸炎	1 (<0.1%)	1 (<0.1%)		
Colonic polyp	結腸ポリープ	3 (0.2%)	5 (0.3%)		
Constipation	便秘	48 (2.8%)	43 (2.5%)	1 (<0.1%)	3 (0.2%)
Crohn's disease	クローン病	0	4 (0.2%)		
Dental caries	齲歯	5 (0.3%)	4 (0.2%)		
Diabetic gastropathy	糖尿病性胃障害	0	1 (<0.1%)		
Diarrhoea	下痢	54 (3.1%)	40 (2.3%)	8 (0.5%)	2 (0.1%)
Diverticulum	憩室	2 (0.1%)	0		
Diverticulum intestinal	腸憩室	3 (0.2%)	5 (0.3%)		
Dry mouth	口内乾燥	4 (0.2%)	4 (0.2%)	2 (0.1%)	0
Duodenal polyp	十二指腸ポリープ	0	1 (<0.1%)		
Duodenal ulcer	十二指腸潰瘍	2 (0.1%)	2 (0.1%)	1 (<0.1%)	0
Duodenitis	十二指腸炎	3 (0.2%)	3 (0.2%)		
Dyspepsia	消化不良	18 (1.0%)	14 (0.8%)	4 (0.2%)	2 (0.1%)
Dysphagia	嚥下障害	1 (<0.1%)	0		
Enterocutaneous fistula	腸管皮膚瘻	2 (0.1%)	0		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Eructation	おくび	0	1 (<0.1%)		
Faecaloma	糞塊	1 (<0.1%)	0		
Faeces discoloured	変色便	1 (<0.1%)	0		
Faeces hard	硬便	1 (<0.1%)	0		
Flatulence	鼓腸	4 (0.2%)	3 (0.2%)	2 (0.1%)	0
Food poisoning	食中毒	2 (0.1%)	2 (0.1%)		
Frequent bowel movements	排便回数増加	1 (<0.1%)	0		
Gastric haemorrhage	胃出血	0	1 (<0.1%)	0	1 (<0.1%)
Gastric ulcer	胃潰瘍	3 (0.2%)	3 (0.2%)		
Gastric ulcer haemorrhage	出血性胃潰瘍	0	1 (<0.1%)		
Gastric ulcer perforation	穿孔性胃潰瘍	0	1 (<0.1%)		
Gastritis	胃炎	8 (0.5%)	5 (0.3%)	1 (<0.1%)	0
Gastritis atrophic	萎縮性胃炎	1 (<0.1%)	0		
Gastritis erosive	びらん性胃炎	2 (0.1%)	0		
Gastrointestinal haemorrhage	胃腸出血	4 (0.2%)	0	3 (0.2%)	0
Gastrointestinal tract mucosal discolouration	消化管粘膜変色	0	1 (<0.1%)		
Gastrooesophageal reflux disease	胃食道逆流性疾患	14 (0.8%)	3 (0.2%)	3 (0.2%)	0
Gastrooesophageal sphincter insufficiency	胃食道括約筋機能不全	1 (<0.1%)	0		
Gingival bleeding	歯肉出血	36 (2.1%)	28 (1.6%)	31 (1.8%)	24 (1.4%)
Gingival pain	歯肉痛	0	1 (<0.1%)		
Gingival recession	歯肉退縮	0	1 (<0.1%)	0	1 (<0.1%)
Gingival swelling	歯肉腫脹	0	1 (<0.1%)	0	1 (<0.1%)
Gingivitis	歯肉炎	2 (0.1%)	2 (0.1%)		
Haematemesis	吐血	2 (0.1%)	7 (0.4%)	2 (0.1%)	6 (0.4%)
Haematochezia	血便排泄	7 (0.4%)	8 (0.5%)	4 (0.2%)	6 (0.4%)
Haemorrhoidal haemorrhage	痔出血	14 (0.8%)	8 (0.5%)	8 (0.5%)	4 (0.2%)
Haemorrhoids	痔核	8 (0.5%)	8 (0.5%)	1 (<0.1%)	0
Hiatus hernia	裂孔ヘルニア	5 (0.3%)	5 (0.3%)		
Hyperchlorhydria	胃酸過多	0	1 (<0.1%)		
Hypoaesthesia oral	口の感覚鈍麻	1 (<0.1%)	0		
Inguinal hernia	鼠径ヘルニア	0	1 (<0.1%)		
Inguinal hernia, obstructive	閉塞性鼠径ヘルニア	0	1 (<0.1%)		
Intestinal cyst	腸管嚢胞	1 (<0.1%)	0		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Intestinal dilatation	腸管拡張症	1 (<0.1%)	0		
Intestinal haemorrhage	腸出血	0	3 (0.2%)	0	2 (0.1%)
Intestinal ischaemia	腸管虚血	0	1 (<0.1%)		
Intestinal obstruction	腸閉塞	1 (<0.1%)	1 (<0.1%)		
Intestinal perforation	腸管穿孔	1 (<0.1%)	0		
Intestinal polyp	腸管ポリープ	3 (0.2%)	0		
Intra-abdominal haematoma	腹腔内血腫	0	13 (0.8%)	0	11 (0.6%)
Intra-abdominal haemorrhage	腹腔内出血	0	1 (<0.1%)	0	1 (<0.1%)
Large intestine perforation	大腸穿孔	0	1 (<0.1%)		
Lip dry	口唇乾燥	1 (<0.1%)	0		
Lip haemorrhage	口唇出血	2 (0.1%)	0		
Lip ulceration	口唇潰瘍	0	1 (<0.1%)		
Lower gastrointestinal haemorrhage	下部消化管出血	1 (<0.1%)	0	1 (<0.1%)	0
Mallory-Weiss syndrome	マロリー・ワイス症候群	1 (<0.1%)	0		
Melaena	メレナ	8 (0.5%)	4 (0.2%)	8 (0.5%)	3 (0.2%)
Melanosis coli	結腸メラノーシス	0	1 (<0.1%)		
Mouth haemorrhage	口腔内出血	6 (0.3%)	2 (0.1%)	5 (0.3%)	2 (0.1%)
Mouth ulceration	口腔内潰瘍形成	1 (<0.1%)	1 (<0.1%)		
Nausea	悪心	47 (2.7%)	38 (2.2%)	10 (0.6%)	10 (0.6%)
Oesophageal pain	食道痛	1 (<0.1%)	0		
Oesophageal ulcer	食道潰瘍	0	1 (<0.1%)		
Oesophageal ulcer haemorrhage	食道潰瘍出血	0	1 (<0.1%)		
Oesophagitis	食道炎	4 (0.2%)	2 (0.1%)		
Oral pain	口腔内痛	1 (<0.1%)	1 (<0.1%)		
Pancreas lipomatosis	膵脂肪腫症	2 (0.1%)	0		
Pancreatic cyst	膵嚢胞	0	1 (<0.1%)		
Pancreatitis	膵炎	1 (<0.1%)	1 (<0.1%)		
Pancreatitis acute	急性膵炎	0	3 (0.2%)		
Paraesthesia oral	口の錯感覚	1 (<0.1%)	0	1 (<0.1%)	0
Peptic ulcer	消化性潰瘍	0	1 (<0.1%)		
Pericoronitis	歯冠周囲炎	0	1 (<0.1%)		
Periodontal disease	歯周病	1 (<0.1%)	0		
Periodontitis	歯周炎	2 (0.1%)	2 (0.1%)		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Peritonitis	腹膜炎	1 (<0.1%)	0		
Proctalgia	肛門周囲痛	1 (<0.1%)	0		
Rectal haemorrhage	直腸出血	36 (2.1%)	19 (1.1%)	27 (1.6%)	11 (0.6%)
Rectal polyp	直腸ポリープ	2 (0.1%)	0		
Reflux oesophagitis	逆流性食道炎	3 (0.2%)	5 (0.3%)		
Retroperitoneal fibrosis	後腹膜線維症	0	1 (<0.1%)		
Small intestinal obstruction	小腸閉塞	0	1 (<0.1%)		
Stomatitis haemorrhagic	出血性口内炎	1 (<0.1%)	0		
Tongue haemorrhage	舌出血	2 (0.1%)	1 (<0.1%)		
Tooth disorder	歯の障害	1 (<0.1%)	2 (0.1%)		
Toothache	歯痛	7 (0.4%)	7 (0.4%)		
Umbilical hernia	臍ヘルニア	1 (<0.1%)	2 (0.1%)		
Upper gastrointestinal haemorrhage	上部消化管出血	0	1 (<0.1%)	0	1 (<0.1%)
Vomiting	嘔吐	18 (1.0%)	22 (1.3%)	4 (0.2%)	3 (0.2%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	197 (11.5%)	178 (10.4%)	21 (1.2%)	26 (1.5%)
Asthenia	無力症	10 (0.6%)	7 (0.4%)		
Axillary pain	腋窩痛	1 (<0.1%)	0		
Catheter site haemorrhage	カテーテル留置部位出血	0	1 (<0.1%)		
Chest discomfort	胸部不快感	1 (<0.1%)	5 (0.3%)		
Chest pain	胸痛	36 (2.1%)	31 (1.8%)	0	1 (<0.1%)
Chills	悪寒	3 (0.2%)	0	1 (<0.1%)	0
Cyst	嚢胞	1 (<0.1%)	1 (<0.1%)		
Death	死亡	0	1 (<0.1%)		
Device leakage	医療機器リーク	1 (<0.1%)	0		
Device occlusion	医療機器閉塞	1 (<0.1%)	0		
Drug resistance	薬剤耐性	0	1 (<0.1%)	0	1 (<0.1%)
Exercise tolerance decreased	運動耐性低下	2 (0.1%)	0		
Facial pain	顔面痛	1 (<0.1%)	1 (<0.1%)		
Fatigue	疲労	24 (1.4%)	15 (0.9%)	5 (0.3%)	2 (0.1%)
Feeling abnormal	異常感	3 (0.2%)	2 (0.1%)		
Feeling cold	冷感	2 (0.1%)	0		
Feeling hot	熱感	0	1 (<0.1%)	0	1 (<0.1%)

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Feeling of body temperature change	体温変動感	1 (<0.1%)	0	1 (<0.1%)	0
Gait disturbance	歩行障害	0	2 (0.1%)		
General physical health deterioration	全身健康状態低下	1 (<0.1%)	1 (<0.1%)		
Generalised oedema	全身性浮腫	1 (<0.1%)	0		
Haemorrhagic cyst	出血性嚢胞	1 (<0.1%)	0		
Hernia	ヘルニア	1 (<0.1%)	1 (<0.1%)		
Impaired healing	治癒不良	0	1 (<0.1%)		
Inflammation	炎症	2 (0.1%)	3 (0.2%)		
Influenza like illness	インフルエンザ様疾患	5 (0.3%)	2 (0.1%)		
Infusion site phlebitis	注入部位静脈炎	0	1 (<0.1%)		
Injection site extravasation	注射部位血管外漏出	0	2 (0.1%)	0	2 (0.1%)
Injection site haematoma	注射部位血腫	2 (0.1%)	12 (0.7%)	2 (0.1%)	12 (0.7%)
Injection site haemorrhage	注射部位出血	0	1 (<0.1%)	0	1 (<0.1%)
Injection site pain	注射部位疼痛	0	1 (<0.1%)	0	1 (<0.1%)
Injection site reaction	注射部位反応	0	1 (<0.1%)		
Injection site swelling	注射部位腫脹	0	1 (<0.1%)	0	1 (<0.1%)
Irritability	易刺激性	1 (<0.1%)	0		
Local swelling	局所腫脹	1 (<0.1%)	0		
Malaise	倦怠感	5 (0.3%)	5 (0.3%)	3 (0.2%)	0
Medical device complication	医療機器合併症	0	1 (<0.1%)		
Multi-organ failure	多臓器不全	3 (0.2%)	1 (<0.1%)		
Non-cardiac chest pain	非心臓性胸痛	2 (0.1%)	1 (<0.1%)		
Oedema	浮腫	15 (0.9%)	8 (0.5%)	1 (<0.1%)	0
Oedema peripheral	末梢性浮腫	41 (2.4%)	41 (2.4%)	5 (0.3%)	1 (<0.1%)
Pain	疼痛	8 (0.5%)	6 (0.4%)	0	1 (<0.1%)
Pelvic mass	骨盤腔内腫瘤	0	1 (<0.1%)		
Polyp	ポリープ	2 (0.1%)	0		
Puncture site haemorrhage	穿刺部位出血	0	2 (0.1%)	0	2 (0.1%)
Pyrexia	発熱	43 (2.5%)	38 (2.2%)	1 (<0.1%)	1 (<0.1%)
Sudden cardiac death	心突然死	1 (<0.1%)	0		
Sudden death	突然死	0	1 (<0.1%)		
Thirst	口渇	1 (<0.1%)	0		
Vessel puncture site haematoma	血管穿刺部位血腫	3 (0.2%)	1 (<0.1%)	1 (<0.1%)	0

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Vessel puncture site haemorrhage	血管穿刺部位出血	2 (0.1%)	1 (<0.1%)	2 (0.1%)	1 (<0.1%)
Vessel puncture site reaction	血管穿刺部位反応	1 (<0.1%)	0		
Hepatobiliary disorders	肝胆道系障害	25 (1.5%)	23 (1.3%)	2 (0.1%)	1 (<0.1%)
Biliary colic	胆道仙痛	1 (<0.1%)	1 (<0.1%)		
Cholangitis	胆管炎	1 (<0.1%)	1 (<0.1%)		
Cholecystitis	胆嚢炎	0	1 (<0.1%)		
Cholecystitis acute	急性胆嚢炎	0	1 (<0.1%)		
Cholecystitis chronic	慢性胆嚢炎	1 (<0.1%)	0		
Cholelithiasis	胆石症	7 (0.4%)	7 (0.4%)		
Gallbladder polyp	胆嚢ポリープ	1 (<0.1%)	1 (<0.1%)		
Hepatic cyst	肝嚢胞	5 (0.3%)	4 (0.2%)		
Hepatic function abnormal	肝機能異常	3 (0.2%)	1 (<0.1%)	1 (<0.1%)	0
Hepatic mass	肝腫瘤	1 (<0.1%)	0		
Hepatic steatosis	脂肪肝	9 (0.5%)	9 (0.5%)		
Hepatitis acute	急性肝炎	1 (<0.1%)	0	1 (<0.1%)	0
Hepatocellular injury	肝細胞損傷	0	1 (<0.1%)		
Hepatomegaly	肝腫大	1 (<0.1%)	0		
Hydrocholecystis	水腫性胆嚢炎	0	1 (<0.1%)		
Hyperbilirubinaemia	高ビリルビン血症	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Jaundice cholestatic	胆汁うっ滞性黄疸	0	1 (<0.1%)		
Immune system disorders	免疫系障害	18 (1.0%)	13 (0.8%)	1 (<0.1%)	1 (<0.1%)
Antiphospholipid syndrome	抗リン脂質抗体症候群	3 (0.2%)	1 (<0.1%)		
Behcet's syndrome	ベーチェット症候群	1 (<0.1%)	1 (<0.1%)		
Contrast media allergy	造影剤アレルギー	0	1 (<0.1%)		
Drug hypersensitivity	薬物過敏症	3 (0.2%)	2 (0.1%)	0	1 (<0.1%)
House dust allergy	家塵アレルギー	1 (<0.1%)	0		
Humoral immune defect	体液性免疫不全	1 (<0.1%)	0		
Hypersensitivity	過敏症	7 (0.4%)	5 (0.3%)	1 (<0.1%)	0
Liver transplant rejection	肝移植拒絶反応	0	1 (<0.1%)		
Seasonal allergy	季節性アレルギー	2 (0.1%)	2 (0.1%)		
Infections and infestations	感染症および寄生虫症	351 (20.4%)	357 (20.9%)	8 (0.5%)	2 (0.1%)
Abdominal abscess	腹部膿瘍	0	1 (<0.1%)		
Abscess	膿瘍	1 (<0.1%)	0		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Abscess limb	四肢膿瘍	1 (<0.1%)	2 (0.1%)		
Acute tonsillitis	急性扁桃炎	1 (<0.1%)	1 (<0.1%)		
Anal abscess	肛門膿瘍	0	1 (<0.1%)		
Appendicitis	虫垂炎	0	1 (<0.1%)		
Arthritis infective	感染性関節炎	0	1 (<0.1%)		
Asymptomatic bacteriuria	無症候性細菌尿	1 (<0.1%)	0		
Bacteraemia	菌血症	1 (<0.1%)	1 (<0.1%)		
Bacterial infection	細菌感染	1 (<0.1%)	0		
Bacterial sepsis	細菌性敗血症	0	1 (<0.1%)		
Balanitis candida	カンジダ性亀頭炎	1 (<0.1%)	0		
Blister infected	感染性水疱	0	1 (<0.1%)		
Body tinea	体部白癬	0	1 (<0.1%)		
Bone tuberculosis	骨結核	1 (<0.1%)	0		
Bronchiectasis	気管支拡張症	1 (<0.1%)	0		
Bronchitis	気管支炎	24 (1.4%)	34 (2.0%)	0	1 (<0.1%)
Bronchopneumonia	気管支肺炎	4 (0.2%)	1 (<0.1%)		
Candidiasis	カンジダ症	0	1 (<0.1%)		
Cardiac valve vegetation	心臓弁疣贅	0	1 (<0.1%)		
Catheter site infection	カテーテル留置部位感染	0	1 (<0.1%)		
Cellulitis	蜂巣炎	14 (0.8%)	22 (1.3%)		
Cerebral toxoplasmosis	脳トキソプラズマ症	0	1 (<0.1%)		
Chlamydial infection	クラミジア感染	1 (<0.1%)	0		
Clostridial infection	クロストリジウム感染	1 (<0.1%)	0		
Conjunctivitis infective	感染性結膜炎	0	1 (<0.1%)		
Cystitis	膀胱炎	10 (0.6%)	13 (0.8%)		
Dengue fever	デング熱	0	1 (<0.1%)		
Dermatophytosis	皮膚糸状菌症	1 (<0.1%)	0		
Dermo-hypodermitis	皮膚皮下組織炎	0	2 (0.1%)		
Device related infection	医療機器関連感染	0	1 (<0.1%)		
Diverticulitis	憩室炎	1 (<0.1%)	1 (<0.1%)		
Dysentery	赤痢	1 (<0.1%)	0		
Ear infection	耳感染	1 (<0.1%)	5 (0.3%)		
Endocarditis staphylococcal	ブドウ球菌性心内膜炎	0	1 (<0.1%)		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Enterocolitis bacterial	細菌性腸炎	1 (<0.1%)	0		
Epiglottitis	喉頭蓋炎	1 (<0.1%)	1 (<0.1%)		
Epstein-Barr virus infection	エプスタイン・バーウイルス感染	1 (<0.1%)	0		
Erysipelas	丹毒	4 (0.2%)	6 (0.4%)		
Escherichia urinary tract infection	大腸菌性尿路感染	1 (<0.1%)	0		
Eye infection	眼感染	2 (0.1%)	1 (<0.1%)		
Folliculitis	毛包炎	2 (0.1%)	1 (<0.1%)		
Fungal infection	真菌感染	1 (<0.1%)	0		
Fungal skin infection	皮膚真菌感染	3 (0.2%)	2 (0.1%)		
Furuncle	せつ	3 (0.2%)	1 (<0.1%)		
Gastroenteritis	胃腸炎	12 (0.7%)	18 (1.1%)		
Gastroenteritis viral	ウイルス性胃腸炎	5 (0.3%)	0		
Genital candidiasis	性器カンジダ症	1 (<0.1%)	0		
Genital infection fungal	真菌性性器感染	0	1 (<0.1%)		
Gingival infection	歯肉感染	2 (0.1%)	0		
Helicobacter gastritis	ヘリコバクター性胃炎	2 (0.1%)	0		
Helicobacter infection	ヘリコバクター感染	0	1 (<0.1%)		
Herpes simplex	単純ヘルペス	1 (<0.1%)	0		
Herpes zoster	帯状疱疹	7 (0.4%)	2 (0.1%)		
Hordeolum	麦粒腫	1 (<0.1%)	1 (<0.1%)		
Incision site abscess	切開部位膿瘍	1 (<0.1%)	0		
Incision site infection	切開部位感染	0	2 (0.1%)		
Infected cyst	感染性嚢腫	0	1 (<0.1%)		
Infected skin ulcer	感染性皮膚潰瘍	0	1 (<0.1%)		
Infection	感染	1 (<0.1%)	2 (0.1%)		
Infective aneurysm	感染性動脈瘤	1 (<0.1%)	0		
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%)	2 (0.1%)		
Influenza	インフルエンザ	38 (2.2%)	38 (2.2%)		
Injection site infection	注射部位感染	0	1 (<0.1%)		
Kidney infection	腎感染	0	1 (<0.1%)		
Laryngitis	喉頭炎	1 (<0.1%)	0		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Lobar pneumonia	大葉性肺炎	1 (<0.1%)	2 (0.1%)		
Localised infection	限局性感染	8 (0.5%)	6 (0.4%)	1 (<0.1%)	0
Lower respiratory tract infection	下気道感染	8 (0.5%)	5 (0.3%)		
Lung infection	肺感染	2 (0.1%)	1 (<0.1%)		
Lymphangitis	リンパ管炎	0	1 (<0.1%)		
Mastitis	乳腺炎	0	1 (<0.1%)		
Mumps	ムンプス	0	1 (<0.1%)		
Myringitis	鼓膜炎	1 (<0.1%)	0		
Nail bed infection	爪床感染	0	1 (<0.1%)		
Nail infection	爪感染	1 (<0.1%)	0		
Nasopharyngitis	鼻咽頭炎	93 (5.4%)	84 (4.9%)	1 (<0.1%)	1 (<0.1%)
Oesophageal candidiasis	食道カンジダ症	1 (<0.1%)	1 (<0.1%)		
Onychomycosis	爪真菌症	0	1 (<0.1%)		
Opisthorchiasis	タイ肝吸虫症	0	1 (<0.1%)		
Oral candidiasis	口腔カンジダ症	4 (0.2%)	2 (0.1%)		
Oral fungal infection	口腔真菌感染	2 (0.1%)	1 (<0.1%)	1 (<0.1%)	0
Oral herpes	口腔ヘルペス	3 (0.2%)	2 (0.1%)		
Oropharyngitis fungal	真菌性口腔咽頭炎	0	1 (<0.1%)		
Otitis externa	外耳炎	1 (<0.1%)	1 (<0.1%)		
Otitis media	中耳炎	3 (0.2%)	1 (<0.1%)		
Paronychia	爪囲炎	2 (0.1%)	1 (<0.1%)		
Pharyngitis	咽頭炎	10 (0.6%)	2 (0.1%)		
Pharyngitis streptococcal	レンサ球菌性咽頭炎	1 (<0.1%)	0		
Pneumonia	肺炎	15 (0.9%)	20 (1.2%)		
Pneumonia bacterial	細菌性肺炎	0	2 (0.1%)		
Post procedural sepsis	処置後敗血症	0	1 (<0.1%)		
Postoperative wound infection	術後創感染	1 (<0.1%)	3 (0.2%)		
Pseudomembranous colitis	偽膜性大腸炎	0	1 (<0.1%)		
Pulmonary sepsis	肺敗血症	0	1 (<0.1%)		
Pulmonary tuberculosis	肺結核	1 (<0.1%)	3 (0.2%)		
Pyelonephritis	腎盂腎炎	2 (0.1%)	3 (0.2%)		
Pyelonephritis acute	急性腎盂腎炎	0	1 (<0.1%)		
Rash pustular	膿疱性皮疹	1 (<0.1%)	0	1 (<0.1%)	0

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Renal abscess	腎膿瘍	1 (<0.1%)	0		
Respiratory tract infection	気道感染	10 (0.6%)	5 (0.3%)		
Rhinitis	鼻炎	10 (0.6%)	6 (0.4%)		
Sepsis	敗血症	4 (0.2%)	5 (0.3%)		
Septic shock	敗血症性ショック	1 (<0.1%)	3 (0.2%)		
Sinusitis	副鼻腔炎	13 (0.8%)	11 (0.6%)	1 (<0.1%)	0
Skin infection	皮膚感染	2 (0.1%)	3 (0.2%)	1 (<0.1%)	0
Sputum purulent	膿性痰	0	1 (<0.1%)		
Staphylococcal skin infection	ブドウ球菌皮膚感染	1 (<0.1%)	0		
Strongyloidiasis	糞線虫症	0	1 (<0.1%)		
Subacute endocarditis	亜急性心内膜炎	1 (<0.1%)	0		
Tinea cruris	股部白癬	0	2 (0.1%)		
Tinea pedis	足部白癬	0	2 (0.1%)		
Tonsillitis	扁桃炎	0	1 (<0.1%)		
Tooth abscess	歯膿瘍	2 (0.1%)	4 (0.2%)		
Tooth infection	歯感染	3 (0.2%)	3 (0.2%)	1 (<0.1%)	0
Tracheitis	気管炎	0	1 (<0.1%)		
Tracheobronchitis	気管気管支炎	1 (<0.1%)	1 (<0.1%)		
Upper respiratory tract infection	上気道感染	15 (0.9%)	24 (1.4%)		
Urinary tract infection	尿路感染	37 (2.2%)	32 (1.9%)	1 (<0.1%)	0
Vaginal infection	腟感染	1 (<0.1%)	1 (<0.1%)		
Vaginitis bacterial	細菌性腟炎	1 (<0.1%)	0		
Viral infection	ウイルス感染	6 (0.3%)	6 (0.4%)		
Viral upper respiratory tract infection	ウイルス性上気道感染	6 (0.3%)	5 (0.3%)		
Vulvovaginal candidiasis	外陰部腟カンジダ症	3 (0.2%)	0		
Vulvovaginal mycotic infection	外陰腟真菌感染	1 (<0.1%)	2 (0.1%)		
Wound abscess	創部膿瘍	1 (<0.1%)	0		
Wound infection	創傷感染	4 (0.2%)	2 (0.1%)		
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	155 (9.0%)	182 (10.6%)	49 (2.9%)	71 (4.1%)
Accident	事故	1 (<0.1%)	1 (<0.1%)		
Accidental overdose	偶発的過量投与	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Alcohol poisoning	アルコール中毒	0	1 (<0.1%)		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Anaemia postoperative	術後貧血	0	1 (<0.1%)		
Animal bite	動物咬傷	3 (0.2%)	1 (<0.1%)		
Animal scratch	動物による引っかき傷	1 (<0.1%)	0		
Ankle fracture	足関節部骨折	0	1 (<0.1%)		
Arthropod bite	節足動物咬傷	2 (0.1%)	1 (<0.1%)		
Arthropod sting	節足動物刺傷	1 (<0.1%)	2 (0.1%)		
Bursa injury	滑液包損傷	0	1 (<0.1%)		
Cartilage injury	軟骨損傷	0	1 (<0.1%)		
Concussion	脳振盪	0	1 (<0.1%)		
Contusion	挫傷	53 (3.1%)	68 (4.0%)	28 (1.6%)	40 (2.3%)
Crushing injury of trunk	体幹の圧挫損傷	1 (<0.1%)	0		
Drug exposure during pregnancy	妊娠時の薬物曝露	0	1 (<0.1%)		
Drug toxicity	薬物毒性	1 (<0.1%)	0	1 (<0.1%)	0
Epicondylitis	上顆炎	0	1 (<0.1%)		
Eschar	焼痂	1 (<0.1%)	0		
Excoriation	擦過傷	5 (0.3%)	4 (0.2%)	1 (<0.1%)	0
Eye injury	眼外傷	1 (<0.1%)	0		
Face injury	顔面損傷	0	1 (<0.1%)		
Facial bones fracture	顔面骨骨折	1 (<0.1%)	0		
Fall	転倒	10 (0.6%)	9 (0.5%)		
Femoral neck fracture	大腿骨頚部骨折	0	2 (0.1%)		
Femur fracture	大腿骨骨折	0	1 (<0.1%)		
Foot fracture	足骨折	2 (0.1%)	1 (<0.1%)		
Forearm fracture	前腕骨折	0	1 (<0.1%)		
Gastroenteritis radiation	放射線胃腸炎	1 (<0.1%)	0		
Graft haemorrhage	移植部位出血	0	1 (<0.1%)		
Hand fracture	手骨折	2 (0.1%)	0		
Humerus fracture	上腕骨骨折	1 (<0.1%)	1 (<0.1%)		
Induced abortion haemorrhage	人工流産による出血	1 (<0.1%)	0		
Inflammation of wound	創部炎症	1 (<0.1%)	0		
Injury	損傷	1 (<0.1%)	0		
Joint dislocation	関節脱臼	2 (0.1%)	2 (0.1%)		
Joint injury	関節損傷	2 (0.1%)	3 (0.2%)		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Joint sprain	関節捻挫	9 (0.5%)	8 (0.5%)		
Ligament injury	靭帯損傷	0	1 (<0.1%)		
Ligament rupture	靭帯断裂	1 (<0.1%)	1 (<0.1%)		
Limb injury	四肢損傷	4 (0.2%)	2 (0.1%)		
Mouth injury	口腔内損傷	0	1 (<0.1%)	0	1 (<0.1%)
Muscle rupture	筋断裂	1 (<0.1%)	1 (<0.1%)		
Muscle strain	筋挫傷	5 (0.3%)	3 (0.2%)		
Open wound	開放創	0	1 (<0.1%)		
Operative haemorrhage	術中出血	1 (<0.1%)	2 (0.1%)		
Overdose	過量投与	2 (0.1%)	2 (0.1%)	1 (<0.1%)	2 (0.1%)
Pelvic fracture	骨盤骨折	0	1 (<0.1%)		
Periorbital haematoma	眼窩周囲血腫	2 (0.1%)	1 (<0.1%)		
Post procedural haematuria	処置後血尿	2 (0.1%)	0	2 (0.1%)	0
Post procedural haemorrhage	処置後出血	7 (0.4%)	6 (0.4%)	4 (0.2%)	3 (0.2%)
Post procedural swelling	処置後腫脹	0	2 (0.1%)		
Post-traumatic pain	外傷後疼痛	2 (0.1%)	0		
Postoperative hernia	術後ヘルニア	0	1 (<0.1%)		
Procedural pain	処置による疼痛	2 (0.1%)	2 (0.1%)		
Radius fracture	橈骨骨折	0	2 (0.1%)		
Rib fracture	肋骨骨折	3 (0.2%)	2 (0.1%)		
Road traffic accident	交通事故	2 (0.1%)	1 (<0.1%)		
Scratch	引っかき傷	2 (0.1%)	0		
Skeletal injury	骨格損傷	4 (0.2%)	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Skin injury	皮膚損傷	0	1 (<0.1%)		
Skin laceration	皮膚裂傷	10 (0.6%)	4 (0.2%)		
Soft tissue injury	軟部組織損傷	0	2 (0.1%)		
Spinal column injury	脊柱損傷	1 (<0.1%)	0		
Spinal compression fracture	脊椎圧迫骨折	1 (<0.1%)	1 (<0.1%)		
Stress fracture	ストレス骨折	1 (<0.1%)	1 (<0.1%)		
Subcutaneous haematoma	皮下血腫	9 (0.5%)	17 (1.0%)	8 (0.5%)	12 (0.7%)
Synovial rupture	滑膜断裂	1 (<0.1%)	1 (<0.1%)		
Tendon injury	腱損傷	0	1 (<0.1%)		
Tendon rupture	腱断裂	0	1 (<0.1%)		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Therapeutic agent toxicity	治療薬毒性	0	2 (0.1%)	0	2 (0.1%)
Thermal burn	熱傷	0	2 (0.1%)		
Thoracic vertebral fracture	胸椎骨折	0	2 (0.1%)		
Tooth fracture	歯牙破折	2 (0.1%)	5 (0.3%)		
Tooth injury	歯牙損傷	1 (<0.1%)	0		
Traumatic fracture	外傷性骨折	0	1 (<0.1%)		
Traumatic haematoma	外傷性血腫	3 (0.2%)	5 (0.3%)	2 (0.1%)	3 (0.2%)
Traumatic haemorrhage	外傷性出血	4 (0.2%)	1 (<0.1%)	1 (<0.1%)	0
Ulna fracture	尺骨骨折	0	2 (0.1%)		
Upper limb fracture	上肢骨折	0	1 (<0.1%)		
Vascular pseudoaneurysm	血管偽動脈瘤	1 (<0.1%)	0		
Wound	創傷	5 (0.3%)	6 (0.4%)		
Wound dehiscence	創し開	1 (<0.1%)	0		
Wound haemorrhage	創傷出血	20 (1.2%)	21 (1.2%)	5 (0.3%)	9 (0.5%)
Wrist fracture	手首関節骨折	0	1 (<0.1%)		
Investigations	臨床検査	86 (5.0%)	179 (10.5%)	27 (1.6%)	76 (4.4%)
Activated partial thromboplastin time prolonged	活性化部分トロンボプラスチン時間延長	1 (<0.1%)	0	1 (<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 increased	アラニン・アミノトランスフェラーゼ増加	20 (1.2%)	52 (3.0%)	11 (0.6%)	21 (1.2%)
Antiphospholipid antibodies positive	抗リン脂質抗体陽性	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	12 (0.7%)	18 (1.1%)	7 (0.4%)	3 (0.2%)
Bilirubin conjugated increased	抱合ビリルビン増加	2 (0.1%)	1 (<0.1%)	1 (<0.1%)	0
Biopsy breast	乳房生検	0	2 (0.1%)		
Biopsy kidney	腎生検	2 (0.1%)	0		
Biopsy lung	肺生検	1 (<0.1%)	0		
Biopsy prostate	前立腺生検	1 (<0.1%)	2 (0.1%)		
Biopsy stomach	胃生検	1 (<0.1%)	0		
Blood albumin increased	血中アルブミン増加	1 (<0.1%)	0	1 (<0.1%)	0

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	6 (0.3%)	9 (0.5%)	2 (0.1%)	1 (<0.1%)
Blood amylase increased	血中アミラーゼ増加	1 (<0.1%)	4 (0.2%)	0	1 (<0.1%)
Blood bilirubin increased	血中ビリルビン増加	5 (0.3%)	2 (0.1%)	2 (0.1%)	0
Blood cholesterol increased	血中コレステロール増加	1 (<0.1%)	2 (0.1%)		
Blood creatinine increased	血中クレアチニン増加	1 (<0.1%)	0		
Blood folate decreased	血中葉酸減少	1 (<0.1%)	0		
Blood glucose decreased	血中ブドウ糖減少	1 (<0.1%)	0		
Blood glucose fluctuation	血中ブドウ糖変動	1 (<0.1%)	0		
Blood glucose increased	血中ブドウ糖増加	0	1 (<0.1%)		
Blood homocysteine increased	血中ホモシステイン増加	2 (0.1%)	1 (<0.1%)		
Blood potassium decreased	血中カリウム減少	2 (0.1%)	1 (<0.1%)		
Blood potassium increased	血中カリウム増加	1 (<0.1%)	0		
Blood pressure increased	血圧上昇	2 (0.1%)	2 (0.1%)		
Blood thromboplastin decreased	血中トロンボプラスチン減少	1 (<0.1%)	0	1 (<0.1%)	0
Blood thyroid stimulating hormone increased	血中甲状腺刺激ホルモン増加	1 (<0.1%)	0		
Blood urine present	尿中血陽性	1 (<0.1%)	0	1 (<0.1%)	0
Body temperature increased	体温上昇	1 (<0.1%)	0		
C-reactive protein increased	Ｃ－反応性蛋白増加	1 (<0.1%)	0		
Carbohydrate antigen 125 increased	糖鎖抗原１２５増加	0	1 (<0.1%)		
Carcinoembryonic antigen increased	癌胎児性抗原増加	1 (<0.1%)	0		
Chest X-ray abnormal	胸部Ｘ線異常	0	1 (<0.1%)		
Coagulation factor VII level decreased	凝固第ＶＩＩ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
Colonoscopy	結腸内視鏡検査	3 (0.2%)	2 (0.1%)		
Computerised tomogram	コンピュータ断層撮影	0	1 (<0.1%)		
Computerised tomogram abdomen	腹部コンピュータ断層撮影	0	1 (<0.1%)		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Free prostate-specific antigen decreased	遊離前立腺特異性抗原減少	1 (<0.1%)	0		
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3 (0.2%)	2 (0.1%)	3 (0.2%)	0
Glomerular filtration rate decreased	糸球体濾過率減少	0	1 (<0.1%)		
Haematocrit decreased	ヘマトクリット減少	0	1 (<0.1%)		
Haemoglobin decreased	ヘモグロビン減少	5 (0.3%)	3 (0.2%)	2 (0.1%)	1 (<0.1%)
Heart rate decreased	心拍数減少	0	1 (<0.1%)	0	1 (<0.1%)
Heart rate irregular	心拍数不整	2 (0.1%)	0		
Hepatic enzyme increased	肝酵素上昇	1 (<0.1%)	15 (0.9%)	0	7 (0.4%)
Influenza A virus test positive	A型インフルエンザウイルス検査陽性	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	5 (0.3%)	0	2 (0.1%)
International normalised ratio fluctuation	ＩＮＲ変動	0	2 (0.1%)	0	2 (0.1%)
International normalised ratio increased	ＩＮＲ増加	1 (<0.1%)	38 (2.2%)	0	29 (1.7%)
Intraocular pressure increased	眼圧上昇	0	1 (<0.1%)		
Lipids increased	脂質増加	2 (0.1%)	0		
Lipoprotein (a) increased	リポ蛋白（ａ）増加	1 (<0.1%)	0		
Liver function test abnormal	肝機能検査異常	7 (0.4%)	19 (1.1%)	4 (0.2%)	4 (0.2%)
Low density lipoprotein increased	低比重リポ蛋白増加	0	1 (<0.1%)		
Lymph node palpable	リンパ節触知	1 (<0.1%)	0		
Lymphocyte count increased	リンパ球数増加	0	1 (<0.1%)		
Neutrophil count decreased	好中球数減少	0	1 (<0.1%)		
Occult blood	便潜血	0	1 (<0.1%)	0	1 (<0.1%)
Oesophagogastroduodenoscopy	食道胃十二指腸内視鏡検査	1 (<0.1%)	1 (<0.1%)		
Platelet count decreased	血小板数減少	0	2 (0.1%)	0	1 (<0.1%)
Platelet count increased	血小板数増加	1 (<0.1%)	0		
Prostatic specific antigen decreased	前立腺特異性抗原減少	1 (<0.1%)	0		
Prostatic specific antigen increased	前立腺特異性抗原増加	1 (<0.1%)	2 (0.1%)		
Protein total increased	総蛋白増加	1 (<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%)

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Red blood cell count decreased	赤血球数減少	0	1 (<0.1%)		
Red blood cells urine positive	尿中赤血球陽性	0	1 (<0.1%)		
Staphylococcus test positive	ブドウ球菌検査陽性	0	1 (<0.1%)		
Transaminases increased	トランスアミナーゼ上昇	4 (0.2%)	2 (0.1%)	2 (0.1%)	1 (<0.1%)
Troponin I increased	トロポニンＩ増加	1 (<0.1%)	0		
Troponin increased	トロポニン増加	0	1 (<0.1%)		
Tumour marker increased	腫瘍マーカー上昇	1 (<0.1%)	0		
Ultrasound Doppler	ドップラー超音波	0	1 (<0.1%)		
Ultrasound scan	超音波スキャン	1 (<0.1%)	0		
Urine ketone body present	尿中ケトン体陽性	0	1 (<0.1%)		
Urogram	尿路造影	1 (<0.1%)	0		
Vitamin B12 decreased	ビタミンＢ１２減少	0	1 (<0.1%)		
Weight decreased	体重減少	4 (0.2%)	1 (<0.1%)	2 (0.1%)	0
Weight increased	体重増加	0	4 (0.2%)		
White blood cell count decreased	白血球数減少	1 (<0.1%)	2 (0.1%)	0	1 (<0.1%)
White blood cell count increased	白血球数増加	0	1 (<0.1%)		
White blood cells urine positive	尿中白血球陽性	0	1 (<0.1%)		
Metabolism and nutrition disorders	代謝および栄養障害	78 (4.5%)	79 (4.6%)	9 (0.5%)	2 (0.1%)
Acidosis	アシドーシス	0	1 (<0.1%)		
Decreased appetite	食欲減退	7 (0.4%)	1 (<0.1%)	5 (0.3%)	0
Dehydration	脱水	1 (<0.1%)	3 (0.2%)		
Diabetes mellitus	糖尿病	4 (0.2%)	8 (0.5%)	0	1 (<0.1%)
Diabetic foot	糖尿病性足病変	0	1 (<0.1%)		
Diabetic ketoacidosis	糖尿病性ケトアシドーシス	1 (<0.1%)	0		
Dyslipidaemia	脂質異常症	0	1 (<0.1%)		
Electrolyte imbalance	電解質失調	0	1 (<0.1%)		
Failure to thrive	成長障害	1 (<0.1%)	0		
Folate deficiency	葉酸欠乏	1 (<0.1%)	1 (<0.1%)		
Gout	痛風	13 (0.8%)	12 (0.7%)	0	1 (<0.1%)
Haemochromatosis	ヘモクロマトーシス	1 (<0.1%)	0		
Hypercalcaemia	高カルシウム血症	1 (<0.1%)	0		
Hypercholesterolaemia	高コレステロール血症	8 (0.5%)	9 (0.5%)		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Hyperglycaemia	高血糖	1 (<0.1%)	1 (<0.1%)		
Hyperhomocysteinaemia	高ホモシステイン血症	2 (0.1%)	4 (0.2%)		
Hyperinsulinaemia	高インスリン血症	0	1 (<0.1%)		
Hyperkalaemia	高カリウム血症	0	2 (0.1%)		
Hyperlipidaemia	高脂血症	2 (0.1%)	7 (0.4%)		
Hypernatraemia	高ナトリウム血症	1 (<0.1%)	0		
Hyperproteinaemia	高蛋白血症	1 (<0.1%)	0		
Hypertriglyceridaemia	高トリグリセリド血症	0	1 (<0.1%)		
Hyperuricaemia	高尿酸血症	2 (0.1%)	1 (<0.1%)	1 (<0.1%)	0
Hypoalbuminaemia	低アルブミン血症	4 (0.2%)	1 (<0.1%)		
Hypocalcaemia	低カルシウム血症	1 (<0.1%)	2 (0.1%)		
Hypochloraemia	低クロール血症	1 (<0.1%)	0		
Hypoglycaemia	低血糖症	4 (0.2%)	2 (0.1%)		
Hypokalaemia	低カリウム血症	10 (0.6%)	13 (0.8%)		
Hypolipidaemia	低脂血症	0	1 (<0.1%)		
Hypomagnesaemia	低マグネシウム血症	1 (<0.1%)	0		
Hyponatraemia	低ナトリウム血症	0	2 (0.1%)		
Hypoproteinaemia	低蛋白血症	1 (<0.1%)	0		
Hypovitaminosis	ビタミン欠乏症	0	1 (<0.1%)		
Iron deficiency	鉄欠乏	5 (0.3%)	0	1 (<0.1%)	0
Lipid metabolism disorder	脂質代謝障害	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	3 (0.2%)	6 (0.4%)		
Obesity	肥満	0	1 (<0.1%)		
Tetany	テタニー	1 (<0.1%)	0	1 (<0.1%)	0
Type 2 diabetes mellitus	２型糖尿病	2 (0.1%)	1 (<0.1%)		
Vitamin B12 deficiency	ビタミンＢ１２欠乏	3 (0.2%)	1 (<0.1%)	1 (<0.1%)	0
Vitamin D deficiency	ビタミンＤ欠乏	3 (0.2%)	2 (0.1%)		
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	253 (14.7%)	228 (13.3%)	5 (0.3%)	17 (1.0%)

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Arthralgia	関節痛	43 (2.5%)	38 (2.2%)		
Arthritis	関節炎	5 (0.3%)	13 (0.8%)		
Back pain	背部痛	50 (2.9%)	31 (1.8%)		
Bone pain	骨痛	4 (0.2%)	1 (<0.1%)		
Bursitis	滑液包炎	6 (0.3%)	3 (0.2%)		
Chondrocalcinosis	軟骨石灰化症	0	1 (<0.1%)		
Coccydynia	尾骨痛	1 (<0.1%)	0		
Costochondritis	肋軟骨炎	1 (<0.1%)	0		
Exostosis	外骨腫	2 (0.1%)	1 (<0.1%)		
Fistula discharge	瘻孔分泌物	1 (<0.1%)	0		
Flank pain	側腹部痛	0	4 (0.2%)		
Foot deformity	足変形	0	2 (0.1%)		
Gouty arthritis	痛風性関節炎	1 (<0.1%)	2 (0.1%)		
Groin pain	鼠径部痛	8 (0.5%)	5 (0.3%)		
Haemarthrosis	出血性関節症	0	4 (0.2%)	0	4 (0.2%)
Intervertebral disc disorder	椎間板障害	1 (<0.1%)	0		
Intervertebral disc protrusion	椎間板突出	1 (<0.1%)	2 (0.1%)		
Jaw cyst	顎骨嚢胞	0	1 (<0.1%)		
Joint effusion	関節滲出液	1 (<0.1%)	2 (0.1%)		
Joint range of motion decreased	関節可動域減少	1 (<0.1%)	0		
Joint stiffness	関節硬直	0	1 (<0.1%)		
Joint swelling	関節腫脹	9 (0.5%)	5 (0.3%)		
Juvenile arthritis	若年性関節炎	0	1 (<0.1%)		
Kyphosis	脊柱後弯症	1 (<0.1%)	0		
Ligament pain	靭帯痛	0	2 (0.1%)		
Limb discomfort	四肢不快感	2 (0.1%)	7 (0.4%)	0	1 (<0.1%)
Lower extremity mass	下肢腫瘤	1 (<0.1%)	1 (<0.1%)		
Medial tibial stress syndrome	脛骨内側過労性症候群	1 (<0.1%)	0		
Monarthritis	単関節炎	0	1 (<0.1%)		
Muscle atrophy	筋萎縮	0	1 (<0.1%)		
Muscle contracture	筋拘縮	1 (<0.1%)	0		
Muscle fatigue	筋肉疲労	2 (0.1%)	0		
Muscle haemorrhage	筋肉内出血	0	5 (0.3%)	0	4 (0.2%)

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Muscle rigidity	筋固縮	1 (<0.1%)	0		
Muscle spasms	筋痙縮	23 (1.3%)	14 (0.8%)	2 (0.1%)	1 (<0.1%)
Muscle tightness	筋緊張	0	1 (<0.1%)		
Muscle twitching	筋攣縮	1 (<0.1%)	0		
Muscular weakness	筋力低下	1 (<0.1%)	1 (<0.1%)		
Musculoskeletal chest pain	筋骨格系胸痛	4 (0.2%)	3 (0.2%)		
Musculoskeletal discomfort	筋骨格不快感	2 (0.1%)	2 (0.1%)		
Musculoskeletal pain	筋骨格痛	8 (0.5%)	16 (0.9%)	0	1 (<0.1%)
Musculoskeletal stiffness	筋骨格硬直	2 (0.1%)	2 (0.1%)		
Myalgia	筋肉痛	11 (0.6%)	5 (0.3%)		
Myosclerosis	筋硬化症	1 (<0.1%)	0		
Myositis	筋炎	1 (<0.1%)	0		
Neck mass	頚部腫瘤	1 (<0.1%)	1 (<0.1%)		
Neck pain	頚部痛	3 (0.2%)	1 (<0.1%)	0	1 (<0.1%)
Osteitis	骨炎	1 (<0.1%)	2 (0.1%)		
Osteoarthritis	変形性関節症	6 (0.3%)	7 (0.4%)		
Osteoarthropathy	骨関節障害	1 (<0.1%)	0		
Osteopenia	骨減少症	0	1 (<0.1%)		
Osteoporosis	骨粗鬆症	3 (0.2%)	2 (0.1%)		
Pain in extremity	四肢痛	76 (4.4%)	66 (3.9%)	3 (0.2%)	5 (0.3%)
Pain in jaw	顎痛	1 (<0.1%)	3 (0.2%)		
Pathological fracture	病的骨折	1 (<0.1%)	0		
Periarthritis	関節周囲炎	1 (<0.1%)	0		
Plantar fasciitis	足底筋膜炎	1 (<0.1%)	3 (0.2%)		
Polymyalgia rheumatica	リウマチ性多発筋痛	1 (<0.1%)	0		
Rotator cuff syndrome	肩回旋筋腱板症候群	2 (0.1%)	3 (0.2%)		
Sacroiliitis	仙腸骨炎	1 (<0.1%)	1 (<0.1%)		
Scoliosis	側弯症	1 (<0.1%)	0		
Spinal osteoarthritis	変形性脊椎症	6 (0.3%)	3 (0.2%)		
Spondylitis	脊椎炎	0	1 (<0.1%)		
Synovial cyst	滑液嚢腫	3 (0.2%)	4 (0.2%)		
Synovitis	滑膜炎	0	2 (0.1%)		
Systemic lupus erythematosus	全身性エリテマトーデス	1 (<0.1%)	0		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Tendon pain	腱痛	0	2 (0.1%)		
Tendonitis	腱炎	6 (0.3%)	6 (0.4%)		
Tenosynovitis	腱鞘炎	0	1 (<0.1%)		
Torticollis	斜頚	1 (<0.1%)	0		
Upper extremity mass	上肢腫瘤	1 (<0.1%)	0		
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）	69 (4.0%)	69 (4.0%)		
Acute leukaemia	急性白血病	0	1 (<0.1%)		
Acute lymphocytic leukaemia	急性リンパ性白血病	1 (<0.1%)	0		
Adenocarcinoma	腺癌	1 (<0.1%)	0		
Adenoma benign	良性腺腫	1 (<0.1%)	0		
Adrenal adenoma	副腎腺腫	1 (<0.1%)	2 (0.1%)		
Angiomyolipoma	血管筋脂肪腫	1 (<0.1%)	0		
B-cell lymphoma	Ｂ細胞性リンパ腫	1 (<0.1%)	0		
Basal cell carcinoma	基底細胞癌	2 (0.1%)	1 (<0.1%)		
Benign lung neoplasm	肺の良性新生物	0	1 (<0.1%)		
Benign mediastinal neoplasm	縦隔の良性新生物	0	1 (<0.1%)		
Bladder cancer	膀胱癌	2 (0.1%)	0		
Bladder transitional cell carcinoma stage I	膀胱移行上皮癌第１期	0	1 (<0.1%)		
Breast cancer	乳癌	3 (0.2%)	1 (<0.1%)		
Breast cancer metastatic	転移性乳癌	1 (<0.1%)	0		
Cervix cancer metastatic	転移性子宮頚部癌	1 (<0.1%)	0		
Cervix carcinoma	子宮頚部癌	2 (0.1%)	5 (0.3%)		
Cervix carcinoma stage III	子宮頚部癌第３期	1 (<0.1%)	0		
Colon cancer	結腸癌	3 (0.2%)	4 (0.2%)		
Colorectal cancer	結腸直腸癌	2 (0.1%)	0		
Ear neoplasm malignant	耳の悪性新生物	0	1 (<0.1%)		
Endometrial cancer	子宮内膜癌	1 (<0.1%)	1 (<0.1%)		
Erythroplasia	紅色肥厚症	0	1 (<0.1%)		
Fibroadenoma of breast	乳腺線維腺腫	0	1 (<0.1%)		
Fibroma	線維腫	0	1 (<0.1%)		
Gastric cancer	胃癌	1 (<0.1%)	1 (<0.1%)		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Gastric cancer recurrent	再発胃癌	1 (<0.1%)	0		
Glioblastoma	神経膠芽細胞腫	1 (<0.1%)	0		
Haemangioma of liver	肝臓血管腫	2 (0.1%)	2 (0.1%)		
Hepatic cancer metastatic	転移性肝癌	1 (<0.1%)	0		
Hepatic neoplasm malignant	肝の悪性新生物	2 (0.1%)	2 (0.1%)		
Hodgkin's disease	ホジキン病	0	1 (<0.1%)		
Large cell carcinoma of the respiratory tract stage unspecified	呼吸器大細胞癌、病期不明	0	1 (<0.1%)		
Large intestine carcinoma	大腸癌	1 (<0.1%)	0		
Lipoma	脂肪腫	3 (0.2%)	2 (0.1%)		
Lung adenocarcinoma	肺腺癌	0	3 (0.2%)		
Lung cancer metastatic	転移性肺癌	1 (<0.1%)	0		
Lung carcinoma cell type unspecified recurrent	再発肺癌、細胞タイプ不明	1 (<0.1%)	0		
Lung neoplasm	肺新生物	2 (0.1%)	6 (0.4%)		
Lung neoplasm malignant	肺の悪性新生物	2 (0.1%)	2 (0.1%)		
Lymphoma	リンパ腫	3 (0.2%)	1 (<0.1%)		
Lymphoma cutis	皮膚型リンパ腫	1 (<0.1%)	0		
Malignant melanoma	悪性黒色腫	1 (<0.1%)	1 (<0.1%)		
Malignant melanoma in situ	表皮内悪性黒色腫	1 (<0.1%)	0		
Meningioma	髄膜腫	0	1 (<0.1%)		
Metastases to abdominal cavity	腹腔内転移	0	1 (<0.1%)		
Metastases to central nervous system	中枢神経系転移	1 (<0.1%)	0		
Metastases to liver	肝転移	2 (0.1%)	4 (0.2%)		
Metastases to lung	肺転移	1 (<0.1%)	1 (<0.1%)		
Metastases to lymph nodes	リンパ節転移	2 (0.1%)	2 (0.1%)		
Metastases to spine	脊椎転移	0	1 (<0.1%)		
Metastatic neoplasm	転移性新生物	2 (0.1%)	0		
Metastatic squamous cell carcinoma	転移性扁平上皮癌	0	1 (<0.1%)		
Non-Hodgkin's lymphoma	非ホジキンリンパ腫	2 (0.1%)	0		
Oesophageal adenocarcinoma	食道腺癌	1 (<0.1%)	0		
Oesophageal carcinoma	食道癌	0	1 (<0.1%)		
Ovarian cancer	卵巣癌	1 (<0.1%)	2 (0.1%)		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Ovarian cancer metastatic	転移性卵巣癌	0	1 (<0.1%)		
Ovarian cancer recurrent	再発卵巣癌	0	1 (<0.1%)		
Ovarian epithelial cancer	卵巣上皮癌	0	1 (<0.1%)		
Pancreatic carcinoma	膵癌	2 (0.1%)	0		
Pelvic neoplasm	骨盤新生物	1 (<0.1%)	0		
Penis carcinoma	陰茎癌	0	1 (<0.1%)		
Pleural neoplasm	胸膜新生物	1 (<0.1%)	0		
Polycythaemia vera	真性多血症	0	1 (<0.1%)		
Prostate cancer	前立腺癌	1 (<0.1%)	2 (0.1%)		
Prostate cancer metastatic	転移性前立腺癌	0	1 (<0.1%)		
Pyogenic granuloma	化膿性肉芽腫	0	1 (<0.1%)		
Rectal adenoma	直腸腺腫	0	1 (<0.1%)		
Rectal cancer	直腸癌	1 (<0.1%)	2 (0.1%)		
Rectal cancer recurrent	再発直腸癌	1 (<0.1%)	0		
Renal cell carcinoma	腎細胞癌	1 (<0.1%)	0		
Renal cell carcinoma recurrent	再発腎細胞癌	0	1 (<0.1%)		
Renal neoplasm	腎新生物	1 (<0.1%)	1 (<0.1%)		
Retroperitoneal neoplasm	後腹膜新生物	0	1 (<0.1%)		
Rhabdomyosarcoma	横紋筋肉腫	1 (<0.1%)	0		
Seborrhoeic keratosis	脂漏性角化症	1 (<0.1%)	0		
Skin cancer	皮膚癌	1 (<0.1%)	1 (<0.1%)		
Small cell lung cancer metastatic	転移性小細胞肺癌	1 (<0.1%)	0		
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0	2 (0.1%)		
Superficial spreading melanoma stage unspecified	表在拡大型黒色腫、病期不明	1 (<0.1%)	0		
Uterine leiomyoma	子宮平滑筋腫	3 (0.2%)	3 (0.2%)		
Uterine neoplasm	子宮新生物	1 (<0.1%)	0		
Waldenstrom's macroglobulinaemia	ワルデンストローム・マクログロブリン血症	1 (<0.1%)	0		
Nervous system disorders	神経系障害	198 (11.5%)	133 (7.8%)	36 (2.1%)	16 (0.9%)
Amnesia	健忘	0	2 (0.1%)		
Aphonia	失声症	1 (<0.1%)	1 (<0.1%)		
Ataxia	運動失調	1 (<0.1%)	0		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Balance disorder	平衡障害	0	1 (<0.1%)		
Brain injury	脳損傷	0	1 (<0.1%)		
Burning sensation	灼熱感	2 (0.1%)	0		
Carpal tunnel syndrome	手根管症候群	0	1 (<0.1%)		
Cerebral arteriosclerosis	脳動脈硬化症	1 (<0.1%)	0		
Cerebral atrophy	大脳萎縮	0	1 (<0.1%)		
Cerebral haemorrhage	脳出血	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Cervical root pain	頚髄神経根痛	1 (<0.1%)	0		
Cervicobrachial syndrome	頚腕症候群	1 (<0.1%)	1 (<0.1%)		
Cognitive disorder	認知障害	1 (<0.1%)	0		
Complex regional pain syndrome	複合性局所疼痛症候群	0	2 (0.1%)		
Convulsion	痙攣	0	1 (<0.1%)		
Dementia	認知症	1 (<0.1%)	1 (<0.1%)		
Diabetic neuropathy	糖尿病性ニューロパチー	0	1 (<0.1%)		
Dizziness	浮動性めまい	38 (2.2%)	22 (1.3%)	5 (0.3%)	3 (0.2%)
Dizziness postural	体位性めまい	0	1 (<0.1%)		
Dysaesthesia	異常感覚	1 (<0.1%)	0	1 (<0.1%)	0
Dysgeusia	味覚異常	3 (0.2%)	0		
Epilepsy	てんかん	2 (0.1%)	0		
Facial neuralgia	顔面部神経痛	0	1 (<0.1%)		
Haemorrhage intracranial	頭蓋内出血	1 (<0.1%)	2 (0.1%)	1 (<0.1%)	1 (<0.1%)
Head discomfort	頭部不快感	1 (<0.1%)	0		
Headache	頭痛	91 (5.3%)	68 (4.0%)	21 (1.2%)	9 (0.5%)
Hyperaesthesia	知覚過敏	1 (<0.1%)	0	1 (<0.1%)	0
Hypoaesthesia	感覚鈍麻	3 (0.2%)	7 (0.4%)	0	1 (<0.1%)
Hypoglycaemic coma	低血糖昏睡	1 (<0.1%)	0		
IIIrd nerve paresis	第３脳神経不全麻痺	0	1 (<0.1%)		
Ischaemic stroke	虚血性脳卒中	3 (0.2%)	5 (0.3%)	0	1 (<0.1%)
Lethargy	嗜眠	5 (0.3%)	2 (0.1%)	1 (<0.1%)	1 (<0.1%)
Meralgia paraesthetica	感覚異常性大腿神経痛	1 (<0.1%)	0		
Metabolic encephalopathy	代謝性脳症	1 (<0.1%)	0		
Migraine	片頭痛	2 (0.1%)	1 (<0.1%)	1 (<0.1%)	0
Mononeuritis	単神経炎	1 (<0.1%)	0		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Motor dysfunction	運動機能障害	0	1 (<0.1%)		
Movement disorder	運動障害	0	1 (<0.1%)		
Multiple sclerosis	多発性硬化症	1 (<0.1%)	0		
Muscle contractions involuntary	不随意性筋収縮	0	1 (<0.1%)		
Myelitis	脊髄炎	0	1 (<0.1%)		
Nerve compression	神経圧迫	0	1 (<0.1%)		
Neuralgia	神経痛	1 (<0.1%)	2 (0.1%)	0	1 (<0.1%)
Neuritis cranial	脳神経炎	0	1 (<0.1%)		
Neuropathy peripheral	末梢性ニューロパチー	2 (0.1%)	3 (0.2%)		
Paraesthesia	錯感覚	17 (1.0%)	7 (0.4%)	4 (0.2%)	1 (<0.1%)
Parkinson's disease	パーキンソン病	1 (<0.1%)	0		
Parkinsonism	パーキンソニズム	0	1 (<0.1%)		
Peripheral nerve palsy	末梢神経麻痺	1 (<0.1%)	0		
Peripheral sensorimotor neuropathy	末梢性感覚運動ニューロパチー	1 (<0.1%)	0		
Polyneuropathy	多発ニューロパチー	1 (<0.1%)	0		
Post herpetic neuralgia	ヘルペス後神経痛	1 (<0.1%)	0		
Presyncope	失神寸前の状態	3 (0.2%)	2 (0.1%)		
Pseudoradicular syndrome	偽性根症候群	1 (<0.1%)	0		
Restless legs syndrome	下肢静止不能症候群	2 (0.1%)	0		
Sciatica	坐骨神経痛	8 (0.5%)	3 (0.2%)	1 (<0.1%)	0
Senile dementia	老年認知症	0	1 (<0.1%)		
Sensory disturbance	感覚障害	2 (0.1%)	0	1 (<0.1%)	0
Somnolence	傾眠	4 (0.2%)	0	1 (<0.1%)	0
Spinal cord compression	脊髄圧迫	1 (<0.1%)	0		
Syncope	失神	10 (0.6%)	6 (0.4%)	1 (<0.1%)	0
Tension headache	緊張性頭痛	2 (0.1%)	1 (<0.1%)		
Transient ischaemic attack	一過性脳虚血発作	1 (<0.1%)	4 (0.2%)		
Tremor	振戦	2 (0.1%)	2 (0.1%)		
Vascular encephalopathy	血管性脳症	0	1 (<0.1%)		
Vertebrobasilar insufficiency	椎骨脳底動脈不全	0	1 (<0.1%)		
Pregnancy, puerperium and perinatal conditions	妊娠、産褥および周産期の状態	2 (0.1%)	2 (0.1%)		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Post abortion haemorrhage	流産後の出血	1 (<0.1%)	0		
Pregnancy	妊娠	1 (<0.1%)	2 (0.1%)		
Psychiatric disorders	精神障害	74 (4.3%)	56 (3.3%)	1 (<0.1%)	2 (0.1%)
Acute psychosis	急性精神病	0	1 (<0.1%)		
Affective disorder	感情障害	1 (<0.1%)	0		
Agitation	激越	1 (<0.1%)	0		
Alcohol abuse	アルコール乱用	0	1 (<0.1%)		
Alcohol withdrawal syndrome	アルコール離脱症候群	0	1 (<0.1%)		
Anxiety	不安	24 (1.4%)	11 (0.6%)		
Attention deficit/hyperactivity disorder	注意欠陥多動性障害	0	1 (<0.1%)		
Completed suicide	自殺既遂	0	1 (<0.1%)		
Confusional state	錯乱状態	2 (0.1%)	2 (0.1%)		
Delirium	譫妄	0	1 (<0.1%)		
Depressed mood	抑うつ気分	2 (0.1%)	1 (<0.1%)		
Depression	うつ病	20 (1.2%)	10 (0.6%)		
Insomnia	不眠症	28 (1.6%)	18 (1.1%)	1 (<0.1%)	1 (<0.1%)
Libido decreased	リビドー減退	2 (0.1%)	0		
Major depression	大うつ病	1 (<0.1%)	0		
Mood swings	気分動揺	1 (<0.1%)	0		
Panic attack	パニック発作	2 (0.1%)	2 (0.1%)		
Psychotic disorder	精神病性障害	1 (<0.1%)	0		
Restlessness	落ち着きのなさ	0	1 (<0.1%)		
Senile psychosis	老人性精神病	0	1 (<0.1%)		
Sleep disorder	睡眠障害	2 (0.1%)	5 (0.3%)	0	1 (<0.1%)
Stress	ストレス	1 (<0.1%)	1 (<0.1%)		
Suicide attempt	自殺企図	1 (<0.1%)	0		
Renal and urinary disorders	腎および尿路障害	71 (4.1%)	78 (4.6%)	28 (1.6%)	34 (2.0%)
Acute prerenal failure	急性腎前性腎不全	1 (<0.1%)	0		
Anuria	無尿	1 (<0.1%)	1 (<0.1%)		
Bladder diverticulum	膀胱憩室	0	1 (<0.1%)		
Calculus ureteric	尿管結石	2 (0.1%)	0		
Calculus urinary	尿路結石	1 (<0.1%)	1 (<0.1%)		
Chromaturia	着色尿	0	2 (0.1%)	0	2 (0.1%)

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Cystitis haemorrhagic	出血性膀胱炎	1 (<0.1%)	0		
Cystitis noninfective	非感染性膀胱炎	0	1 (<0.1%)		
Dysuria	排尿困難	2 (0.1%)	3 (0.2%)		
Glomerulonephritis chronic	慢性糸球体腎炎	1 (<0.1%)	0		
Haematuria	血尿	39 (2.3%)	41 (2.4%)	27 (1.6%)	32 (1.9%)
Hydronephrosis	水腎症	1 (<0.1%)	2 (0.1%)		
Lupus nephritis	ループス腎炎	1 (<0.1%)	0		
Nephrolithiasis	腎結石症	3 (0.2%)	7 (0.4%)		
Nephropathy	腎症	1 (<0.1%)	2 (0.1%)		
Nephrotic syndrome	ネフローゼ症候群	1 (<0.1%)	0		
Nocturia	夜間頻尿	0	2 (0.1%)		
Pollakiuria	頻尿	3 (0.2%)	0	1 (<0.1%)	0
Pyelocaliectasis	腎盂腎杯拡張症	1 (<0.1%)	0		
Renal colic	腎仙痛	0	2 (0.1%)		
Renal cyst	腎嚢胞	9 (0.5%)	12 (0.7%)		
Renal failure	腎不全	3 (0.2%)	1 (<0.1%)		
Renal failure acute	急性腎不全	2 (0.1%)	6 (0.4%)		
Renal failure chronic	慢性腎不全	0	2 (0.1%)		
Residual urine	残尿	1 (<0.1%)	0		
Urethral haemorrhage	尿道出血	0	1 (<0.1%)	0	1 (<0.1%)
Urinary incontinence	尿失禁	1 (<0.1%)	1 (<0.1%)		
Urinary retention	尿閉	2 (0.1%)	2 (0.1%)		
Urinary tract obstruction	尿路閉塞	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Urine odour abnormal	尿臭異常	0	1 (<0.1%)	0	1 (<0.1%)
Reproductive system and breast disorders	生殖系および乳房障害	115 (6.7%)	65 (3.8%)	76 (4.4%)	32 (1.9%)
Adenomyosis	腺筋症	1 (<0.1%)	0		
Adnexa uteri cyst	子宮付属器嚢胞	1 (<0.1%)	0		
Benign prostatic hyperplasia	良性前立腺肥大症	6 (0.3%)	10 (0.6%)		
Breast engorgement	乳房うっ滞	0	1 (<0.1%)		
Breast hyperplasia	乳房過形成	1 (<0.1%)	0		
Breast mass	乳房腫瘤	2 (0.1%)	1 (<0.1%)		
Breast pain	乳房痛	1 (<0.1%)	0		
Cervical polyp	子宮頚管ポリープ	2 (0.1%)	0		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
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	3 (0.2%)	6 (0.4%)	1 (<0.1%)	2 (0.1%)
Endometrial hyperplasia	子宮内膜増殖症	1 (<0.1%)	0		
Epididymitis	精巣上体炎	0	1 (<0.1%)		
Erectile dysfunction	勃起不全	3 (0.2%)	3 (0.2%)	1 (<0.1%)	1 (<0.1%)
Fibrocystic breast disease	線維嚢胞性乳腺疾患	1 (<0.1%)	0		
Genital cyst	生殖器嚢胞	1 (<0.1%)	0		
Genital discharge	性器分泌物	0	1 (<0.1%)		
Genital pain	生殖器痛	0	1 (<0.1%)		
Gynaecomastia	女性化乳房	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Haemorrhagic ovarian cyst	出血性卵巣嚢胞	1 (<0.1%)	0		
Menometrorrhagia	機能性子宮出血	2 (0.1%)	0	1 (<0.1%)	0
Menorrhagia	月経過多	49 (2.9%)	19 (1.1%)	40 (2.3%)	16 (0.9%)
Menstrual disorder	月経障害	2 (0.1%)	0	2 (0.1%)	0
Menstruation irregular	不規則月経	1 (<0.1%)	0	1 (<0.1%)	0
Metrorrhagia	不正子宮出血	10 (0.6%)	3 (0.2%)	8 (0.5%)	3 (0.2%)
Oedema genital	性器浮腫	1 (<0.1%)	0		
Oligomenorrhoea	希発月経	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Ovarian cyst	卵巣嚢胞	3 (0.2%)	1 (<0.1%)		
Ovarian mass	卵巣腫瘤	1 (<0.1%)	0		
Penile haemorrhage	陰茎出血	0	1 (<0.1%)	0	1 (<0.1%)
Penile swelling	陰茎腫脹	0	1 (<0.1%)		
Postmenopausal haemorrhage	閉経後出血	1 (<0.1%)	1 (<0.1%)		
Premenstrual syndrome	月経前症候群	0	1 (<0.1%)		
Prostatitis	前立腺炎	1 (<0.1%)	2 (0.1%)		
Prostatomegaly	前立腺腫大	1 (<0.1%)	0		
Pruritus genital	陰部そう痒症	0	1 (<0.1%)		
Scrotal swelling	陰嚢腫脹	0	2 (0.1%)		
Uterine enlargement	子宮肥大	1 (<0.1%)	0		
Uterine haemorrhage	子宮出血	0	1 (<0.1%)	0	1 (<0.1%)
Uterine polyp	子宮ポリープ	1 (<0.1%)	0		
Vaginal discharge	腟分泌物	2 (0.1%)	1 (<0.1%)		
Vaginal haemorrhage	腟出血	28 (1.6%)	11 (0.6%)	25 (1.5%)	8 (0.5%)

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Vulvovaginal pain	外陰腟痛	0	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal pruritus	外陰腟そう痒症	0	1 (<0.1%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	234 (13.6%)	206 (12.0%)	84 (4.9%)	67 (3.9%)
Acute respiratory failure	急性呼吸不全	0	1 (<0.1%)		
Allergic pharyngitis	アレルギー性咽頭炎	0	1 (<0.1%)		
Asthma	喘息	4 (0.2%)	4 (0.2%)		
Atelectasis	無気肺	1 (<0.1%)	1 (<0.1%)		
Bronchitis chronic	慢性気管支炎	2 (0.1%)	0		
Bronchospasm	気管支痙攣	1 (<0.1%)	3 (0.2%)		
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	5 (0.3%)	3 (0.2%)		
Cough	咳嗽	72 (4.2%)	51 (3.0%)	2 (0.1%)	1 (<0.1%)
Dysphonia	発声障害	3 (0.2%)	1 (<0.1%)		
Dyspnoea	呼吸困難	33 (1.9%)	37 (2.2%)	2 (0.1%)	1 (<0.1%)
Dyspnoea at rest	安静時呼吸困難	1 (<0.1%)	0		
Dyspnoea exertional	労作性呼吸困難	7 (0.4%)	6 (0.4%)	3 (0.2%)	0
Emphysema	肺気腫	1 (<0.1%)	0		
Epistaxis	鼻出血	89 (5.2%)	74 (4.3%)	67 (3.9%)	56 (3.3%)
Haemoptysis	喀血	19 (1.1%)	17 (1.0%)	13 (0.8%)	10 (0.6%)
Haemothorax	血胸	0	1 (<0.1%)	0	1 (<0.1%)
Hiccups	しゃっくり	1 (<0.1%)	0		
Hyperventilation	過換気	0	1 (<0.1%)		
Hypoxia	低酸素症	0	1 (<0.1%)		
Increased upper airway secretion	上気道分泌増加	1 (<0.1%)	0		
Interstitial lung disease	間質性肺疾患	0	1 (<0.1%)		
Lung consolidation	肺硬化	0	1 (<0.1%)		
Lung disorder	肺障害	2 (0.1%)	1 (<0.1%)		
Nasal congestion	鼻閉	3 (0.2%)	2 (0.1%)		
Oropharyngeal blistering	口腔咽頭水疱形成	0	1 (<0.1%)		
Oropharyngeal pain	口腔咽頭痛	16 (0.9%)	6 (0.4%)		
Orthopnoea	起坐呼吸	1 (<0.1%)	0		
Painful respiration	呼吸時疼痛	1 (<0.1%)	0		
Paranasal cyst	副鼻腔嚢胞	1 (<0.1%)	0		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Pharyngeal inflammation	咽頭の炎症	1 (<0.1%)	0		
Pleural effusion	胸水	4 (0.2%)	4 (0.2%)		
Pleural fibrosis	胸膜線維症	0	1 (<0.1%)		
Pleurisy	胸膜炎	0	1 (<0.1%)		
Pleuritic pain	胸膜痛	0	1 (<0.1%)		
Postnasal drip	後鼻漏	0	1 (<0.1%)		
Productive cough	湿性咳嗽	3 (0.2%)	3 (0.2%)	1 (<0.1%)	1 (<0.1%)
Pulmonary embolism	肺塞栓症	1 (<0.1%)	1 (<0.1%)		
Pulmonary fibrosis	肺線維症	1 (<0.1%)	0		
Pulmonary hypertension	肺高血圧症	0	3 (0.2%)		
Pulmonary infarction	肺梗塞	0	1 (<0.1%)		
Pulmonary mass	肺腫瘤	1 (<0.1%)	0		
Pulmonary oedema	肺水腫	0	1 (<0.1%)		
Rales	ラ音	0	1 (<0.1%)		
Respiratory distress	呼吸窮迫	0	1 (<0.1%)		
Respiratory failure	呼吸不全	2 (0.1%)	0		
Respiratory tract congestion	気道うっ血	1 (<0.1%)	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	0	3 (0.2%)		
Rhinitis atrophic	萎縮性鼻炎	1 (<0.1%)	0		
Rhinorrhoea	鼻漏	2 (0.1%)	7 (0.4%)		
Sinus congestion	副鼻腔うっ血	1 (<0.1%)	2 (0.1%)		
Sleep apnoea syndrome	睡眠時無呼吸症候群	0	1 (<0.1%)		
Sputum retention	痰貯留	1 (<0.1%)	0		
Tachypnoea	頻呼吸	2 (0.1%)	2 (0.1%)		
Throat irritation	咽喉刺激感	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Upper airway obstruction	上気道閉塞	2 (0.1%)	0		
Wegener's granulomatosis	ウェゲナー肉芽腫症	1 (<0.1%)	0		
Wheezing	喘鳴	2 (0.1%)	1 (<0.1%)		
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	149 (8.7%)	163 (9.5%)	50 (2.9%)	50 (2.9%)
Acne	ざ瘡	1 (<0.1%)	0	1 (<0.1%)	0
Actinic keratosis	日光性角化症	0	1 (<0.1%)		
Alopecia	脱毛症	10 (0.6%)	14 (0.8%)	5 (0.3%)	9 (0.5%)

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Blister	水疱	1 (<0.1%)	2 (0.1%)		
Blood blister	血性水疱	0	1 (<0.1%)		
Decubitus ulcer	褥瘡性潰瘍	3 (0.2%)	2 (0.1%)		
Dermal cyst	皮膚嚢腫	1 (<0.1%)	1 (<0.1%)		
Dermatitis	皮膚炎	4 (0.2%)	6 (0.4%)	0	1 (<0.1%)
Dermatitis allergic	アレルギー性皮膚炎	1 (<0.1%)	2 (0.1%)	1 (<0.1%)	0
Dermatitis contact	接触性皮膚炎	2 (0.1%)	2 (0.1%)		
Dermatitis exfoliative	剥脱性皮膚炎	0	2 (0.1%)	0	1 (<0.1%)
Dermatitis herpetiformis	疱疹状皮膚炎	1 (<0.1%)	0		
Dermatosis	皮膚症	0	1 (<0.1%)		
Drug eruption	薬疹	1 (<0.1%)	3 (0.2%)	1 (<0.1%)	0
Dry skin	皮膚乾燥	6 (0.3%)	10 (0.6%)	3 (0.2%)	1 (<0.1%)
Ecchymosis	斑状出血	3 (0.2%)	7 (0.4%)	2 (0.1%)	7 (0.4%)
Eczema	湿疹	6 (0.3%)	8 (0.5%)	1 (<0.1%)	0
Ephelides	雀卵斑	1 (<0.1%)	0		
Erythema	紅斑	4 (0.2%)	10 (0.6%)	2 (0.1%)	0
Erythema multiforme	多形紅斑	0	1 (<0.1%)		
Exfoliative rash	剥脱性発疹	1 (<0.1%)	0		
Generalised erythema	全身紅斑	1 (<0.1%)	0		
Haemorrhage subcutaneous	皮下出血	1 (<0.1%)	0	1 (<0.1%)	0
Haemorrhagic urticaria	出血性蕁麻疹	0	1 (<0.1%)		
Henoch-Schonlein purpura	ヘノッホ・シェーンライン紫斑病	0	1 (<0.1%)		
Hyperhidrosis	多汗症	6 (0.3%)	2 (0.1%)	1 (<0.1%)	0
Hypoaesthesia facial	顔面感覚鈍麻	1 (<0.1%)	0		
Increased tendency to bruise	挫傷発生の増加傾向	1 (<0.1%)	2 (0.1%)	1 (<0.1%)	2 (0.1%)
Leukocytoclastic vasculitis	白血球破砕性血管炎	0	1 (<0.1%)	0	1 (<0.1%)
Livedo reticularis	網状皮斑	0	1 (<0.1%)		
Nail bed bleeding	爪床出血	1 (<0.1%)	0	1 (<0.1%)	0
Nail bed inflammation	爪床の炎症	0	1 (<0.1%)		
Night sweats	寝汗	7 (0.4%)	5 (0.3%)	5 (0.3%)	5 (0.3%)
Onychoclasis	爪破損	1 (<0.1%)	0		
Panniculitis	脂肪織炎	1 (<0.1%)	0		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Petechiae	点状出血	2 (0.1%)	6 (0.4%)	2 (0.1%)	3 (0.2%)
Photosensitivity allergic reaction	アレルギー性光線過敏性反応	1 (<0.1%)	0		
Pigmentation disorder	色素沈着障害	1 (<0.1%)	1 (<0.1%)		
Pruritus	そう痒症	29 (1.7%)	31 (1.8%)	9 (0.5%)	7 (0.4%)
Pruritus allergic	アレルギー性そう痒症	0	1 (<0.1%)		
Pruritus generalised	全身性そう痒症	1 (<0.1%)	1 (<0.1%)		
Psoriasis	乾癬	2 (0.1%)	1 (<0.1%)		
Purpura	紫斑	0	3 (0.2%)		
Rash	発疹	26 (1.5%)	27 (1.6%)	10 (0.6%)	3 (0.2%)
Rash erythematous	紅斑性皮疹	0	2 (0.1%)	0	1 (<0.1%)
Rash generalised	全身性皮疹	0	1 (<0.1%)	0	1 (<0.1%)
Rash macular	斑状皮疹	0	1 (<0.1%)		
Rash papular	丘疹	1 (<0.1%)	1 (<0.1%)		
Rash pruritic	そう痒性皮疹	0	2 (0.1%)	0	1 (<0.1%)
Scab	痂皮	1 (<0.1%)	0		
Scar	瘢痕	0	1 (<0.1%)		
Seborrhoeic dermatitis	脂漏性皮膚炎	1 (<0.1%)	0		
Skin discolouration	皮膚変色	4 (0.2%)	2 (0.1%)		
Skin disorder	皮膚障害	1 (<0.1%)	1 (<0.1%)		
Skin exfoliation	皮膚剥脱	1 (<0.1%)	0	1 (<0.1%)	0
Skin fragility	皮膚脆弱性	1 (<0.1%)	0		
Skin haemorrhage	皮膚出血	9 (0.5%)	7 (0.4%)	6 (0.3%)	5 (0.3%)
Skin hyperpigmentation	皮膚色素過剰	1 (<0.1%)	0		
Skin induration	皮膚硬結	1 (<0.1%)	0		
Skin irritation	皮膚刺激	0	2 (0.1%)		
Skin lesion	皮膚病変	5 (0.3%)	3 (0.2%)	0	1 (<0.1%)
Skin mass	皮膚腫瘤	0	1 (<0.1%)		
Skin oedema	皮膚浮腫	0	1 (<0.1%)		
Skin striae	皮膚線条	0	1 (<0.1%)		
Skin swelling	皮膚腫脹	0	1 (<0.1%)		
Skin ulcer	皮膚潰瘍	7 (0.4%)	9 (0.5%)	0	2 (0.1%)
Skin ulcer haemorrhage	出血性皮膚潰瘍	0	1 (<0.1%)	0	1 (<0.1%)

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Spider naevus	くも状母斑	1 (<0.1%)	0	1 (<0.1%)	0
Stasis dermatitis	うっ滞性皮膚炎	0	1 (<0.1%)	0	1 (<0.1%)
Telangiectasia	毛細血管拡張症	0	1 (<0.1%)		
Urticaria	蕁麻疹	5 (0.3%)	3 (0.2%)	0	1 (<0.1%)
Surgical and medical procedures	外科および内科処置	12 (0.7%)	11 (0.6%)		
Abortion induced	人工流産	0	1 (<0.1%)		
Bariatric gastric balloon insertion	肥満症に対する胃内バルーン挿入	0	1 (<0.1%)		
Bladder catheter removal	膀胱カテーテル除去	1 (<0.1%)	0		
Cataract operation	白内障手術	1 (<0.1%)	0		
Cerumen removal	耳垢除去	1 (<0.1%)	0		
Colon polypectomy	結腸ポリープ切除	0	1 (<0.1%)		
Dental cleaning	歯牙清掃	1 (<0.1%)	0		
Dental implantation	歯科インプラント埋込み	2 (0.1%)	0		
Ear tube insertion	耳チューブ挿入	1 (<0.1%)	0		
High frequency ablation	高周波アブレーション	1 (<0.1%)	0		
Ileostomy closure	回腸瘻閉鎖	1 (<0.1%)	0		
Incisional hernia repair	瘢痕ヘルニア修復	1 (<0.1%)	0		
Intervertebral disc operation	椎間板手術	0	1 (<0.1%)		
Intestinal polypectomy	腸ポリープ切除	0	1 (<0.1%)		
Intra-uterine contraceptive device insertion	子宮内避妊具挿入	1 (<0.1%)	0		
Knee operation	膝手術	1 (<0.1%)	0		
Meniscus operation	半月板手術	1 (<0.1%)	0		
Removal of internal fixation	内固定除去	0	1 (<0.1%)		
Sinus operation	副鼻腔手術	1 (<0.1%)	0		
Skin neoplasm excision	皮膚新生物切除	0	1 (<0.1%)		
Tooth extraction	抜歯	0	1 (<0.1%)		
Transurethral prostatectomy	経尿道的前立腺摘除	0	1 (<0.1%)		
Uterine polypectomy	子宮ポリープ切除	0	1 (<0.1%)		
Vasectomy	精管切除	1 (<0.1%)	0		
Vena cava filter insertion	大静脈フィルター挿入	0	1 (<0.1%)		
Vascular disorders	血管障害	137 (8.0%)	172 (10.1%)	35 (2.0%)	45 (2.6%)
Angiosclerosis	血管硬化	1 (<0.1%)	0		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Aortic aneurysm	大動脈瘤	1 (<0.1%)	3 (0.2%)		
Aortic arteriosclerosis	大動脈硬化症	4 (0.2%)	1 (<0.1%)		
Aortic stenosis	大動脈狭窄	1 (<0.1%)	0		
Arterial haemorrhage	動脈出血	0	1 (<0.1%)		
Arterial thrombosis limb	四肢動脈血栓症	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Arteriosclerosis	動脈硬化症	2 (0.1%)	4 (0.2%)		
Arteriosclerosis obliterans	閉塞性動脈硬化症	0	1 (<0.1%)		
Bleeding varicose vein	出血性静脈瘤	2 (0.1%)	0		
Blue toe syndrome	青趾症候群	0	1 (<0.1%)	0	1 (<0.1%)
Circulatory collapse	循環虚脱	1 (<0.1%)	0	1 (<0.1%)	0
Collateral circulation	側副血行	4 (0.2%)	6 (0.4%)		
Essential hypertension	本態性高血圧症	1 (<0.1%)	1 (<0.1%)		
Extremity necrosis	四肢壊死	0	1 (<0.1%)		
Femoral artery occlusion	大腿動脈閉塞	1 (<0.1%)	0		
Haematoma	血腫	37 (2.2%)	59 (3.4%)	25 (1.5%)	38 (2.2%)
Hot flush	ほてり	2 (0.1%)	2 (0.1%)	1 (<0.1%)	1 (<0.1%)
Hypertension	高血圧	38 (2.2%)	40 (2.3%)	0	1 (<0.1%)
Hypertensive crisis	高血圧クリーゼ	0	1 (<0.1%)		
Hypotension	低血圧	4 (0.2%)	7 (0.4%)	1 (<0.1%)	0
Iliac artery stenosis	腸骨動脈狭窄	0	1 (<0.1%)		
Intermittent claudication	間欠性跛行	1 (<0.1%)	0		
Jugular vein thrombosis	頚静脈血栓症	0	1 (<0.1%)		
Lymphoedema	リンパ浮腫	1 (<0.1%)	0		
Lymphorrhoea	リンパ漏	0	1 (<0.1%)		
May-Thurner syndrome	マイ・トゥルナー症候群	0	1 (<0.1%)		
Neovascularisation	血管新生	2 (0.1%)	0		
Orthostatic hypotension	起立性低血圧	3 (0.2%)	1 (<0.1%)		
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	3 (0.2%)	2 (0.1%)		
Peripheral artery aneurysm	末梢動脈瘤	1 (<0.1%)	0		
Peripheral coldness	末梢冷感	3 (0.2%)	0	3 (0.2%)	0
Peripheral embolism	末梢血管塞栓症	0	1 (<0.1%)		
Peripheral ischaemia	末梢性虚血	1 (<0.1%)	1 (<0.1%)		
Peripheral vascular disorder	末梢血管障害	1 (<0.1%)	1 (<0.1%)		

表 2.7.4.7-1 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)	Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Phlebitis	静脈炎	1 (<0.1%)	2 (0.1%)	0	1 (<0.1%)
Phlebitis superficial	表在性静脈炎	1 (<0.1%)	1 (<0.1%)		
Post thrombotic syndrome	血栓後症候群	10 (0.6%)	10 (0.6%)	1 (<0.1%)	0
Raynaud's phenomenon	レイノー現象	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Shock haemorrhagic	出血性ショック	0	1 (<0.1%)	0	1 (<0.1%)
Superficial vein prominence	表在静脈隆起	1 (<0.1%)	0		
Thrombophlebitis	血栓性静脈炎	0	3 (0.2%)		
Thrombophlebitis migrans	遊走性血栓静脈炎	0	1 (<0.1%)		
Thrombophlebitis superficial	表在性血栓性静脈炎	1 (<0.1%)	1 (<0.1%)		
Thrombosis	血栓症	1 (<0.1%)	2 (0.1%)		
Varicose ulceration	静脈瘤性潰瘍	0	1 (<0.1%)		
Varicose vein	静脈瘤	6 (0.3%)	8 (0.5%)	1 (<0.1%)	0
Vasodilatation	血管拡張	3 (0.2%)	1 (<0.1%)	1 (<0.1%)	0
Vasospasm	血管痙攣	0	1 (<0.1%)		
Vein pain	静脈痛	1 (<0.1%)	3 (0.2%)		
Venous insufficiency	静脈不全	4 (0.2%)	8 (0.5%)		
Venous thrombosis limb	四肢静脈血栓症	1 (<0.1%)	0	1 (<0.1%)	0

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 9:58
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表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11702-PE、安全性解析対象集団）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		Treatment-emergent		Treatment-emergent 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		1937 (80.3%)	1901 (79.0%)	776 (32.2%)	784 (32.6%)
Blood and lymphatic system disorders	血液およびリンパ系障害	85 (3.5%)	78 (3.2%)	27 (1.1%)	22 (0.9%)
Anaemia	貧血	53 (2.2%)	37 (1.5%)	17 (0.7%)	10 (0.4%)
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%)
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	1 (<0.1%)	0		
Haemolytic anaemia	溶血性貧血	1 (<0.1%)	0		
Haemorrhagic anaemia	出血性貧血	1 (<0.1%)	2 (<0.1%)	1 (<0.1%)	2 (<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	5 (0.2%)	8 (0.3%)	3 (0.1%)	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	2 (<0.1%)	3 (0.1%)	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		
Lymphadenopathy	リンパ節症	4 (0.2%)	5 (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%)	0	1 (<0.1%)	0
Neutropenia	好中球減少症	2 (<0.1%)	2 (<0.1%)		
Normochromic normocytic anaemia	正色素性正球性貧血	1 (<0.1%)	0	1 (<0.1%)	0
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%)

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Splenic infarction	脾臓梗塞	0	1 (<0.1%)		
Splenic lesion	脾臓病変	0	1 (<0.1%)		
Splenomegaly	脾腫	3 (0.1%)	1 (<0.1%)		
Spontaneous haematoma	特発性血腫	0	1 (<0.1%)	0	1 (<0.1%)
Thrombocytopenia	血小板減少症	3 (0.1%)	7 (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	207 (8.6%)	197 (8.2%)	14 (0.6%)	3 (0.1%)
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	5 (0.2%)	11 (0.5%)		
Angina pectoris	狭心症	8 (0.3%)	4 (0.2%)		
Angina unstable	不安定狭心症	9 (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	3 (0.1%)	4 (0.2%)		
Arteriosclerosis coronary artery	冠動脈硬化症	2 (<0.1%)	0		
Atrial fibrillation	心房細動	21 (0.9%)	24 (1.0%)		
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%)	3 (0.1%)		
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 disorder	心障害	1 (<0.1%)	0		
Cardiac failure	心不全	12 (0.5%)	15 (0.6%)		
Cardiac failure acute	急性心不全	3 (0.1%)	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%)	5 (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		
Cardiomegaly	心拡大	1 (<0.1%)	1 (<0.1%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Cardiomyopathy	心筋症	0	3 (0.1%)		
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		
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	3 (0.1%)	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	7 (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	24 (1.0%)	22 (0.9%)		
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%)	5 (0.2%)		
Pericardial haemorrhage	心嚢内出血	0	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		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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	1 (<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	46 (1.9%)	38 (1.6%)	5 (0.2%)	0
Tricuspid valve incompetence	三尖弁閉鎖不全症	7 (0.3%)	11 (0.5%)	1 (<0.1%)	0
Ventricular extrasystoles	心室性期外収縮	0	2 (<0.1%)		
Ventricular hypertrophy	心室肥大	4 (0.2%)	3 (0.1%)		
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	29 (1.2%)	20 (0.8%)		
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	12 (0.5%)	12 (0.5%)		
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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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%)	0		
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	1 (<0.1%)	0		
Ear and labyrinth disorders	耳および迷路障害	70 (2.9%)	67 (2.8%)	5 (0.2%)	10 (0.4%)
Auricular perichondritis	耳介軟骨膜炎	1 (<0.1%)	0		
Deafness	難聴	2 (<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%)	4 (0.2%)		
Ear disorder	耳の障害	0	1 (<0.1%)		
Ear haemorrhage	耳出血	2 (<0.1%)	9 (0.4%)	2 (<0.1%)	7 (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	17 (0.7%)	6 (0.2%)	2 (<0.1%)	1 (<0.1%)
Tympanic membrane perforation	鼓膜穿孔	0	1 (<0.1%)		
Vertigo	回転性めまい	39 (1.6%)	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	21 (0.9%)	24 (1.0%)	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	3 (0.1%)	4 (0.2%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Hyperparathyroidism	副甲状腺機能亢進症	0	1 (<0.1%)		
Hyperthyroidism	甲状腺機能亢進症	4 (0.2%)	6 (0.2%)	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	98 (4.1%)	95 (4.0%)	35 (1.5%)	35 (1.5%)
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	27 (1.1%)	26 (1.1%)	20 (0.8%)	25 (1.0%)
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	2 (<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		
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		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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		
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%)	1 (<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	737 (30.6%)	672 (27.9%)	211 (8.7%)	176 (7.3%)

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Abdominal discomfort	腹部不快感	16 (0.7%)	15 (0.6%)	5 (0.2%)	1 (<0.1%)
Abdominal distension	腹部膨満	11 (0.5%)	4 (0.2%)		
Abdominal hernia	腹部ヘルニア	1 (<0.1%)	0		
Abdominal mass	腹部腫瘤	0	1 (<0.1%)	0	1 (<0.1%)
Abdominal pain	腹痛	45 (1.9%)	38 (1.6%)	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	53 (2.2%)	41 (1.7%)	4 (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%)		
Aerophagia	空気嚥下	1 (<0.1%)	1 (<0.1%)		
Anal fissure	裂肛	2 (<0.1%)	2 (<0.1%)		
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	14 (0.6%)	13 (0.5%)		
Colonic stenosis	結腸狭窄	1 (<0.1%)	0		
Constipation	便秘	139 (5.8%)	131 (5.4%)	4 (0.2%)	1 (<0.1%)

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Dental caries	齲歯	9 (0.4%)	9 (0.4%)		
Diarrhoea	下痢	125 (5.2%)	124 (5.2%)	12 (0.5%)	5 (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		
Diverticulum	憩室	4 (0.2%)	8 (0.3%)		
Diverticulum gastric	胃憩室	0	1 (<0.1%)		
Diverticulum intestinal	腸憩室	15 (0.6%)	6 (0.2%)		
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	42 (1.7%)	40 (1.7%)	9 (0.4%)	3 (0.1%)
Dysphagia	嚥下障害	4 (0.2%)	5 (0.2%)		
Enteritis	小腸炎	2 (<0.1%)	1 (<0.1%)		
Enterocolitis	腸炎	0	1 (<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%)	1 (<0.1%)	1 (<0.1%)	0
Faeces discoloured	変色便	0	1 (<0.1%)		
Flatulence	鼓腸	5 (0.2%)	4 (0.2%)	0	1 (<0.1%)
Food poisoning	食中毒	2 (<0.1%)	1 (<0.1%)		
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	4 (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%)

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Gastric varices	胃静脈瘤	1 (<0.1%)	0		
Gastritis	胃炎	24 (1.0%)	21 (0.9%)	1 (<0.1%)	1 (<0.1%)
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	12 (0.5%)	5 (0.2%)	9 (0.4%)	5 (0.2%)
Gastrointestinal pain	消化器痛	0	3 (0.1%)	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	29 (1.2%)	28 (1.2%)	3 (0.1%)	1 (<0.1%)
Gastrooesophageal sphincter insufficiency	胃食道括約筋機能不全	1 (<0.1%)	0		
Gingival bleeding	歯肉出血	57 (2.4%)	76 (3.2%)	46 (1.9%)	64 (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	10 (0.4%)	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	11 (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	20 (0.8%)	18 (0.7%)	1 (<0.1%)	0
Hiatus hernia	裂孔ヘルニア	21 (0.9%)	11 (0.5%)		
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%)		
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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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 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	9 (0.4%)	10 (0.4%)	5 (0.2%)	9 (0.4%)
Lumbar hernia	腰ヘルニア	1 (<0.1%)	0		
Melaena	メレナ	8 (0.3%)	14 (0.6%)	4 (0.2%)	13 (0.5%)
Mouth haemorrhage	口腔内出血	7 (0.3%)	4 (0.2%)	5 (0.2%)	1 (<0.1%)
Mouth ulceration	口腔内潰瘍形成	4 (0.2%)	5 (0.2%)	0	1 (<0.1%)
Nausea	悪心	106 (4.4%)	122 (5.1%)	18 (0.7%)	7 (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	5 (0.2%)	10 (0.4%)		
Pancreatic atrophy	膵萎縮	1 (<0.1%)	0		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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%)
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	2 (<0.1%)	0		
Proctitis	直腸炎	1 (<0.1%)	0		
Rectal haemorrhage	直腸出血	57 (2.4%)	41 (1.7%)	41 (1.7%)	32 (1.3%)
Rectal polyp	直腸ポリープ	3 (0.1%)	5 (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	2 (<0.1%)	0	2 (<0.1%)
Salivary gland enlargement	唾液腺腫大	1 (<0.1%)	1 (<0.1%)		
Sigmoiditis	S状結腸炎	2 (<0.1%)	0		
Small intestinal obstruction	小腸閉塞	1 (<0.1%)	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	3 (0.1%)	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		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Tooth loss	歯の脱落	2 (<0.1%)	0		
Toothache	歯痛	31 (1.3%)	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	51 (2.1%)	74 (3.1%)	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	502 (20.8%)	480 (20.0%)	42 (1.7%)	37 (1.5%)
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%)		
Asthenia	無力症	51 (2.1%)	53 (2.2%)	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	2 (<0.1%)	3 (0.1%)	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	20 (0.8%)	17 (0.7%)	0	1 (<0.1%)
Chest pain	胸痛	183 (7.6%)	185 (7.7%)	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	66 (2.7%)	53 (2.2%)	13 (0.5%)	3 (0.1%)

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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%)	3 (0.1%)		
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	3 (0.1%)	3 (0.1%)		
Hypothermia	低体温	1 (<0.1%)	0		
Impaired healing	治癒不良	1 (<0.1%)	0		
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	16 (0.7%)	19 (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%)		
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	4 (0.2%)	13 (0.5%)	2 (<0.1%)	10 (0.4%)
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%)
Localised oedema	限局性浮腫	2 (<0.1%)	1 (<0.1%)		
Malaise	倦怠感	12 (0.5%)	8 (0.3%)	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%)		
Mucosal inflammation	粘膜の炎症	1 (<0.1%)	0		
Non-cardiac chest pain	非心臓性胸痛	10 (0.4%)	9 (0.4%)		
Oedema	浮腫	18 (0.7%)	22 (0.9%)	3 (0.1%)	1 (<0.1%)

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Oedema peripheral	末梢性浮腫	87 (3.6%)	94 (3.9%)	3 (0.1%)	6 (0.2%)
Pain	疼痛	15 (0.6%)	8 (0.3%)		
Pelvic mass	骨盤腔内腫瘤	1 (<0.1%)	0		
Polyp	ポリープ	2 (<0.1%)	1 (<0.1%)		
Pyrexia	発熱	67 (2.8%)	70 (2.9%)		
Sensation of pressure	圧迫感	0	1 (<0.1%)		
Sudden death	突然死	3 (0.1%)	1 (<0.1%)	2 (<0.1%)	0
Tenderness	圧痛	0	1 (<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	88 (3.6%)	101 (4.2%)	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	1 (<0.1%)	1 (<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%)		
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	2 (<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%)	1 (<0.1%)		
Hepatic congestion	肝臓うっ血	1 (<0.1%)	0		
Hepatic cyst	肝嚢胞	7 (0.3%)	9 (0.4%)		
Hepatic failure	肝不全	1 (<0.1%)	1 (<0.1%)		
Hepatic function abnormal	肝機能異常	5 (0.2%)	12 (0.5%)	4 (0.2%)	8 (0.3%)
Hepatic mass	肝腫瘤	0	1 (<0.1%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Hepatic pain	肝臓痛	1 (<0.1%)	0		
Hepatic steatosis	脂肪肝	39 (1.6%)	42 (1.7%)		
Hepatic vein dilatation	肝静脈拡張	0	1 (<0.1%)		
Hepatitis	肝炎	0	1 (<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%)		
Immune system disorders	免疫系障害	38 (1.6%)	25 (1.0%)	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	7 (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%)	11 (0.5%)		
Infections and infestations	感染症および寄生虫症	746 (30.9%)	740 (30.8%)	12 (0.5%)	7 (0.3%)
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%)		
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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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	1 (<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	108 (4.5%)	89 (3.7%)	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	5 (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	5 (0.2%)	3 (0.1%)		
Catheter site infection	カテーテル留置部位感染	1 (<0.1%)	0		
Cellulitis	蜂巣炎	10 (0.4%)	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%)		
Chronic sinusitis	慢性副鼻腔炎	0	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	14 (0.6%)	29 (1.2%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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	1 (<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%)		
Ear infection	耳感染	9 (0.4%)	3 (0.1%)		
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	3 (0.1%)	7 (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	28 (1.2%)	37 (1.5%)	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	2 (<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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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	3 (0.1%)	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	1 (<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%)	11 (0.5%)		
Hordeolum	麦粒腫	1 (<0.1%)	2 (<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	2 (<0.1%)	3 (0.1%)		
Infectious peritonitis	感染性腹膜炎	3 (0.1%)	0		
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	58 (2.4%)	51 (2.1%)	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%)	6 (0.2%)		
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	3 (0.1%)	1 (<0.1%)		
Localised infection	限局性感染	13 (0.5%)	6 (0.2%)		
Lower respiratory tract infection	下気道感染	18 (0.7%)	30 (1.2%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Lung abscess	肺膿瘍	1 (<0.1%)	1 (<0.1%)		
Lung infection	肺感染	22 (0.9%)	18 (0.7%)		
Lyme disease	ライム病	0	1 (<0.1%)		
Mastitis	乳腺炎	1 (<0.1%)	0		
Nasopharyngitis	鼻咽頭炎	181 (7.5%)	189 (7.9%)	5 (0.2%)	1 (<0.1%)
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	3 (0.1%)	3 (0.1%)		
Oral herpes	口腔ヘルペス	6 (0.2%)	5 (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%)	0		
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%)	12 (0.5%)		
Pharyngitis streptococcal	レンサ球菌性咽頭炎	1 (<0.1%)	1 (<0.1%)		
Pilonidal cyst	毛巣嚢胞	1 (<0.1%)	1 (<0.1%)		
Pneumonia	肺炎	34 (1.4%)	44 (1.8%)	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		
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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Pyelonephritis	腎盂腎炎	5 (0.2%)	4 (0.2%)		
Pyelonephritis acute	急性腎盂腎炎	0	1 (<0.1%)		
Respiratory tract infection	気道感染	23 (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	17 (0.7%)	22 (0.9%)	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	9 (0.4%)	3 (0.1%)		
Sepsis syndrome	敗血症症候群	1 (<0.1%)	0		
Sinobronchitis	副鼻腔気管支炎	0	1 (<0.1%)		
Sinusitis	副鼻腔炎	35 (1.5%)	30 (1.2%)	1 (<0.1%)	1 (<0.1%)
Skin bacterial infection	皮膚細菌感染	0	2 (<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	1 (<0.1%)	0		
Staphylococcal infection	ブドウ球菌感染	1 (<0.1%)	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%)	9 (0.4%)		
Tooth infection	歯感染	11 (0.5%)	8 (0.3%)		
Tracheitis	気管炎	6 (0.2%)	2 (<0.1%)		
Tracheobronchitis	気管気管支炎	1 (<0.1%)	2 (<0.1%)		
Upper respiratory tract infection	上気道感染	48 (2.0%)	44 (1.8%)	0	1 (<0.1%)
Urethritis	尿道炎	1 (<0.1%)	1 (<0.1%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent 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	93 (3.9%)	95 (4.0%)		
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%)	1 (<0.1%)		
Vaginal abscess	腟膿瘍	1 (<0.1%)	0		
Vaginal infection	腟感染	7 (0.3%)	2 (<0.1%)		
Vestibular neuronitis	前庭神経炎	0	2 (<0.1%)		
Viraemia	ウイルス血症	0	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	2 (<0.1%)	1 (<0.1%)		
Vulvitis	外陰部炎	1 (<0.1%)	1 (<0.1%)		
Vulvovaginal candidiasis	外陰部腟カンジダ症	1 (<0.1%)	1 (<0.1%)		
Vulvovaginal mycotic infection	外陰腟真菌感染	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	301 (12.5%)	358 (14.9%)	110 (4.6%)	167 (6.9%)
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	2 (<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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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		
Concussion	脳振盪	1 (<0.1%)	2 (<0.1%)		
Contusion	挫傷	92 (3.8%)	129 (5.4%)	53 (2.2%)	86 (3.6%)
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	3 (0.1%)	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	19 (0.8%)	19 (0.8%)		
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%)	3 (0.1%)		
Foreign body in eye	眼内異物	0	1 (<0.1%)		
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	3 (0.1%)	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	0	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	2 (<0.1%)	1 (<0.1%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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	7 (0.3%)	8 (0.3%)	1 (<0.1%)	0
Ligament rupture	靭帯断裂	4 (0.2%)	1 (<0.1%)		
Ligament sprain	靭帯捻挫	12 (0.5%)	11 (0.5%)		
Limb crushing injury	四肢圧挫損傷	1 (<0.1%)	0		
Limb injury	四肢損傷	5 (0.2%)	9 (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%)	0		
Muscle strain	肉離れ	5 (0.2%)	9 (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	3 (0.1%)	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		
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	11 (0.5%)	10 (0.4%)	7 (0.3%)	5 (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 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	4 (0.2%)	8 (0.3%)		
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%)	5 (0.2%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Road traffic accident	交通事故	1 (<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%)		
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	33 (1.4%)	43 (1.8%)	21 (0.9%)	32 (1.3%)
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	2 (<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	1 (<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	9 (0.4%)	8 (0.3%)	6 (0.2%)	1 (<0.1%)
Ulna fracture	尺骨骨折	0	1 (<0.1%)		
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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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	39 (1.6%)	44 (1.8%)	16 (0.7%)	18 (0.7%)
Wrist fracture	手首関節骨折	0	2 (<0.1%)		
Investigations	臨床検査	229 (9.5%)	316 (13.1%)	76 (3.2%)	160 (6.7%)
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
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	52 (2.2%)	77 (3.2%)	26 (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	20 (0.8%)	26 (1.1%)	10 (0.4%)	11 (0.5%)
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	4 (0.2%)	1 (<0.1%)	3 (0.1%)	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%)
Blood amylase increased	血中アミラーゼ増加	7 (0.3%)	5 (0.2%)	2 (<0.1%)	1 (<0.1%)
Blood bilirubin increased	血中ビリルビン増加	9 (0.4%)	4 (0.2%)	5 (0.2%)	0
Blood cholesterol increased	血中コレステロール増加	3 (0.1%)	4 (0.2%)		
Blood creatinine increased	血中クレアチニン増加	1 (<0.1%)	6 (0.2%)	0	1 (<0.1%)

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Blood follicle stimulating hormone increased	血中卵胞刺激ホルモン増加	0	1 (<0.1%)		
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%)	2 (<0.1%)	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 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%)	2 (<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%)		
C-reactive protein increased	Ｃ－反応性蛋白増加	3 (0.1%)	2 (<0.1%)	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	1 (<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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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%)	3 (0.1%)	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	7 (0.3%)	3 (0.1%)	1 (<0.1%)	1 (<0.1%)
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	11 (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%)

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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	6 (0.2%)	82 (3.4%)	4 (0.2%)	76 (3.2%)
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%)	37 (1.5%)	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		
Neutrophil count decreased	好中球数減少	0	1 (<0.1%)		
Occult blood positive	便潜血陽性	9 (0.4%)	5 (0.2%)	5 (0.2%)	1 (<0.1%)
Platelet count decreased	血小板数減少	2 (<0.1%)	0		
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%)		
Prothrombin level decreased	プロトロンビン量減少	1 (<0.1%)	0	1 (<0.1%)	0
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%)	2 (<0.1%)		
Thyroid gland scan abnormal	甲状腺スキャン異常	0	1 (<0.1%)		
Transaminases increased	トランスアミナーゼ上昇	6 (0.2%)	9 (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	1 (<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%)	12 (0.5%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Weight increased	体重増加	15 (0.6%)	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	196 (8.1%)	218 (9.1%)	7 (0.3%)	8 (0.3%)
Acidosis	アシドーシス	1 (<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	15 (0.6%)	19 (0.8%)	2 (<0.1%)	2 (<0.1%)
Dehydration	脱水	8 (0.3%)	8 (0.3%)		
Diabetes mellitus	糖尿病	17 (0.7%)	8 (0.3%)		
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	16 (0.7%)	23 (1.0%)	2 (<0.1%)	2 (<0.1%)
Hypercalcaemia	高カルシウム血症	2 (<0.1%)	1 (<0.1%)		
Hypercholesterolaemia	高コレステロール血症	18 (0.7%)	29 (1.2%)		
Hyperglycaemia	高血糖	8 (0.3%)	9 (0.4%)		
Hyperhomocysteinaemia	高ホモシステイン血症	9 (0.4%)	6 (0.2%)		
Hyperkalaemia	高カリウム血症	2 (<0.1%)	9 (0.4%)		
Hyperlipidaemia	高脂血症	11 (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	5 (0.2%)	5 (0.2%)		
Hypoalbuminaemia	低アルブミン血症	0	3 (0.1%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Hypocalcaemia	低カルシウム血症	2 (<0.1%)	3 (0.1%)		
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	38 (1.6%)	46 (1.9%)	0	1 (<0.1%)
Hypomagnesaemia	低マグネシウム血症	3 (0.1%)	0		
Hyponatraemia	低ナトリウム血症	4 (0.2%)	6 (0.2%)		
Hypophosphataemia	低リン酸血症	0	5 (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	10 (0.4%)	5 (0.2%)	1 (<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	1 (<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	10 (0.4%)	8 (0.3%)		
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	11 (0.5%)	3 (0.1%)		
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%)	4 (0.2%)	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	530 (22.0%)	547 (22.7%)	31 (1.3%)	31 (1.3%)
Ankylosing spondylitis	強直性脊椎炎	0	1 (<0.1%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Arthralgia	関節痛	85 (3.5%)	77 (3.2%)	7 (0.3%)	2 (<0.1%)
Arthritis	関節炎	10 (0.4%)	9 (0.4%)	1 (<0.1%)	0
Articular calcification	関節石灰化	1 (<0.1%)	0		
Back pain	背部痛	88 (3.6%)	131 (5.4%)		
Bone cyst	骨嚢腫	0	1 (<0.1%)		
Bone pain	骨痛	9 (0.4%)	6 (0.2%)		
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%)	4 (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	5 (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	5 (0.2%)	5 (0.2%)		
Haemarthrosis	出血性関節症	4 (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	15 (0.6%)	13 (0.5%)		
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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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	2 (<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	49 (2.0%)	54 (2.2%)	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%)	1 (<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	29 (1.2%)	23 (1.0%)	0	1 (<0.1%)
Musculoskeletal discomfort	筋骨格不快感	1 (<0.1%)	3 (0.1%)		
Musculoskeletal pain	筋骨格痛	40 (1.7%)	39 (1.6%)	2 (<0.1%)	0
Musculoskeletal stiffness	筋骨格硬直	6 (0.2%)	2 (<0.1%)		
Myalgia	筋肉痛	37 (1.5%)	32 (1.3%)	5 (0.2%)	2 (<0.1%)
Myalgia intercostal	肋間筋肉痛	0	1 (<0.1%)		
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	15 (0.6%)	22 (0.9%)		
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	27 (1.1%)	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	154 (6.4%)	154 (6.4%)	9 (0.4%)	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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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%)		
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	9 (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	1 (<0.1%)		
Tendon disorder	腱障害	3 (0.1%)	2 (<0.1%)		
Tendon pain	腱痛	0	2 (<0.1%)		
Tendonitis	腱炎	13 (0.5%)	4 (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		
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）	113 (4.7%)	104 (4.3%)	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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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%)	0		
Basal cell carcinoma	基底細胞癌	7 (0.3%)	7 (0.3%)		
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	0	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%)	0		
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		
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	5 (0.2%)	0		
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	1 (<0.1%)	0		
Colorectal cancer	結腸直腸癌	2 (<0.1%)	0		
Essential thrombocythaemia	本態性血小板血症	1 (<0.1%)	0		
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		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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%)		
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%)	0		
Inflammatory pseudotumour	炎症性偽腫瘍	1 (<0.1%)	0		
Lipoma	脂肪腫	3 (0.1%)	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%)		
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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Metastases to liver	肝転移	2 (<0.1%)	4 (0.2%)		
Metastases to lung	肺転移	0	3 (0.1%)		
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	1 (<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%)		
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		
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%)	0		
Rectal cancer metastatic	転移性直腸癌	0	1 (<0.1%)		
Rectal neoplasm	直腸新生物	1 (<0.1%)	0		
Renal cancer	腎癌	1 (<0.1%)	0		
Renal cell carcinoma	腎細胞癌	1 (<0.1%)	0		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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		
Squamous cell carcinoma	扁平上皮癌	0	1 (<0.1%)		
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	2 (<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	410 (17.0%)	389 (16.2%)	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%)		
Anosmia	無嗅覚	1 (<0.1%)	0		
Ataxia	運動失調	2 (<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	1 (<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	0	1 (<0.1%)		
Cerebral haemorrhage	脳出血	0	4 (0.2%)	0	3 (0.1%)

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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
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		
Complex regional pain syndrome	複合性局所疼痛症候群	0	3 (0.1%)		
Convulsion	痙攣	3 (0.1%)	2 (<0.1%)	1 (<0.1%)	0
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	64 (2.7%)	86 (3.6%)	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	193 (8.0%)	174 (7.2%)	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%)	0	1 (<0.1%)	0

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Hyperaesthesia	知覚過敏	1 (<0.1%)	0		
Hypersomnia	過眠症	0	1 (<0.1%)		
Hypoaesthesia	感覚鈍麻	12 (0.5%)	18 (0.7%)	2 (<0.1%)	0
Intercostal neuralgia	肋間神経痛	1 (<0.1%)	0		
Ischaemic stroke	虚血性脳卒中	11 (0.5%)	6 (0.2%)	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%)	1 (<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%)		
Orthostatic intolerance	起立不耐性	0	1 (<0.1%)		
Paraesthesia	錯感覚	29 (1.2%)	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	1 (<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	11 (0.5%)	9 (0.4%)		
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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Restless legs syndrome	下肢静止不能症候群	4 (0.2%)	4 (0.2%)	2 (<0.1%)	0
Sciatica	坐骨神経痛	17 (0.7%)	17 (0.7%)	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	3 (0.1%)	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	21 (0.9%)	18 (0.7%)	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	14 (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	217 (9.0%)	216 (9.0%)	10 (0.4%)	5 (0.2%)
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%)	1 (<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%)		
Alcohol withdrawal syndrome	アルコール離脱症候群	0	1 (<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	80 (3.3%)	76 (3.2%)	2 (<0.1%)	0
Anxiety disorder	不安障害	0	1 (<0.1%)		
Apathy	無感情	1 (<0.1%)	0		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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	8 (0.3%)	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	2 (<0.1%)	1 (<0.1%)		
Depression	うつ病	39 (1.6%)	42 (1.7%)	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	67 (2.8%)	76 (3.2%)	3 (0.1%)	1 (<0.1%)
Libido increased	リビド一亢進	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	1 (<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%)	3 (0.1%)		
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	2 (<0.1%)	0		
Sleep disorder	睡眠障害	5 (0.2%)	10 (0.4%)	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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Suicide attempt	自殺企図	1 (<0.1%)	2 (<0.1%)		
Renal and urinary disorders	腎および尿路障害	149 (6.2%)	169 (7.0%)	52 (2.2%)	54 (2.2%)
Acute prerenal failure	急性腎前性腎不全	1 (<0.1%)	0		
Anuria	無尿	0	1 (<0.1%)		
Bilirubinuria	ビリルビン尿	0	1 (<0.1%)		
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	0	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	72 (3.0%)	72 (3.0%)	49 (2.0%)	52 (2.2%)
Hydronephrosis	水腎症	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%)		
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	9 (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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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	18 (0.7%)	26 (1.1%)		
Renal failure	腎不全	2 (<0.1%)	3 (0.1%)	0	1 (<0.1%)
Renal failure acute	急性腎不全	3 (0.1%)	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	3 (0.1%)	3 (0.1%)		
Renal mass	腎腫瘤	2 (<0.1%)	2 (<0.1%)		
Renal pain	腎臓痛	2 (<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%)		
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	178 (7.4%)	136 (5.7%)	97 (4.0%)	59 (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	12 (0.5%)	6 (0.2%)		
Breast calcifications	乳房石灰化	0	1 (<0.1%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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	3 (0.1%)	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	1 (<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%)	1 (<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	0	3 (0.1%)		
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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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	73 (3.0%)	45 (1.9%)	61 (2.5%)	34 (1.4%)
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%)	16 (0.7%)	10 (0.4%)	14 (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	2 (<0.1%)	0		
Prostatitis	前立腺炎	4 (0.2%)	6 (0.2%)		
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 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	1 (<0.1%)	0		
Uterine polyp	子宮ポリープ	2 (<0.1%)	2 (<0.1%)		
Uterine prolapse	子宮脱	1 (<0.1%)	0		
Uterine spasm	子宮痙攣	1 (<0.1%)	0		
Vaginal discharge	腟分泌物	0	1 (<0.1%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Vaginal haemorrhage	腟出血	26 (1.1%)	12 (0.5%)	19 (0.8%)	8 (0.3%)
Vaginal inflammation	腟の炎症	0	1 (<0.1%)		
Vulval disorder	外陰部障害	1 (<0.1%)	0		
Vulvovaginal discomfort	外陰腟不快感	1 (<0.1%)	0		
Vulvovaginal dryness	外陰腟乾燥	1 (<0.1%)	1 (<0.1%)		
Vulvovaginal pruritus	外陰腟そう痒症	2 (<0.1%)	0		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	655 (27.2%)	646 (26.9%)	246 (10.2%)	201 (8.4%)
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	1 (<0.1%)	1 (<0.1%)		
Acute respiratory failure	急性呼吸不全	1 (<0.1%)	0		
Allergic cough	アレルギー性咳嗽	0	3 (0.1%)		
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%)	16 (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	2 (<0.1%)	4 (0.2%)		
Bronchopneumopathy	気管支肺症	1 (<0.1%)	1 (<0.1%)		
Bronchospasm	気管支痙攣	4 (0.2%)	5 (0.2%)		
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	17 (0.7%)	12 (0.5%)	1 (<0.1%)	0
Cough	咳嗽	155 (6.4%)	169 (7.0%)	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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Dysphonia	発声障害	4 (0.2%)	6 (0.2%)		
Dyspnoea	呼吸困難	161 (6.7%)	136 (5.7%)	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%)	21 (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	2 (<0.1%)	2 (<0.1%)		
Epistaxis	鼻出血	218 (9.0%)	197 (8.2%)	173 (7.2%)	159 (6.6%)
Haemoptysis	喀血	81 (3.4%)	81 (3.4%)	62 (2.6%)	45 (1.9%)
Haemothorax	血胸	2 (<0.1%)	2 (<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	5 (0.2%)	5 (0.2%)		
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%)	5 (0.2%)		
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		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Oropharyngeal pain	口腔咽頭痛	27 (1.1%)	28 (1.2%)		
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	20 (0.8%)	28 (1.2%)	0	1 (<0.1%)
Pleural fibrosis	胸膜線維症	3 (0.1%)	0		
Pleural haemorrhage	胸腔内出血	1 (<0.1%)	0		
Pleurisy	胸膜炎	6 (0.2%)	11 (0.5%)		
Pleuritic pain	胸膜痛	22 (0.9%)	19 (0.8%)		
Pneumonia aspiration	誤嚥性肺炎	1 (<0.1%)	0		
Pneumothorax	気胸	1 (<0.1%)	4 (0.2%)		
Productive cough	湿性咳嗽	9 (0.4%)	9 (0.4%)	2 (<0.1%)	0
Pulmonary arterial hypertension	肺動脈高血圧症	1 (<0.1%)	1 (<0.1%)		
Pulmonary congestion	肺うっ血	3 (0.1%)	2 (<0.1%)	0	1 (<0.1%)
Pulmonary embolism	肺塞栓症	4 (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	9 (0.4%)	12 (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%)

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent 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%)	3 (0.1%)	2 (<0.1%)	0
Respiratory tract congestion	気道うっ血	2 (<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	8 (0.3%)	6 (0.2%)		
Rhinitis seasonal	季節性鼻炎	1 (<0.1%)	2 (<0.1%)		
Rhinorrhoea	鼻漏	6 (0.2%)	7 (0.3%)	1 (<0.1%)	0
Sinus congestion	副鼻腔うっ血	6 (0.2%)	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	11 (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%)	0		
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	312 (12.9%)	264 (11.0%)	105 (4.4%)	78 (3.2%)
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%)	1 (<0.1%)		
Dermal cyst	皮膚嚢腫	2 (<0.1%)	1 (<0.1%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Dermatitis	皮膚炎	6 (0.2%)	4 (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%)
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%)	0	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%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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	54 (2.2%)	27 (1.1%)	21 (0.9%)	7 (0.3%)
Pruritus generalised	全身性そう痒症	4 (0.2%)	3 (0.1%)	0	1 (<0.1%)
Psoriasis	乾癬	4 (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	71 (2.9%)	61 (2.5%)	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		
Rosacea	酒さ	2 (<0.1%)	0		
Scar	瘢痕	1 (<0.1%)	0		
Scar pain	瘢痕痛	0	1 (<0.1%)		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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%)	1 (<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	12 (0.5%)	8 (0.3%)	5 (0.2%)	5 (0.2%)
Skin irritation	皮膚刺激	1 (<0.1%)	2 (<0.1%)		
Skin lesion	皮膚病変	8 (0.3%)	4 (0.2%)		
Skin mass	皮膚腫瘤	0	1 (<0.1%)		
Skin necrosis	皮膚壊死	0	1 (<0.1%)	0	1 (<0.1%)
Skin ulcer	皮膚潰瘍	6 (0.2%)	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	10 (0.4%)	6 (0.2%)	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%)	4 (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%)	0		
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	254 (10.5%)	293 (12.2%)	49 (2.0%)	77 (3.2%)

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Aortic aneurysm	大動脈瘤	2 (<0.1%)	6 (0.2%)		
Aortic aneurysm rupture	大動脈瘤破裂	0	1 (<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	1 (<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%)	0		
Arterial stenosis	動脈狭窄	1 (<0.1%)	0		
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	5 (0.2%)	6 (0.2%)	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	57 (2.4%)	92 (3.8%)	37 (1.5%)	68 (2.8%)
Hot flush	ほてり	8 (0.3%)	11 (0.5%)	2 (<0.1%)	2 (<0.1%)
Hypertension	高血圧	111 (4.6%)	88 (3.7%)	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	26 (1.1%)	19 (0.8%)		
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%)		
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		

表 2.7.4.7-2 TEAE 及び治験薬との因果関係が否定できない TEAE（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}		Treatment-emergent		Treatment-emergent study drug-related	
		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)	Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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%)	7 (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%)		
Thrombophlebitis superficial	表在性血栓性静脈炎	3 (0.1%)	1 (<0.1%)		
Thrombosis	血栓症	0	1 (<0.1%)		
Varicose ulceration	静脈瘤性潰瘍	0	1 (<0.1%)		
Varicose vein	静脈瘤	3 (0.1%)	13 (0.5%)		
Vasoconstriction	血管収縮	1 (<0.1%)	0	1 (<0.1%)	0
Vasodilatation	血管拡張	1 (<0.1%)	3 (0.1%)		
Vein pain	静脈痛	3 (0.1%)	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	9 (0.4%)	12 (0.5%)		
Venous thrombosis	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.
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表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Number of subjects (%) with at least one adverse event		325 (55.1%)	335 (56.0%)	63 (10.7%)	98 (16.4%)
Blood and lymphatic system disorders	血液およびリンパ系障害	2 (0.3%)	5 (0.8%)	0	1 (0.2%)
Anaemia	貧血	2 (0.3%)	4 (0.7%)	0	1 (0.2%)
Iron deficiency anaemia	鉄欠乏性貧血	0	1 (0.2%)		
Cardiac disorders	心臓障害	11 (1.9%)	21 (3.5%)		
Acute myocardial infarction	急性心筋梗塞	1 (0.2%)	0		
Angina pectoris	狭心症	0	2 (0.3%)		
Angina unstable	不安定狭心症	0	3 (0.5%)		
Arrhythmia	不整脈	0	2 (0.3%)		
Atrial fibrillation	心房細動	4 (0.7%)	5 (0.8%)		
Bradycardia	徐脈	2 (0.3%)	1 (0.2%)		
Cardiac arrest	心停止	0	1 (0.2%)		
Cardiac failure congestive	うっ血性心不全	0	1 (0.2%)		
Cardiomyopathy	心筋症	1 (0.2%)	0		
Extrasystoles	期外収縮	0	1 (0.2%)		
Myocardial ischaemia	心筋虚血	0	1 (0.2%)		
Palpitations	動悸	3 (0.5%)	3 (0.5%)		
Pericarditis	心膜炎	0	1 (0.2%)		
Sick sinus syndrome	洞不全症候群	1 (0.2%)	0		
Sinus bradycardia	洞性徐脈	0	1 (0.2%)		
Supraventricular tachycardia	上室性頻脈	2 (0.3%)	0		
Tachycardia	頻脈	0	2 (0.3%)		
Tachycardia paroxysmal	発作性頻脈	1 (0.2%)	0		
Congenital, familial and genetic disorders	先天性、家族性および遺伝性障害	2 (0.3%)	1 (0.2%)		
Basal cell naevus syndrome	基底細胞母斑症候群	1 (0.2%)	0		
Factor V Leiden mutation	第Ⅴ因子ライデン変異	1 (0.2%)	0		
Hydrocele	陰嚢水瘤	0	1 (0.2%)		
Ear and labyrinth disorders	耳および迷路障害	6 (1.0%)	6 (1.0%)	1 (0.2%)	0
Deafness unilateral	片耳難聴	0	1 (0.2%)		
Ear haemorrhage	耳出血	1 (0.2%)	1 (0.2%)	1 (0.2%)	0
Ear pain	耳痛	1 (0.2%)	0		
Motion sickness	乗物酔い	1 (0.2%)	0		

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Tinnitus	耳鳴	0	1 (0.2%)		
Vertigo	回転性めまい	3 (0.5%)	3 (0.5%)		
Endocrine disorders	内分泌障害	1 (0.2%)	1 (0.2%)		
Goitre	甲状腺腫	1 (0.2%)	0		
Hyperthyroidism	甲状腺機能亢進症	0	1 (0.2%)		
Hypothyroidism	甲状腺機能低下症	1 (0.2%)	0		
Eye disorders	眼障害	6 (1.0%)	15 (2.5%)	0	4 (0.7%)
Cataract	白内障	0	2 (0.3%)	0	1 (0.2%)
Conjunctival haemorrhage	結膜出血	0	6 (1.0%)	0	2 (0.3%)
Conjunctivitis	結膜炎	0	1 (0.2%)		
Dry eye	眼乾燥	1 (0.2%)	1 (0.2%)		
Eye pain	眼痛	1 (0.2%)	0		
Eye pruritus	眼そう痒症	0	1 (0.2%)		
Ocular hyperaemia	眼充血	0	1 (0.2%)	0	1 (0.2%)
Photopsia	光視症	1 (0.2%)	0		
Scleral haemorrhage	強膜出血	0	1 (0.2%)		
Vision blurred	霧視	1 (0.2%)	2 (0.3%)		
Visual impairment	視力障害	2 (0.3%)	0		
Vitreous detachment	硝子体剥離	0	1 (0.2%)		
Gastrointestinal disorders	胃腸障害	48 (8.1%)	88 (14.7%)	12 (2.0%)	23 (3.8%)
Abdominal discomfort	腹部不快感	1 (0.2%)	5 (0.8%)	1 (0.2%)	1 (0.2%)
Abdominal distension	腹部膨満	0	1 (0.2%)		
Abdominal hernia	腹部ヘルニア	1 (0.2%)	0		
Abdominal hernia obstructive	閉塞を伴う腹部ヘルニア	1 (0.2%)	0		
Abdominal pain	腹痛	7 (1.2%)	2 (0.3%)	1 (0.2%)	0
Abdominal pain lower	下腹部痛	2 (0.3%)	0		
Abdominal pain upper	上腹部痛	1 (0.2%)	10 (1.7%)	0	4 (0.7%)
Colitis ischaemic	虚血性大腸炎	1 (0.2%)	0		
Constipation	便秘	5 (0.8%)	6 (1.0%)		
Diarrhoea	下痢	8 (1.4%)	7 (1.2%)	1 (0.2%)	0
Diverticulum	憩室	2 (0.3%)	1 (0.2%)		
Dry mouth	口内乾燥	1 (0.2%)	2 (0.3%)	1 (0.2%)	0

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Dyspepsia	消化不良	4 (0.7%)	8 (1.3%)	1 (0.2%)	0
Dysphagia	嚥下障害	0	1 (0.2%)		
Epigastric discomfort	心窩部不快感	0	1 (0.2%)		
Flatulence	鼓腸	2 (0.3%)	0		
Food poisoning	食中毒	0	1 (0.2%)		
Gastric disorder	胃障害	1 (0.2%)	0		
Gastric ulcer	胃潰瘍	1 (0.2%)	1 (0.2%)		
Gastritis	胃炎	4 (0.7%)	3 (0.5%)	1 (0.2%)	1 (0.2%)
Gastritis haemorrhagic	出血性胃炎	0	1 (0.2%)	0	1 (0.2%)
Gastrointestinal haemorrhage	胃腸出血	0	2 (0.3%)	0	2 (0.3%)
Gastrooesophageal reflux disease	胃食道逆流性疾患	0	3 (0.5%)		
Gingival bleeding	歯肉出血	2 (0.3%)	11 (1.8%)	2 (0.3%)	7 (1.2%)
Gingivitis	歯肉炎	0	1 (0.2%)		
Haematochezia	血便排泄	1 (0.2%)	0	1 (0.2%)	0
Haemorrhoidal haemorrhage	痔出血	1 (0.2%)	3 (0.5%)	0	1 (0.2%)
Haemorrhoids	痔核	2 (0.3%)	2 (0.3%)		
Hiatus hernia	裂孔ヘルニア	0	1 (0.2%)		
Inguinal hernia	鼠径ヘルニア	2 (0.3%)	1 (0.2%)		
Intestinal obstruction	腸閉塞	0	1 (0.2%)		
Intra-abdominal haematoma	腹腔内血腫	1 (0.2%)	0	1 (0.2%)	0
Lip haematoma	口唇血腫	0	1 (0.2%)	0	1 (0.2%)
Lip pain	口唇痛	1 (0.2%)	0		
Melaena	メレナ	0	1 (0.2%)	0	1 (0.2%)
Mouth haemorrhage	口腔内出血	0	1 (0.2%)	0	1 (0.2%)
Mouth ulceration	口腔内潰瘍形成	1 (0.2%)	0		
Nausea	悪心	6 (1.0%)	7 (1.2%)	2 (0.3%)	0
Oral pain	口腔内痛	0	1 (0.2%)		
Rectal haemorrhage	直腸出血	4 (0.7%)	4 (0.7%)	1 (0.2%)	3 (0.5%)
Retching	レッチング	0	1 (0.2%)		
Sigmoiditis	S状結腸炎	0	1 (0.2%)		
Tongue blistering	舌水疱形成	0	1 (0.2%)		
Toothache	歯痛	0	6 (1.0%)		

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Vomiting	嘔吐	6 (1.0%)	3 (0.5%)	1 (0.2%)	0
General disorders and administration site conditions	一般・全身障害および投与部位の状態	51 (8.6%)	59 (9.9%)	4 (0.7%)	7 (1.2%)
Asthenia	無力症	6 (1.0%)	4 (0.7%)		
Chest discomfort	胸部不快感	3 (0.5%)	0		
Chest pain	胸痛	15 (2.5%)	16 (2.7%)	1 (0.2%)	3 (0.5%)
Cyst	嚢胞	1 (0.2%)	0		
Drug intolerance	薬物不耐性	0	1 (0.2%)		
Exercise tolerance decreased	運動耐性低下	0	1 (0.2%)		
Fatigue	疲労	3 (0.5%)	6 (1.0%)	0	3 (0.5%)
Feeling cold	冷感	0	1 (0.2%)		
General physical health deterioration	全身健康状態低下	0	1 (0.2%)		
Hunger	空腹	1 (0.2%)	0		
Inflammation	炎症	1 (0.2%)	1 (0.2%)		
Influenza like illness	インフルエンザ様疾患	1 (0.2%)	4 (0.7%)		
Malaise	倦怠感	1 (0.2%)	2 (0.3%)		
Non-cardiac chest pain	非心臓性胸痛	1 (0.2%)	0		
Oedema	浮腫	0	2 (0.3%)		
Oedema peripheral	末梢性浮腫	17 (2.9%)	13 (2.2%)	1 (0.2%)	1 (0.2%)
Pain	疼痛	0	2 (0.3%)		
Pitting oedema	圧痕浮腫	3 (0.5%)	2 (0.3%)		
Pyrexia	発熱	7 (1.2%)	5 (0.8%)	1 (0.2%)	0
Thirst	口渇	1 (0.2%)	0	1 (0.2%)	0
Hepatobiliary disorders	肝胆道系障害	4 (0.7%)	4 (0.7%)		
Biliary colic	胆道仙痛	2 (0.3%)	0		
Cholecystitis	胆嚢炎	1 (0.2%)	1 (0.2%)		
Cholelithiasis	胆石症	0	3 (0.5%)		
Cholestasis	胆汁うっ滞	1 (0.2%)	0		
Hepatic steatosis	脂肪肝	0	1 (0.2%)		
Immune system disorders	免疫系障害	3 (0.5%)	8 (1.3%)	0	1 (0.2%)
Antiphospholipid syndrome	抗リン脂質抗体症候群	0	1 (0.2%)		
Drug hypersensitivity	薬物過敏症	0	1 (0.2%)	0	1 (0.2%)

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Hypersensitivity	過敏症	2 (0.3%)	2 (0.3%)		
Seasonal allergy	季節性アレルギー	1 (0.2%)	4 (0.7%)		
Infections and infestations	感染症および寄生虫症	111 (18.8%)	106 (17.7%)		
Abdominal abscess	腹部膿瘍	0	1 (0.2%)		
Abdominal infection	腹部感染	0	1 (0.2%)		
Appendicitis	虫垂炎	0	1 (0.2%)		
Bronchiolitis	細気管支炎	0	1 (0.2%)		
Bronchitis	気管支炎	17 (2.9%)	11 (1.8%)		
Candidiasis	カンジダ症	1 (0.2%)	1 (0.2%)		
Cellulitis	蜂巣炎	3 (0.5%)	1 (0.2%)		
Cystitis	膀胱炎	1 (0.2%)	2 (0.3%)		
Diverticulitis	憩室炎	1 (0.2%)	0		
Ear infection	耳感染	1 (0.2%)	1 (0.2%)		
Enterocolitis infectious	感染性小腸結腸炎	1 (0.2%)	0		
Erysipelas	丹毒	2 (0.3%)	1 (0.2%)		
Folliculitis	毛包炎	1 (0.2%)	0		
Fungal skin infection	皮膚真菌感染	1 (0.2%)	2 (0.3%)		
Furuncle	せつ	1 (0.2%)	1 (0.2%)		
Gastroenteritis	胃腸炎	10 (1.7%)	5 (0.8%)		
Gonorrhoea	淋疾	0	1 (0.2%)		
Helicobacter infection	ヘリコバクター感染	1 (0.2%)	0		
Herpes zoster	帯状疱疹	3 (0.5%)	2 (0.3%)		
Influenza	インフルエンザ	12 (2.0%)	11 (1.8%)		
Intestinal gangrene	腸壊疽	1 (0.2%)	0		
Labyrinthitis	迷路炎	1 (0.2%)	0		
Laryngitis	喉頭炎	0	2 (0.3%)		
Localised infection	限局性感染	2 (0.3%)	2 (0.3%)		
Lower respiratory tract infection	下気道感染	5 (0.8%)	2 (0.3%)		
Lung abscess	肺膿瘍	0	1 (0.2%)		
Lung infection	肺感染	1 (0.2%)	0		
Nasopharyngitis	鼻咽頭炎	30 (5.1%)	31 (5.2%)		
Omphalitis	臍炎	0	1 (0.2%)		

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Oral herpes	口腔ヘルペス	1 (0.2%)	0		
Otitis media	中耳炎	1 (0.2%)	0		
Pelvic infection	骨盤内感染	1 (0.2%)	0		
Pharyngitis	咽頭炎	6 (1.0%)	2 (0.3%)		
Pneumonia	肺炎	2 (0.3%)	4 (0.7%)		
Post procedural infection	処置後感染	2 (0.3%)	1 (0.2%)		
Postoperative abscess	術後膿瘍	0	1 (0.2%)		
Pulpitis dental	歯髄炎	1 (0.2%)	0		
Respiratory tract infection	気道感染	3 (0.5%)	2 (0.3%)		
Respiratory tract infection viral	ウイルス性気道感染	0	1 (0.2%)		
Rhinitis	鼻炎	2 (0.3%)	3 (0.5%)		
Sinusitis	副鼻腔炎	3 (0.5%)	7 (1.2%)		
Skin infection	皮膚感染	0	1 (0.2%)		
Subcutaneous abscess	皮下組織膿瘍	1 (0.2%)	0		
Thrombophlebitis septic	化膿性血栓静脈炎	1 (0.2%)	0		
Tinea pedis	足部白癬	0	1 (0.2%)		
Tonsillitis	扁桃炎	0	2 (0.3%)		
Tooth abscess	歯膿瘍	0	2 (0.3%)		
Tooth infection	歯感染	2 (0.3%)	2 (0.3%)		
Upper respiratory tract infection	上気道感染	11 (1.9%)	8 (1.3%)		
Urinary tract infection	尿路感染	3 (0.5%)	7 (1.2%)		
Vaginal infection	腟感染	2 (0.3%)	0		
Viral infection	ウイルス感染	2 (0.3%)	3 (0.5%)		
Viral upper respiratory tract infection	ウイルス性上気道感染	1 (0.2%)	0		
Wound infection	創傷感染	0	1 (0.2%)		
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	54 (9.2%)	55 (9.2%)	12 (2.0%)	11 (1.8%)
Accident	事故	0	1 (0.2%)		
Anaemia postoperative	術後貧血	0	1 (0.2%)	0	1 (0.2%)
Ankle fracture	足関節部骨折	0	1 (0.2%)		
Arthropod bite	節足動物咬傷	3 (0.5%)	1 (0.2%)		
Arthropod sting	節足動物刺傷	1 (0.2%)	1 (0.2%)		
Back injury	背部損傷	1 (0.2%)	0		

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Carbon monoxide poisoning	一酸化炭素中毒	0	1 (0.2%)		
Chest injury	胸部損傷	1 (0.2%)	0		
Contusion	挫傷	16 (2.7%)	19 (3.2%)	6 (1.0%)	9 (1.5%)
Drug exposure during pregnancy	妊娠時の薬物曝露	1 (0.2%)	0		
Excoriation	擦過傷	2 (0.3%)	4 (0.7%)		
Eye injury	眼外傷	1 (0.2%)	0	1 (0.2%)	0
Face injury	顔面損傷	0	1 (0.2%)		
Fall	転倒・転落	7 (1.2%)	4 (0.7%)		
Hand fracture	手骨折	2 (0.3%)	1 (0.2%)		
Joint dislocation	関節脱臼	0	2 (0.3%)		
Joint injury	関節損傷	0	3 (0.5%)		
Joint sprain	関節捻挫	5 (0.8%)	4 (0.7%)		
Ligament rupture	靭帯断裂	0	1 (0.2%)		
Limb injury	四肢損傷	2 (0.3%)	2 (0.3%)		
Muscle strain	筋挫傷	3 (0.5%)	3 (0.5%)		
Open wound	開放創	0	1 (0.2%)		
Periorbital haematoma	眼窩周囲血腫	1 (0.2%)	0	1 (0.2%)	0
Post procedural haematoma	処置後血腫	1 (0.2%)	0	1 (0.2%)	0
Post procedural haemorrhage	処置後出血	2 (0.3%)	4 (0.7%)	0	2 (0.3%)
Procedural nausea	処置による悪心	1 (0.2%)	0		
Procedural pain	処置による疼痛	1 (0.2%)	0		
Radius fracture	橈骨骨折	2 (0.3%)	0		
Rib fracture	肋骨骨折	0	1 (0.2%)		
Skin injury	皮膚損傷	1 (0.2%)	0		
Skin laceration	皮膚裂傷	0	2 (0.3%)		
Skull fracture	頭蓋骨骨折	0	1 (0.2%)		
Subcutaneous haematoma	皮下血腫	2 (0.3%)	0	2 (0.3%)	0
Synovial rupture	滑膜断裂	0	1 (0.2%)		
Tendon rupture	腱断裂	0	2 (0.3%)		
Tooth avulsion	歯の完全脱臼	1 (0.2%)	0		
Tooth fracture	歯牙破折	0	1 (0.2%)		
Traumatic fracture	外傷性骨折	1 (0.2%)	0		

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Traumatic haematoma	外傷性血腫	2 (0.3%)	0		
Traumatic haemorrhage	外傷性出血	1 (0.2%)	2 (0.3%)	0	1 (0.2%)
Ulna fracture	尺骨骨折	0	1 (0.2%)		
Wound	創傷	1 (0.2%)	2 (0.3%)		
Wound secretion	創部分泌	1 (0.2%)	1 (0.2%)	1 (0.2%)	0
Investigations	臨床検査	23 (3.9%)	30 (5.0%)	4 (0.7%)	11 (1.8%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	4 (0.7%)	2 (0.3%)	1 (0.2%)	2 (0.3%)
Antiphospholipid antibodies positive	抗リン脂質抗体陽性	0	1 (0.2%)		
Arthroscopy	関節鏡検査	0	1 (0.2%)		
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3 (0.5%)	4 (0.7%)	0	3 (0.5%)
Bilirubin conjugated increased	抱合ビリルビン増加	2 (0.3%)	1 (0.2%)	1 (0.2%)	1 (0.2%)
Biopsy prostate	前立腺生検	1 (0.2%)	1 (0.2%)		
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0	1 (0.2%)	0	1 (0.2%)
Blood amylase increased	血中アミラーゼ増加	0	1 (0.2%)	0	1 (0.2%)
Blood bilirubin increased	血中ビリルビン増加	2 (0.3%)	2 (0.3%)	1 (0.2%)	1 (0.2%)
Blood cholesterol increased	血中コレステロール増加	1 (0.2%)	1 (0.2%)		
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	2 (0.3%)	0		
Blood creatinine increased	血中クレアチニン増加	1 (0.2%)	0		
Blood culture positive	血液培養陽性	0	1 (0.2%)		
Blood glucose increased	血中ブドウ糖増加	0	1 (0.2%)		
Blood pressure increased	血圧上昇	0	1 (0.2%)		
Blood testosterone decreased	血中テストステロン減少	0	1 (0.2%)		
Blood urine present	尿中血陽性	0	1 (0.2%)	0	1 (0.2%)
Cardiac murmur	心雑音	0	1 (0.2%)		
Catheterisation cardiac	心カテーテル	1 (0.2%)	0		
Colonoscopy	結腸内視鏡検査	3 (0.5%)	2 (0.3%)		
Creatinine renal clearance decreased	腎クレアチニン・クリアランス減少	0	1 (0.2%)		
Endoscopy upper gastrointestinal tract	上部消化管内視鏡検査	1 (0.2%)	1 (0.2%)		
Fibrin D dimer increased	フィブリンDダイマー増加	1 (0.2%)	0		

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Haemoglobin decreased	ヘモグロビン減少	0	1 (0.2%)	0	1 (0.2%)
Hepatic enzyme increased	肝酵素上昇	0	3 (0.5%)	0	1 (0.2%)
Hysteroscopy	ヒステロスコピー	0	1 (0.2%)		
Liver function test abnormal	肝機能検査異常	3 (0.5%)	4 (0.7%)	2 (0.3%)	3 (0.5%)
Protein S decreased	プロテインＳ減少	0	1 (0.2%)	0	1 (0.2%)
Prothrombin time prolonged	プロトロンビン時間延長	0	1 (0.2%)	0	1 (0.2%)
Sigmoidoscopy	Ｓ状結腸鏡検査	1 (0.2%)	0		
Vitamin B12 decreased	ビタミンＢ１２減少	1 (0.2%)	0		
Vitamin D decreased	ビタミンD減少	1 (0.2%)	0		
Weight decreased	体重減少	2 (0.3%)	1 (0.2%)		
Metabolism and nutrition disorders	代謝および栄養障害	10 (1.7%)	12 (2.0%)	1 (0.2%)	0
Diabetes mellitus	糖尿病	1 (0.2%)	2 (0.3%)		
Diabetic ketoacidosis	糖尿病性ケトアシドーシス	1 (0.2%)	0		
Glucose tolerance impaired	耐糖能障害	0	1 (0.2%)		
Gout	痛風	1 (0.2%)	3 (0.5%)	1 (0.2%)	0
Hypercholesterolaemia	高コレステロール血症	0	1 (0.2%)		
Hyperglycaemia	高血糖	0	1 (0.2%)		
Hyperkalaemia	高カリウム血症	1 (0.2%)	1 (0.2%)		
Hyperlipidaemia	高脂血症	2 (0.3%)	1 (0.2%)		
Hyperuricaemia	高尿酸血症	0	1 (0.2%)		
Hypokalaemia	低カリウム血症	2 (0.3%)	1 (0.2%)		
Hyponatraemia	低ナトリウム血症	1 (0.2%)	0		
Iron deficiency	鉄欠乏	2 (0.3%)	0		
Metabolic syndrome	代謝症候群	0	1 (0.2%)		
Vitamin D deficiency	ビタミンD欠乏	0	1 (0.2%)		
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	92 (15.6%)	110 (18.4%)	8 (1.4%)	6 (1.0%)
Arthralgia	関節痛	21 (3.6%)	20 (3.3%)		
Arthritis	関節炎	2 (0.3%)	4 (0.7%)		
Back pain	背部痛	7 (1.2%)	22 (3.7%)		
Bone cyst	骨嚢腫	1 (0.2%)	0		
Bone pain	骨痛	0	1 (0.2%)		
Bursitis	滑液包炎	2 (0.3%)	2 (0.3%)		

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Coccydynia	尾骨痛	1 (0.2%)	1 (0.2%)		
Costochondritis	肋軟骨炎	1 (0.2%)	1 (0.2%)		
Exostosis	外骨腫	1 (0.2%)	1 (0.2%)		
Fibromyalgia	線維筋痛	1 (0.2%)	0		
Gouty arthritis	痛風性関節炎	0	1 (0.2%)		
Intervertebral disc protrusion	椎間板突出	0	2 (0.3%)		
Joint stiffness	関節硬直	1 (0.2%)	0		
Joint swelling	関節腫脹	3 (0.5%)	4 (0.7%)		
Limb discomfort	四肢不快感	0	2 (0.3%)		
Muscle fatigue	筋肉疲労	1 (0.2%)	0		
Muscle spasms	筋痙縮	7 (1.2%)	9 (1.5%)	1 (0.2%)	2 (0.3%)
Muscle tightness	筋緊張	1 (0.2%)	0		
Muscular weakness	筋力低下	0	1 (0.2%)		
Musculoskeletal chest pain	筋骨格系胸痛	2 (0.3%)	5 (0.8%)		
Musculoskeletal discomfort	筋骨格不快感	1 (0.2%)	0		
Musculoskeletal pain	筋骨格痛	3 (0.5%)	4 (0.7%)	0	1 (0.2%)
Musculoskeletal stiffness	筋骨格硬直	1 (0.2%)	0		
Myalgia	筋肉痛	8 (1.4%)	4 (0.7%)		
Neck pain	頚部痛	3 (0.5%)	0		
Osteoarthritis	骨関節炎	5 (0.8%)	10 (1.7%)	0	1 (0.2%)
Osteopenia	骨減少症	0	1 (0.2%)		
Osteoporosis	骨粗鬆症	1 (0.2%)	0		
Pain in extremity	四肢痛	35 (5.9%)	29 (4.8%)	8 (1.4%)	2 (0.3%)
Plantar fasciitis	足底筋膜炎	0	1 (0.2%)		
Polymyalgia rheumatica	リウマチ性多発筋痛	0	1 (0.2%)		
Rheumatoid arthritis	関節リウマチ	1 (0.2%)	1 (0.2%)		
Rotator cuff syndrome	肩回旋筋腱板症候群	1 (0.2%)	1 (0.2%)		
Spinal column stenosis	脊柱管狭窄症	1 (0.2%)	0		
Spinal osteoarthritis	変形性脊椎炎	1 (0.2%)	1 (0.2%)		
Spondylolysis	脊椎分離	0	1 (0.2%)		
Synovial cyst	滑液嚢腫	2 (0.3%)	1 (0.2%)		
Temporomandibular joint syndrome	顎関節症候群	0	1 (0.2%)		

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Tendonitis	腱炎	1 (0.2%)	0		
Torticollis	斜頚	1 (0.2%)	1 (0.2%)		
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）	10 (1.7%)	4 (0.7%)	2 (0.3%)	0
Basal cell carcinoma	基底細胞癌	1 (0.2%)	1 (0.2%)		
Benign vascular neoplasm	血管の良性新生物	1 (0.2%)	0	1 (0.2%)	0
Colon cancer	結腸癌	1 (0.2%)	0		
Colorectal cancer	結腸直腸癌	1 (0.2%)	0		
Endometrial cancer	子宮内膜癌	1 (0.2%)	0		
Haemangioma of liver	肝臓血管腫	0	1 (0.2%)		
Kaposi's sarcoma	カポジ肉腫	1 (0.2%)	0		
Malignant melanoma in situ	表皮内悪性黒色腫	1 (0.2%)	0		
Naevus haemorrhage	母斑出血	1 (0.2%)	0	1 (0.2%)	0
Oesophageal neoplasm	食道新生物	0	1 (0.2%)		
Prostate cancer recurrent	再発前立腺癌	1 (0.2%)	0		
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0	1 (0.2%)		
Uterine leiomyoma	子宮平滑筋腫	1 (0.2%)	0		
Vaginal neoplasm	膣新生物	1 (0.2%)	0		
Nervous system disorders	神経系障害	43 (7.3%)	43 (7.2%)	5 (0.8%)	7 (1.2%)
Aphonia	失声症	1 (0.2%)	0		
Burning sensation	灼熱感	2 (0.3%)	0		
Carotid arteriosclerosis	頚動脈硬化症	0	1 (0.2%)		
Carpal tunnel syndrome	手根管症候群	0	2 (0.3%)		
Convulsion	痙攣	0	1 (0.2%)		
Dizziness	浮動性めまい	8 (1.4%)	6 (1.0%)	2 (0.3%)	1 (0.2%)
Dizziness postural	体位性めまい	1 (0.2%)	1 (0.2%)		
Dysarthria	構語障害	1 (0.2%)	0		
Dysgeusia	味覚異常	2 (0.3%)	0	2 (0.3%)	0
Dysphasia	不全失語症	1 (0.2%)	0		
Epilepsy	てんかん	2 (0.3%)	1 (0.2%)		
Haemorrhage intracranial	頭蓋内出血	1 (0.2%)	0	1 (0.2%)	0
Headache	頭痛	15 (2.5%)	18 (3.0%)	0	5 (0.8%)

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Hydrocephalus	水頭症	0	1 (0.2%)		
Hypoaesthesia	感覚鈍麻	0	2 (0.3%)	0	1 (0.2%)
Ischaemic stroke	虚血性脳卒中	1 (0.2%)	0		
Lethargy	嗜眠	0	1 (0.2%)		
Mental impairment	精神的機能障害	0	1 (0.2%)		
Migraine	片頭痛	3 (0.5%)	1 (0.2%)		
Paraesthesia	錯感覚	1 (0.2%)	2 (0.3%)		
Phantom pain	幻痛	0	1 (0.2%)		
Polyneuropathy	多発ニューロパチー	1 (0.2%)	0		
Presyncope	失神寸前の状態	0	1 (0.2%)		
Sciatica	坐骨神経痛	2 (0.3%)	3 (0.5%)		
Sensory disturbance	感覚障害	1 (0.2%)	0		
Somnolence	傾眠	0	1 (0.2%)	0	1 (0.2%)
Syncope	失神	4 (0.7%)	3 (0.5%)		
Transient ischaemic attack	一過性脳虚血発作	1 (0.2%)	1 (0.2%)		
Tremor	振戦	1 (0.2%)	0		
Vascular dementia	血管性認知症	1 (0.2%)	0		
Pregnancy, puerperium and perinatal conditions	妊娠、産褥および周産期の状態	0	1 (0.2%)		
Pregnancy	妊娠	0	1 (0.2%)		
Psychiatric disorders	精神障害	10 (1.7%)	15 (2.5%)		
Anxiety	不安	3 (0.5%)	3 (0.5%)		
Depressed mood	抑うつ気分	1 (0.2%)	1 (0.2%)		
Depression	うつ病	0	5 (0.8%)		
Insomnia	不眠症	4 (0.7%)	4 (0.7%)		
Mood altered	気分変化	0	1 (0.2%)		
Nervousness	神経過敏	1 (0.2%)	0		
Panic attack	パニック発作	0	1 (0.2%)		
Schizophrenia	統合失調症	1 (0.2%)	0		
Stress	ストレス	1 (0.2%)	0		
Renal and urinary disorders	腎および尿路障害	8 (1.4%)	16 (2.7%)	2 (0.3%)	10 (1.7%)
Cystitis haemorrhagic	出血性膀胱炎	0	1 (0.2%)	0	1 (0.2%)
Dysuria	排尿困難	0	2 (0.3%)		

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Haematuria	血尿	2 (0.3%)	13 (2.2%)	1 (0.2%)	10 (1.7%)
Hydronephrosis	水腎症	1 (0.2%)	0		
Nephritis	腎炎	1 (0.2%)	0		
Nocturia	夜間頻尿	1 (0.2%)	0		
Pollakiuria	頻尿	1 (0.2%)	1 (0.2%)	1 (0.2%)	0
Proteinuria	蛋白尿	0	1 (0.2%)		
Renal cyst	腎嚢胞	1 (0.2%)	0		
Renal failure	腎不全	1 (0.2%)	0		
Renal failure acute	急性腎不全	0	1 (0.2%)		
Urinary incontinence	尿失禁	0	1 (0.2%)		
Reproductive system and breast disorders	生殖系および乳房障害	15 (2.5%)	15 (2.5%)	5 (0.8%)	7 (1.2%)
Bartholin's cyst	バルトリン嚢腫	1 (0.2%)	0		
Benign prostatic hyperplasia	良性前立腺肥大症	0	2 (0.3%)		
Dysmenorrhoea	月経困難症	1 (0.2%)	0		
Epididymitis	精巣上体炎	0	1 (0.2%)		
Erectile dysfunction	勃起不全	1 (0.2%)	0		
Gynaecomastia	女性化乳房	1 (0.2%)	0		
Menometrorrhagia	機能性子宮出血	0	1 (0.2%)	0	1 (0.2%)
Menorrhagia	月経過多	2 (0.3%)	5 (0.8%)	2 (0.3%)	5 (0.8%)
Menstruation irregular	不規則月経	1 (0.2%)	0		
Metrorrhagia	不正子宮出血	0	2 (0.3%)	0	2 (0.3%)
Peyronie's disease	ペイロニー病	0	1 (0.2%)		
Postmenopausal haemorrhage	閉経後出血	1 (0.2%)	0	1 (0.2%)	0
Prostatitis	前立腺炎	2 (0.3%)	0		
Prostatomegaly	前立腺腫大	0	2 (0.3%)		
Scrotal cyst	陰嚢嚢胞	0	1 (0.2%)		
Testicular swelling	精巣腫脹	1 (0.2%)	0		
Uterine polyp	子宮ポリープ	0	1 (0.2%)		
Vaginal haemorrhage	腟出血	5 (0.8%)	1 (0.2%)	2 (0.3%)	1 (0.2%)
Vaginal prolapse	腟脱	1 (0.2%)	0		
Vulvovaginal discomfort	外陰腟不快感	1 (0.2%)	0		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	54 (9.2%)	57 (9.5%)	15 (2.5%)	21 (3.5%)

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Acute pulmonary oedema	急性肺水腫	0	2 (0.3%)		
Apnoeic attack	無呼吸発作	0	1 (0.2%)		
Asthma	喘息	1 (0.2%)	1 (0.2%)		
Atelectasis	無気肺	1 (0.2%)	0		
Bronchitis chronic	慢性気管支炎	0	1 (0.2%)		
Bronchospasm	気管支痙攣	0	1 (0.2%)		
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	0	3 (0.5%)		
Cough	咳嗽	21 (3.6%)	16 (2.7%)	2 (0.3%)	2 (0.3%)
Dry throat	咽喉乾燥	0	1 (0.2%)		
Dyspnoea	呼吸困難	11 (1.9%)	7 (1.2%)		
Dyspnoea exertional	労作性呼吸困難	3 (0.5%)	4 (0.7%)	2 (0.3%)	1 (0.2%)
Epistaxis	鼻出血	11 (1.9%)	24 (4.0%)	9 (1.5%)	17 (2.8%)
Haemoptysis	喀血	1 (0.2%)	1 (0.2%)	1 (0.2%)	1 (0.2%)
Lung disorder	肺障害	0	1 (0.2%)		
Nasal cavity mass	鼻腔腫瘤	1 (0.2%)	0		
Nasal congestion	鼻閉	1 (0.2%)	0		
Oropharyngeal pain	口腔咽頭痛	2 (0.3%)	6 (1.0%)	1 (0.2%)	0
Pleuritic pain	胸膜痛	1 (0.2%)	0		
Productive cough	湿性咳嗽	0	2 (0.3%)		
Pulmonary arterial hypertension	肺動脈高血圧症	1 (0.2%)	0		
Pulmonary embolism	肺塞栓症	1 (0.2%)	0	1 (0.2%)	0
Pulmonary hypertension	肺高血圧症	0	1 (0.2%)		
Rales	ラ音	1 (0.2%)	0		
Respiratory failure	呼吸不全	1 (0.2%)	0		
Rhinitis allergic	アレルギー性鼻炎	1 (0.2%)	1 (0.2%)		
Rhinorrhoea	鼻漏	1 (0.2%)	1 (0.2%)		
Sleep apnoea syndrome	睡眠時無呼吸症候群	2 (0.3%)	0		
Sneezing	くしゃみ	0	1 (0.2%)		
Tachypnoea	頻呼吸	0	1 (0.2%)	0	1 (0.2%)
Throat irritation	咽喉刺激感	0	1 (0.2%)		
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	36 (6.1%)	36 (6.0%)	6 (1.0%)	9 (1.5%)
Acne	ざ瘡	0	4 (0.7%)	0	4 (0.7%)

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Actinic keratosis	日光性角化症	1 (0.2%)	1 (0.2%)		
Alopecia	脱毛症	1 (0.2%)	1 (0.2%)	1 (0.2%)	1 (0.2%)
Dermatitis	皮膚炎	1 (0.2%)	3 (0.5%)		
Dermatitis allergic	アレルギー性皮膚炎	2 (0.3%)	1 (0.2%)	1 (0.2%)	0
Dermatitis contact	接触性皮膚炎	0	1 (0.2%)		
Dry skin	皮膚乾燥	0	1 (0.2%)	0	1 (0.2%)
Ecchymosis	斑状出血	1 (0.2%)	1 (0.2%)	1 (0.2%)	1 (0.2%)
Eczema	湿疹	7 (1.2%)	1 (0.2%)		
Ephelides	雀卵斑	0	1 (0.2%)		
Erythema	紅斑	1 (0.2%)	0	1 (0.2%)	0
Hyperhidrosis	多汗症	1 (0.2%)	3 (0.5%)		
Onychoclasis	爪破損	2 (0.3%)	0	1 (0.2%)	0
Panniculitis	脂肪織炎	0	1 (0.2%)		
Petechiae	点状出血	0	1 (0.2%)	0	1 (0.2%)
Plantar erythema	足底紅斑	1 (0.2%)	0	1 (0.2%)	0
Pruritus	そう痒症	2 (0.3%)	2 (0.3%)		
Pruritus generalised	全身性そう痒症	0	1 (0.2%)		
Psoriasis	乾癬	1 (0.2%)	0		
Purpura senile	老人性紫斑	0	1 (0.2%)		
Rash	発疹	7 (1.2%)	5 (0.8%)	0	1 (0.2%)
Rash generalised	全身性皮疹	1 (0.2%)	0		
Rash macular	斑状皮疹	0	1 (0.2%)		
Seborrhoeic dermatitis	脂漏性皮膚炎	1 (0.2%)	0		
Skin discolouration	皮膚変色	1 (0.2%)	1 (0.2%)		
Skin exfoliation	皮膚剥脱	1 (0.2%)	0		
Skin haemorrhage	皮膚出血	1 (0.2%)	3 (0.5%)		
Skin hyperpigmentation	皮膚色素過剰	0	1 (0.2%)		
Skin induration	皮膚硬結	1 (0.2%)	0		
Skin irritation	皮膚刺激	0	1 (0.2%)		
Skin lesion	皮膚病変	1 (0.2%)	1 (0.2%)	1 (0.2%)	0
Skin ulcer	皮膚潰瘍	3 (0.5%)	2 (0.3%)	1 (0.2%)	0
Stasis dermatitis	うっ滞性皮膚炎	0	2 (0.3%)		

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Stevens-Johnson syndrome	スティーブンス・ジョンソン症候群	1 (0.2%)	0		
Urticaria	蕁麻疹	0	1 (0.2%)	0	1 (0.2%)
Social circumstances	社会環境	0	1 (0.2%)		
Activities of daily living impaired	日常生活動作障害者	0	1 (0.2%)		
Surgical and medical procedures	外科および内科処置	10 (1.7%)	18 (3.0%)		
Anal fistula excision	痔瘻切除	1 (0.2%)	0		
Appendicectomy	虫垂切除	0	1 (0.2%)		
Bladder calculus removal	膀胱結石除去	0	1 (0.2%)		
Bunion operation	バニオン手術	0	1 (0.2%)		
Cataract operation	白内障手術	0	2 (0.3%)		
Dental implantation	歯科インプラント埋込み	0	1 (0.2%)		
Dental operation	歯科手術	3 (0.5%)	0		
Elective surgery	待期的手術	0	1 (0.2%)		
Haemorrhoid operation	痔核手術	0	1 (0.2%)		
Knee arthroplasty	膝関節形成	1 (0.2%)	0		
Knee operation	膝手術	1 (0.2%)	0		
Medical device removal	医療機器除去	0	1 (0.2%)		
Mole excision	色素性母斑切除	1 (0.2%)	0		
Oesophagogastric fundoplasty	食道－胃底部形成術	1 (0.2%)	0		
Polypectomy	ポリープ切除	1 (0.2%)	0		
Skin neoplasm excision	皮膚新生物切除	0	1 (0.2%)		
Tooth extraction	抜歯	1 (0.2%)	5 (0.8%)		
Transurethral prostatectomy	経尿道的前立腺摘除	1 (0.2%)	0		
Umbilical hernia repair	臍帯ヘルニア修復	0	1 (0.2%)		
Uterine dilation and curettage	子宮頚管拡張および子宮内掻爬	0	1 (0.2%)		
Wart excision	疣贅切除	0	1 (0.2%)		
Vascular disorders	血管障害	48 (8.1%)	38 (6.4%)	10 (1.7%)	12 (2.0%)
Bleeding varicose vein	出血性静脈瘤	0	1 (0.2%)	0	1 (0.2%)
Circulatory collapse	循環虚脱	0	1 (0.2%)	0	1 (0.2%)
Diabetic microangiopathy	糖尿病性微小血管症	0	1 (0.2%)		
Erythromelalgia	紅痛症	1 (0.2%)	0		

表 2.7.4.7-3 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Treatment-emergent		Treatment-emergent study drug-related	
		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Flushing	潮紅	1 (0.2%)	0	1 (0.2%)	0
Haematoma	血腫	8 (1.4%)	7 (1.2%)	4 (0.7%)	6 (1.0%)
Hot flush	ほてり	1 (0.2%)	1 (0.2%)		
Hypertension	高血圧	9 (1.5%)	6 (1.0%)		
Hypotension	低血圧	2 (0.3%)	1 (0.2%)		
Orthostatic hypotension	起立性低血圧	1 (0.2%)	0		
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	1 (0.2%)	0	1 (0.2%)	0
Phlebitis	静脈炎	2 (0.3%)	2 (0.3%)		
Phlebitis superficial	表在性静脈炎	2 (0.3%)	0		
Post thrombotic syndrome	血栓後症候群	1 (0.2%)	2 (0.3%)		
Thrombophlebitis	血栓性静脈炎	9 (1.5%)	1 (0.2%)	1 (0.2%)	0
Thrombophlebitis superficial	表在性血栓性静脈炎	4 (0.7%)	1 (0.2%)	1 (0.2%)	0
Varicophlebitis	静脈瘤性静脈炎	1 (0.2%)	0		
Varicose vein	静脈瘤	3 (0.5%)	0		
Vascular rupture	血管破裂	0	1 (0.2%)	0	1 (0.2%)
Vein disorder	静脈障害	0	1 (0.2%)	0	1 (0.2%)
Venous insufficiency	静脈不全	0	2 (0.3%)		
Wound haemorrhage	血液およびリンパ系障害	7 (1.2%)	11 (1.8%)	2 (0.3%)	2 (0.3%)

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 10:05
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表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Number of subjects (%) with at least one adverse event		617 (35.9%)	325 (18.9%)	135 (7.9%)	1 (<0.1%)	600 (35.1%)	346 (20.2%)	134 (7.8%)	
Blood and lymphatic system disorders	血液およびリンパ系障害	19 (1.1%)	26 (1.5%)	12 (0.7%)		23 (1.3%)	18 (1.1%)	4 (0.2%)	
Anaemia	貧血	6 (0.3%)	18 (1.0%)	7 (0.4%)		10 (0.6%)	14 (0.8%)	1 (<0.1%)	
Anaemia haemolytic autoimmune	自己免疫性溶血性貧血	1 (<0.1%)	0	0		0	0	0	
Anaemia macrocytic	大球性貧血	0	1 (<0.1%)	0		0	0	0	
Autoimmune thrombocytopenia	自己免疫性血小板減少症	0	0	0		0	0	1 (<0.1%)	
Bone marrow failure	骨髄機能不全	0	1 (<0.1%)	0		0	0	0	
Deficiency anaemia	欠乏性貧血	1 (<0.1%)	0	0		0	0	0	
Febrile neutropenia	発熱性好中球減少症	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Haemorrhagic anaemia	出血性貧血	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Haemorrhagic diathesis	出血性素因	1 (<0.1%)	0	0		2 (0.1%)	0	0	
Hypercoagulation	凝固亢進	2 (0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Iron deficiency anaemia	鉄欠乏性貧血	1 (<0.1%)	2 (0.1%)	0		3 (0.2%)	0	0	
Leukocytosis	白血球増加症	0	0	0		3 (0.2%)	0	0	
Leukopenia	白血球減少症	1 (<0.1%)	0	1 (<0.1%)		3 (0.2%)	0	1 (<0.1%)	
Lymphadenitis	リンパ節炎	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Lymphadenopathy	リンパ節症	2 (0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Lymphadenopathy mediastinal	縦隔リンパ節腫脹	0	2 (0.1%)	0		0	0	1 (<0.1%)	
Microcytic anaemia	小球性貧血	0	0	1 (<0.1%)		0	0	0	
Nephrogenic anaemia	腎性貧血	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Neutropenia	好中球減少症	0	1 (<0.1%)	0		0	0	0	
Pernicious anaemia	悪性貧血	1 (<0.1%)	0	0		0	0	0	
Polycythaemia	赤血球増加症	1 (<0.1%)	0	0		0	0	0	
Splenomegaly	脾腫	1 (<0.1%)	0	0		0	0	0	
Spontaneous haematoma	特発性血腫	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Thrombocytopenia	血小板減少症	1 (<0.1%)	0	2 (0.1%)		1 (<0.1%)	2 (0.1%)	0	
Cardiac disorders	心臓障害	39 (2.3%)	5 (0.3%)	9 (0.5%)		24 (1.4%)	18 (1.1%)	5 (0.3%)	
Acute coronary syndrome	急性冠動脈症候群	0	1 (<0.1%)	0		0	0	0	
Acute myocardial infarction	急性心筋梗塞	0	0	4 (0.2%)		0	1 (<0.1%)	0	
Angina pectoris	狭心症	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Angina unstable	不安定狭心症	1 (<0.1%)	0	0		2 (0.1%)	1 (<0.1%)	1 (<0.1%)	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Aortic valve disease	大動脈弁疾患	0	0	0		0	1 (<0.1%)	0	
Aortic valve incompetence	大動脈弁閉鎖不全症	2 (0.1%)	0	0		0	0	0	
Arrhythmia	不整脈	0	0	1 (<0.1%)		0	0	0	
Atrial fibrillation	心房細動	3 (0.2%)	1 (<0.1%)	0		4 (0.2%)	4 (0.2%)	0	
Atrial flutter	心房粗動	0	1 (<0.1%)	0		0	0	0	
Atrioventricular block	房室ブロック	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Atrioventricular block second degree	第二度房室ブロック	1 (<0.1%)	0	0		0	0	0	
Bradycardia	徐脈	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Bundle branch block left	左脚ブロック	0	0	0		0	1 (<0.1%)	0	
Cardiac arrest	心停止	0	0	0		0	0	1 (<0.1%)	
Cardiac disorder	心障害	0	0	1 (<0.1%)		0	0	0	
Cardiac failure	心不全	2 (0.1%)	0	1 (<0.1%)		2 (0.1%)	2 (0.1%)	0	
Cardiac failure chronic	慢性心不全	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Cardiac failure congestive	うっ血性心不全	0	0	0		0	1 (<0.1%)	1 (<0.1%)	
Coronary artery disease	冠動脈疾患	0	0	0		0	1 (<0.1%)	0	
Cyanosis	チアノーゼ	1 (<0.1%)	0	0		3 (0.2%)	0	0	
Diastolic dysfunction	拡張機能障害	1 (<0.1%)	0	0		0	0	0	
Hypertensive heart disease	高血圧性心疾患	0	0	0		1 (<0.1%)	0	0	
Left ventricular hypertrophy	左室肥大	1 (<0.1%)	0	0		0	2 (0.1%)	0	
Mitral valve incompetence	僧帽弁閉鎖不全症	1 (<0.1%)	0	0		1 (<0.1%)	2 (0.1%)	0	
Mitral valve prolapse	僧帽弁逸脱	0	0	0		1 (<0.1%)	0	0	
Myocardial infarction	心筋梗塞	0	0	0		0	0	1 (<0.1%)	
Myocardial ischaemia	心筋虚血	0	0	0		2 (0.1%)	0	0	
Palpitations	動悸	15 (0.9%)	0	0		4 (0.2%)	1 (<0.1%)	0	
Pericardial cyst	心膜嚢胞	1 (<0.1%)	0	0		0	0	0	
Pericarditis	心膜炎	0	0	1 (<0.1%)		0	0	0	
Right ventricular failure	右室不全	0	0	1 (<0.1%)		0	0	0	
Sick sinus syndrome	洞不全症候群	0	0	0		0	0	1 (<0.1%)	
Sinoatrial block	洞房ブロック	0	0	0		1 (<0.1%)	0	0	
Sinus arrhythmia	洞性不整脈	0	0	0		2 (0.1%)	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Sinus tachycardia	洞性頻脈	1 (<0.1%)	0	0		0	0	0	
Supraventricular tachycardia	上室性頻脈	0	0	0		0	1 (<0.1%)	0	
Tachyarrhythmia	頻脈性不整脈	0	1 (<0.1%)	0		0	0	0	
Tachycardia	頻脈	9 (0.5%)	0	0		4 (0.2%)	1 (<0.1%)	0	
Tricuspid valve incompetence	三尖弁閉鎖不全症	0	0	0		1 (<0.1%)	0	0	
Ventricular extrasystoles	心室性期外収縮	1 (<0.1%)	0	0		0	0	0	
Ventricular tachycardia	心室性頻脈	0	0	0		1 (<0.1%)	0	0	
Congenital, familial and genetic disorders	先天性、家族性および遺伝性障害	18 (1.0%)	1 (<0.1%)	0		13 (0.8%)	2 (0.1%)	0	
Adenomatous polyposis coli	大腸腺腫性ポリポーシス	0	0	0		1 (<0.1%)	0	0	
Antithrombin III deficiency	アンチトロンビンＩＩＩ欠乏症	2 (0.1%)	0	0		0	0	0	
Congenital cystic kidney disease	先天性嚢胞性腎疾患	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Congenital urethral anomaly	先天性尿道異常	1 (<0.1%)	0	0		0	0	0	
Dolichocolon	過長結腸	1 (<0.1%)	0	0		0	0	0	
Dysplastic naevus syndrome	異形成母斑症候群	1 (<0.1%)	0	0		0	0	0	
Factor II mutation	第ＩＩ因子突然変異	3 (0.2%)	0	0		2 (0.1%)	0	0	
Factor V Leiden mutation	第Ｖ因子ライデン変異	8 (0.5%)	0	0		8 (0.5%)	0	0	
Gene mutation	遺伝子突然変異	2 (0.1%)	0	0		3 (0.2%)	0	0	
Hip dysplasia	股関節形成不全	0	0	0		1 (<0.1%)	0	0	
Mixed hyperlipidaemia	混合型高脂血症	0	1 (<0.1%)	0		0	0	0	
Phimosis	包茎	0	0	0		0	1 (<0.1%)	0	
Ear and labyrinth disorders	耳および迷路障害	15 (0.9%)	8 (0.5%)	1 (<0.1%)		19 (1.1%)	2 (0.1%)	1 (<0.1%)	
Deafness	難聴	1 (<0.1%)	0	0		0	0	0	
Deafness neurosensory	感音性難聴	1 (<0.1%)	0	0		0	0	0	
Deafness unilateral	片耳難聴	0	0	0		1 (<0.1%)	0	0	
Ear discomfort	耳不快感	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Ear haemorrhage	耳出血	2 (0.1%)	0	0		2 (0.1%)	1 (<0.1%)	1 (<0.1%)	
Ear pain	耳痛	0	2 (0.1%)	0		2 (0.1%)	0	0	
External ear inflammation	外耳の炎症	0	0	0		1 (<0.1%)	0	0	
Hearing impaired	聴覚障害	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Hypoacusis	聴力低下	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Tinnitus	耳鳴	3 (0.2%)	0	0		2 (0.1%)	0	0	
Vertigo	回転性めまい	7 (0.4%)	6 (0.3%)	1 (<0.1%)		9 (0.5%)	1 (<0.1%)	0	
Vertigo labyrinthine	迷路性回転性めまい	0	0	0		1 (<0.1%)	0	0	
Endocrine disorders	内分泌障害	2 (0.1%)	2 (0.1%)	0		9 (0.5%)	0	0	
Basedow's disease	バセドウ病	0	1 (<0.1%)	0		0	0	0	
Cushingoid	クッシング様	0	0	0		1 (<0.1%)	0	0	
Goitre	甲状腺腫	1 (<0.1%)	1 (<0.1%)	0		2 (0.1%)	0	0	
Hyperthyroidism	甲状腺機能亢進症	0	0	0		2 (0.1%)	0	0	
Hypothyroidism	甲状腺機能低下症	1 (<0.1%)	0	0		4 (0.2%)	0	0	
Eye disorders	眼障害	28 (1.6%)	12 (0.7%)	0		34 (2.0%)	5 (0.3%)	0	
Asthenopia	眼精疲労	1 (<0.1%)	0	0		0	0	0	
Blepharochalasis	眼瞼皮膚弛緩症	0	0	0		1 (<0.1%)	0	0	
Cataract	白内障	3 (0.2%)	1 (<0.1%)	0		1 (<0.1%)	2 (0.1%)	0	
Cataract cortical	皮質白内障	1 (<0.1%)	0	0		0	0	0	
Conjunctival haemorrhage	結膜出血	11 (0.6%)	1 (<0.1%)	0		20 (1.2%)	1 (<0.1%)	0	
Conjunctivitis	結膜炎	3 (0.2%)	1 (<0.1%)	0		2 (0.1%)	0	0	
Diabetic retinopathy	糖尿病性網膜症	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Dry eye	眼乾燥	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Entropion	眼瞼内反	0	0	0		1 (<0.1%)	0	0	
Eye haemorrhage	眼出血	0	2 (0.1%)	0		2 (0.1%)	1 (<0.1%)	0	
Eye inflammation	眼の炎症	1 (<0.1%)	0	0		0	0	0	
Eye movement disorder	眼運動障害	1 (<0.1%)	0	0		0	0	0	
Eye pain	眼痛	1 (<0.1%)	0	0		0	0	0	
Eye pruritus	眼そう痒症	1 (<0.1%)	0	0		0	0	0	
Hypermetropia	遠視	1 (<0.1%)	0	0		0	0	0	
Hyphaema	前房出血	0	1 (<0.1%)	0		0	0	0	
Keratoconjunctivitis sicca	乾性角結膜炎	0	0	0		1 (<0.1%)	0	0	
Lacrimal haemorrhage	涙器出血	0	0	0		1 (<0.1%)	0	0	
Macular hole	黄斑円孔	0	1 (<0.1%)	0		0	0	0	
Maculopathy	黄斑症	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Ocular hyperaemia	眼充血	0	0	0		3 (0.2%)	0	0	
Retinal detachment	網膜剥離	0	1 (<0.1%)	0		0	0	0	
Retinal exudates	網膜滲出物	0	1 (<0.1%)	0		0	0	0	
Retinopathy	網膜症	1 (<0.1%)	0	0		0	0	0	
Vision blurred	霧視	2 (0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Visual impairment	視力障害	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Vitreous detachment	硝子体剥離	0	1 (<0.1%)	0		0	0	0	
Vitreous haemorrhage	硝子体出血	0	0	0		0	1 (<0.1%)	0	
Gastrointestinal disorders	胃腸障害	259 (15.1%)	61 (3.6%)	17 (1.0%)		202 (11.8%)	78 (4.6%)	15 (0.9%)	
Abdominal discomfort	腹部不快感	13 (0.8%)	1 (<0.1%)	0		5 (0.3%)	3 (0.2%)	0	
Abdominal distension	腹部膨満	5 (0.3%)	0	0		4 (0.2%)	1 (<0.1%)	0	
Abdominal pain	腹痛	16 (0.9%)	5 (0.3%)	3 (0.2%)		7 (0.4%)	8 (0.5%)	0	
Abdominal pain lower	下腹部痛	4 (0.2%)	2 (0.1%)	0		1 (<0.1%)	0	0	
Abdominal pain upper	上腹部痛	14 (0.8%)	4 (0.2%)	0		7 (0.4%)	2 (0.1%)	0	
Abdominal wall cyst	腹壁嚢胞	0	0	1 (<0.1%)		0	0	0	
Abdominal wall haematoma	腹壁血腫	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Aerophagia	空気嚥下	0	0	0		0	1 (<0.1%)	0	
Anal haemorrhage	肛門出血	0	0	0		1 (<0.1%)	0	0	
Anal skin tags	肛門皮膚垂	0	0	0		1 (<0.1%)	0	0	
Ascites	腹水	0	3 (0.2%)	0		1 (<0.1%)	0	1 (<0.1%)	
Barrett's oesophagus	バレット食道	1 (<0.1%)	0	0		0	0	0	
Chapped lips	口唇のひび割れ	1 (<0.1%)	0	0		0	0	0	
Coeliac artery stenosis	腹腔動脈狭窄	0	0	0		1 (<0.1%)	0	0	
Coeliac disease	セリアック病	1 (<0.1%)	0	0		0	0	0	
Colitis	大腸炎	0	0	0		0	1 (<0.1%)	0	
Colitis ulcerative	潰瘍性大腸炎	0	0	1 (<0.1%)		0	0	1 (<0.1%)	
Colonic polyp	結腸ポリープ	2 (0.1%)	1 (<0.1%)	0		4 (0.2%)	1 (<0.1%)	0	
Constipation	便秘	42 (2.4%)	5 (0.3%)	1 (<0.1%)		39 (2.3%)	3 (0.2%)	1 (<0.1%)	
Crohn's disease	クローン病	0	0	0		1 (<0.1%)	2 (0.1%)	1 (<0.1%)	
Dental caries	齲歯	5 (0.3%)	0	0		4 (0.2%)	0	0	
Diabetic gastropathy	糖尿病性胃障害	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Diarrhoea	下痢	44 (2.6%)	9 (0.5%)	1 (<0.1%)		32 (1.9%)	7 (0.4%)	1 (<0.1%)	
Diverticulum	憩室	2 (0.1%)	0	0		0	0	0	
Diverticulum intestinal	腸憩室	3 (0.2%)	0	0		4 (0.2%)	1 (<0.1%)	0	
Dry mouth	口内乾燥	4 (0.2%)	0	0		4 (0.2%)	0	0	
Duodenal polyp	十二指腸ポリープ	0	0	0		1 (<0.1%)	0	0	
Duodenal ulcer	十二指腸潰瘍	2 (0.1%)	0	0		0	2 (0.1%)	0	
Duodenitis	十二指腸炎	3 (0.2%)	0	0		3 (0.2%)	0	0	
Dyspepsia	消化不良	16 (0.9%)	2 (0.1%)	0		12 (0.7%)	2 (0.1%)	0	
Dysphagia	嚥下障害	1 (<0.1%)	0	0		0	0	0	
Enterocutaneous fistula	腸管皮膚瘻	0	0	2 (0.1%)		0	0	0	
Eructation	おくび	0	0	0		1 (<0.1%)	0	0	
Faecaloma	糞塊	1 (<0.1%)	0	0		0	0	0	
Faeces discoloured	変色便	0	1 (<0.1%)	0		0	0	0	
Faeces hard	硬便	1 (<0.1%)	0	0		0	0	0	
Flatulence	鼓腸	3 (0.2%)	1 (<0.1%)	0		3 (0.2%)	0	0	
Food poisoning	食中毒	2 (0.1%)	0	0		2 (0.1%)	0	0	
Frequent bowel movements	排便回数増加	1 (<0.1%)	0	0		0	0	0	
Gastric haemorrhage	胃出血	0	0	0		0	1 (<0.1%)	0	
Gastric ulcer	胃潰瘍	3 (0.2%)	0	0		2 (0.1%)	1 (<0.1%)	0	
Gastric ulcer haemorrhage	出血性胃潰瘍	0	0	0		0	1 (<0.1%)	0	
Gastric ulcer perforation	穿孔性胃潰瘍	0	0	0		0	1 (<0.1%)	0	
Gastritis	胃炎	7 (0.4%)	1 (<0.1%)	0		3 (0.2%)	2 (0.1%)	0	
Gastritis atrophic	萎縮性胃炎	0	1 (<0.1%)	0		0	0	0	
Gastritis erosive	びらん性胃炎	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Gastrointestinal haemorrhage	胃腸出血	0	1 (<0.1%)	3 (0.2%)		0	0	0	
Gastrointestinal tract mucosal discolouration	消化管粘膜変色	0	0	0		1 (<0.1%)	0	0	
Gastrooesophageal reflux disease	胃食道逆流性疾患	11 (0.6%)	3 (0.2%)	0		3 (0.2%)	0	0	
Gastrooesophageal sphincter insufficiency	胃食道括約筋機能不全	1 (<0.1%)	0	0		0	0	0	
Gingival bleeding	歯肉出血	36 (2.1%)	0	0		22 (1.3%)	6 (0.4%)	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Gingival pain	歯肉痛	0	0	0		1 (<0.1%)	0	0	
Gingival recession	歯肉退縮	0	0	0		1 (<0.1%)	0	0	
Gingival swelling	歯肉腫脹	0	0	0		0	1 (<0.1%)	0	
Gingivitis	歯肉炎	1 (<0.1%)	1 (<0.1%)	0		2 (0.1%)	0	0	
Haematemesis	吐血	0	1 (<0.1%)	1 (<0.1%)		3 (0.2%)	3 (0.2%)	1 (<0.1%)	
Haematochezia	血便排泄	7 (0.4%)	0	0		4 (0.2%)	3 (0.2%)	1 (<0.1%)	
Haemorrhoidal haemorrhage	痔出血	14 (0.8%)	0	0		6 (0.4%)	2 (0.1%)	0	
Haemorrhoids	痔核	6 (0.3%)	1 (<0.1%)	1 (<0.1%)		7 (0.4%)	1 (<0.1%)	0	
Hiatus hernia	裂孔ヘルニア	4 (0.2%)	1 (<0.1%)	0		5 (0.3%)	0	0	
Hyperchlorhydria	胃酸過多	0	0	0		1 (<0.1%)	0	0	
Hypoaesthesia oral	口の感覚鈍麻	1 (<0.1%)	0	0		0	0	0	
Inguinal hernia	鼠径ヘルニア	0	0	0		1 (<0.1%)	0	0	
Inguinal hernia, obstructive	閉塞性鼠径ヘルニア	0	0	0		0	0	1 (<0.1%)	
Intestinal cyst	腸管嚢胞	1 (<0.1%)	0	0		0	0	0	
Intestinal dilatation	腸管拡張症	0	1 (<0.1%)	0		0	0	0	
Intestinal haemorrhage	腸出血	0	0	0		1 (<0.1%)	2 (0.1%)	0	
Intestinal ischaemia	腸管虚血	0	0	0		0	1 (<0.1%)	0	
Intestinal obstruction	腸閉塞	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Intestinal perforation	腸管穿孔	0	0	1 (<0.1%)		0	0	0	
Intestinal polyp	腸管ポリープ	2 (0.1%)	1 (<0.1%)	0		0	0	0	
Intra-abdominal haematoma	腹腔内血腫	0	0	0		10 (0.6%)	3 (0.2%)	0	
Intra-abdominal haemorrhage	腹腔内出血	0	0	0		1 (<0.1%)	0	0	
Large intestine perforation	大腸穿孔	0	0	0		0	0	1 (<0.1%)	
Lip dry	口唇乾燥	1 (<0.1%)	0	0		0	0	0	
Lip haemorrhage	口唇出血	2 (0.1%)	0	0		0	0	0	
Lip ulceration	口唇潰瘍	0	0	0		1 (<0.1%)	0	0	
Lower gastrointestinal haemorrhage	下部消化管出血	1 (<0.1%)	0	0		0	0	0	
Mallory-Weiss syndrome	マロリー・ワイス症候群	1 (<0.1%)	0	0		0	0	0	
Melaena	メレナ	5 (0.3%)	3 (0.2%)	0		1 (<0.1%)	2 (0.1%)	1 (<0.1%)	
Melanosis coli	結腸メラノーシス	0	0	0		1 (<0.1%)	0	0	
Mouth haemorrhage	口腔内出血	6 (0.3%)	0	0		2 (0.1%)	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Mouth ulceration	口腔内潰瘍形成	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Nausea	悪心	37 (2.2%)	10 (0.6%)	0		29 (1.7%)	9 (0.5%)	0	
Oesophageal pain	食道痛	1 (<0.1%)	0	0		0	0	0	
Oesophageal ulcer	食道潰瘍	0	0	0		1 (<0.1%)	0	0	
Oesophageal ulcer haemorrhage	食道潰瘍出血	0	0	0		0	0	1 (<0.1%)	
Oesophagitis	食道炎	3 (0.2%)	1 (<0.1%)	0		0	2 (0.1%)	0	
Oral pain	口腔内痛	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Pancreas lipomatosis	膵脂肪腫症	2 (0.1%)	0	0		0	0	0	
Pancreatic cyst	膵嚢胞	0	0	0		1 (<0.1%)	0	0	
Pancreatitis	膵炎	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Pancreatitis acute	急性膵炎	0	0	0		1 (<0.1%)	2 (0.1%)	0	
Paraesthesia oral	口の錯感覚	1 (<0.1%)	0	0		0	0	0	
Peptic ulcer	消化性潰瘍	0	0	0		0	1 (<0.1%)	0	
Pericoronitis	歯冠周囲炎	0	0	0		0	1 (<0.1%)	0	
Periodontal disease	歯周病	0	1 (<0.1%)	0		0	0	0	
Periodontitis	歯周炎	2 (0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Peritonitis	腹膜炎	0	1 (<0.1%)	0		0	0	0	
Proctalgia	肛門周囲痛	1 (<0.1%)	0	0		0	0	0	
Rectal haemorrhage	直腸出血	31 (1.8%)	4 (0.2%)	1 (<0.1%)		13 (0.8%)	2 (0.1%)	4 (0.2%)	
Rectal polyp	直腸ポリープ	2 (0.1%)	0	0		0	0	0	
Reflux oesophagitis	逆流性食道炎	1 (<0.1%)	2 (0.1%)	0		4 (0.2%)	0	1 (<0.1%)	
Retroperitoneal fibrosis	後腹膜線維症	0	0	0		0	0	1 (<0.1%)	
Small intestinal obstruction	小腸閉塞	0	0	0		1 (<0.1%)	0	0	
Stomatitis haemorrhagic	出血性口内炎	1 (<0.1%)	0	0		0	0	0	
Tongue haemorrhage	舌出血	0	2 (0.1%)	0		1 (<0.1%)	0	0	
Tooth disorder	歯の障害	1 (<0.1%)	0	0		2 (0.1%)	0	0	
Toothache	歯痛	6 (0.3%)	1 (<0.1%)	0		5 (0.3%)	2 (0.1%)	0	
Umbilical hernia	臍ヘルニア	1 (<0.1%)	0	0		2 (0.1%)	0	0	
Upper gastrointestinal haemorrhage	上部消化管出血	0	0	0		1 (<0.1%)	0	0	
Vomiting	嘔吐	11 (0.6%)	7 (0.4%)	0		15 (0.9%)	7 (0.4%)	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
General disorders and administration site conditions	一般・全身障害および投与部位の状態	144 (8.4%)	42 (2.4%)	11 (0.6%)		127 (7.4%)	40 (2.3%)	11 (0.6%)	
Asthenia	無力症	8 (0.5%)	2 (0.1%)	0		3 (0.2%)	3 (0.2%)	1 (<0.1%)	
Axillary pain	腋窩痛	1 (<0.1%)	0	0		0	0	0	
Catheter site haemorrhage	カテーテル留置部位出血	0	0	0		1 (<0.1%)	0	0	
Chest discomfort	胸部不快感	1 (<0.1%)	0	0		4 (0.2%)	1 (<0.1%)	0	
Chest pain	胸痛	29 (1.7%)	6 (0.3%)	1 (<0.1%)		18 (1.1%)	11 (0.6%)	2 (0.1%)	
Chills	悪寒	3 (0.2%)	0	0		0	0	0	
Cyst	嚢胞	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Death	死亡	0	0	0		0	0	1 (<0.1%)	
Device leakage	医療機器リーク	1 (<0.1%)	0	0		0	0	0	
Device occlusion	医療機器閉塞	1 (<0.1%)	0	0		0	0	0	
Drug resistance	薬剤耐性	0	0	0		0	1 (<0.1%)	0	
Exercise tolerance decreased	運動耐性低下	2 (0.1%)	0	0		0	0	0	
Facial pain	顔面痛	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Fatigue	疲労	18 (1.0%)	6 (0.3%)	0		11 (0.6%)	2 (0.1%)	2 (0.1%)	
Feeling abnormal	異常感	2 (0.1%)	1 (<0.1%)	0		2 (0.1%)	0	0	
Feeling cold	冷感	2 (0.1%)	0	0		0	0	0	
Feeling hot	熱感	0	0	0		1 (<0.1%)	0	0	
Feeling of body temperature change	体温変動感	1 (<0.1%)	0	0		0	0	0	
Gait disturbance	歩行障害	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
General physical health deterioration	全身健康状態低下	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Generalised oedema	全身性浮腫	0	0	1 (<0.1%)		0	0	0	
Haemorrhagic cyst	出血性嚢胞	1 (<0.1%)	0	0		0	0	0	
Hernia	ヘルニア	1 (<0.1%)	0	0		0	0	1 (<0.1%)	
Impaired healing	治癒不良	0	0	0		0	1 (<0.1%)	0	
Inflammation	炎症	0	2 (0.1%)	0		3 (0.2%)	0	0	
Influenza like illness	インフルエンザ様疾患	4 (0.2%)	1 (<0.1%)	0		2 (0.1%)	0	0	
Infusion site phlebitis	注入部位静脈炎	0	0	0		1 (<0.1%)	0	0	
Injection site extravasation	注射部位血管外漏出	0	0	0		2 (0.1%)	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Injection site haematoma	注射部位血腫	2 (0.1%)	0	0		11 (0.6%)	1 (<0.1%)	0	
Injection site haemorrhage	注射部位出血	0	0	0		1 (<0.1%)	0	0	
Injection site pain	注射部位疼痛	0	0	0		1 (<0.1%)	0	0	
Injection site reaction	注射部位反応	0	0	0		1 (<0.1%)	0	0	
Injection site swelling	注射部位腫脹	0	0	0		1 (<0.1%)	0	0	
Irritability	易刺激性	1 (<0.1%)	0	0		0	0	0	
Local swelling	局所腫脹	1 (<0.1%)	0	0		0	0	0	
Malaise	倦怠感	5 (0.3%)	0	0		2 (0.1%)	2 (0.1%)	1 (<0.1%)	
Medical device complication	医療機器合併症	0	0	0		1 (<0.1%)	0	0	
Multi-organ failure	多臓器不全	0	0	3 (0.2%)		0	0	1 (<0.1%)	
Non-cardiac chest pain	非心臓性胸痛	0	2 (0.1%)	0		1 (<0.1%)	0	0	
Oedema	浮腫	14 (0.8%)	1 (<0.1%)	0		5 (0.3%)	3 (0.2%)	0	
Oedema peripheral	末梢性浮腫	28 (1.6%)	12 (0.7%)	1 (<0.1%)		31 (1.8%)	10 (0.6%)	0	
Pain	疼痛	3 (0.2%)	3 (0.2%)	2 (0.1%)		5 (0.3%)	1 (<0.1%)	0	
Pelvic mass	骨盤腔内腫瘤	0	0	0		0	0	1 (<0.1%)	
Polyp	ポリープ	2 (0.1%)	0	0		0	0	0	
Puncture site haemorrhage	穿刺部位出血	0	0	0		2 (0.1%)	0	0	
Pyrexia	発熱	35 (2.0%)	6 (0.3%)	2 (0.1%)		31 (1.8%)	6 (0.4%)	1 (<0.1%)	
Sudden cardiac death	心突然死	0	0	1 (<0.1%)		0	0	0	
Sudden death	突然死	0	0	0		0	0	1 (<0.1%)	
Thirst	口渇	1 (<0.1%)	0	0		0	0	0	
Vessel puncture site haematoma	血管穿刺部位血腫	3 (0.2%)	0	0		1 (<0.1%)	0	0	
Vessel puncture site haemorrhage	血管穿刺部位出血	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Vessel puncture site reaction	血管穿刺部位反応	1 (<0.1%)	0	0		0	0	0	
Hepatobiliary disorders	肝胆道系障害	18 (1.0%)	5 (0.3%)	2 (0.1%)		18 (1.1%)	4 (0.2%)	1 (<0.1%)	
Biliary colic	胆道仙痛	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Cholangitis	胆管炎	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Cholecystitis	胆嚢炎	0	0	0		0	1 (<0.1%)	0	
Cholecystitis acute	急性胆嚢炎	0	0	0		0	1 (<0.1%)	0	
Cholecystitis chronic	慢性胆嚢炎	1 (<0.1%)	0	0		0	0	0	
Cholelithiasis	胆石症	6 (0.3%)	1 (<0.1%)	0		6 (0.4%)	1 (<0.1%)	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Gallbladder polyp	胆嚢ポリープ	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Hepatic cyst	肝嚢胞	5 (0.3%)	0	0		4 (0.2%)	0	0	
Hepatic function abnormal	肝機能異常	1 (<0.1%)	2 (0.1%)	0		1 (<0.1%)	0	0	
Hepatic mass	肝腫瘤	0	0	1 (<0.1%)		0	0	0	
Hepatic steatosis	脂肪肝	8 (0.5%)	1 (<0.1%)	0		8 (0.5%)	1 (<0.1%)	0	
Hepatitis acute	急性肝炎	0	0	1 (<0.1%)		0	0	0	
Hepatocellular injury	肝細胞損傷	0	0	0		1 (<0.1%)	0	0	
Hepatomegaly	肝腫大	1 (<0.1%)	0	0		0	0	0	
Hydrocholecystis	水腫性胆嚢炎	0	0	0		0	1 (<0.1%)	0	
Hyperbilirubinaemia	高ビリルビン血症	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Jaundice cholestatic	胆汁うっ滞性黄疸	0	0	0		0	0	1 (<0.1%)	
Immune system disorders	免疫系障害	13 (0.8%)	5 (0.3%)	0		10 (0.6%)	3 (0.2%)	0	
Antiphospholipid syndrome	抗リン脂質抗体症候群	2 (0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Behcet's syndrome	ベーチェット症候群	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Contrast media allergy	造影剤アレルギー	0	0	0		1 (<0.1%)	0	0	
Drug hypersensitivity	薬物過敏症	2 (0.1%)	1 (<0.1%)	0		2 (0.1%)	0	0	
House dust allergy	家塵アレルギー	1 (<0.1%)	0	0		0	0	0	
Humoral immune defect	体液性免疫不全	1 (<0.1%)	0	0		0	0	0	
Hypersensitivity	過敏症	5 (0.3%)	2 (0.1%)	0		3 (0.2%)	2 (0.1%)	0	
Liver transplant rejection	肝移植拒絶反応	0	0	0		0	1 (<0.1%)	0	
Seasonal allergy	季節性アレルギー	2 (0.1%)	0	0		2 (0.1%)	0	0	
Infections and infestations	感染症および寄生虫症	248 (14.4%)	86 (5.0%)	17 (1.0%)		234 (13.7%)	96 (5.6%)	27 (1.6%)	
Abdominal abscess	腹部膿瘍	0	0	0		0	1 (<0.1%)	0	
Abscess	膿瘍	0	0	1 (<0.1%)		0	0	0	
Abscess limb	四肢膿瘍	0	1 (<0.1%)	0		0	1 (<0.1%)	1 (<0.1%)	
Acute tonsillitis	急性扁桃炎	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Anal abscess	肛門膿瘍	0	0	0		1 (<0.1%)	0	0	
Appendicitis	虫垂炎	0	0	0		0	1 (<0.1%)	0	
Arthritis infective	感染性関節炎	0	0	0		0	1 (<0.1%)	0	
Asymptomatic bacteriuria	無症候性細菌尿	1 (<0.1%)	0	0		0	0	0	
Bacteraemia	菌血症	0	1 (<0.1%)	0		1 (<0.1%)	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Bacterial infection	細菌感染	1 (<0.1%)	0	0		0	0	0	
Bacterial sepsis	細菌性敗血症	0	0	0		0	1 (<0.1%)	0	
Balanitis candida	カンジダ性亀頭炎	1 (<0.1%)	0	0		0	0	0	
Blister infected	感染性水疱	0	0	0		1 (<0.1%)	0	0	
Body tinea	体部白癬	0	0	0		1 (<0.1%)	0	0	
Bone tuberculosis	骨結核	0	1 (<0.1%)	0		0	0	0	
Bronchiectasis	気管支拡張症	1 (<0.1%)	0	0		0	0	0	
Bronchitis	気管支炎	17 (1.0%)	7 (0.4%)	0		25 (1.5%)	9 (0.5%)	0	
Bronchopneumonia	気管支肺炎	1 (<0.1%)	2 (0.1%)	1 (<0.1%)		0	0	1 (<0.1%)	
Candidiasis	カンジダ症	0	0	0		1 (<0.1%)	0	0	
Cardiac valve vegetation	心臓弁疣贅	0	0	0		0	1 (<0.1%)	0	
Catheter site infection	カテーテル留置部位感染	0	0	0		1 (<0.1%)	0	0	
Cellulitis	蜂巣炎	6 (0.3%)	5 (0.3%)	3 (0.2%)		11 (0.6%)	10 (0.6%)	1 (<0.1%)	
Cerebral toxoplasmosis	脳トキソプラズマ症	0	0	0		0	0	1 (<0.1%)	
Chlamydial infection	クラミジア感染	1 (<0.1%)	0	0		0	0	0	
Clostridial infection	クロストリジウム感染	0	1 (<0.1%)	0		0	0	0	
Conjunctivitis infective	感染性結膜炎	0	0	0		0	1 (<0.1%)	0	
Cystitis	膀胱炎	8 (0.5%)	2 (0.1%)	0		11 (0.6%)	2 (0.1%)	0	
Dengue fever	デング熱	0	0	0		0	1 (<0.1%)	0	
Dermatophytosis	皮膚糸状菌症	1 (<0.1%)	0	0		0	0	0	
Dermo-hypodermitis	皮膚皮下組織炎	0	0	0		2 (0.1%)	0	0	
Device related infection	医療機器関連感染	0	0	0		0	0	1 (<0.1%)	
Diverticulitis	憩室炎	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Dysentery	赤痢	0	1 (<0.1%)	0		0	0	0	
Ear infection	耳感染	1 (<0.1%)	0	0		4 (0.2%)	1 (<0.1%)	0	
Endocarditis staphylococcal	ブドウ球菌性心内膜炎	0	0	0		0	1 (<0.1%)	0	
Enterocolitis bacterial	細菌性腸炎	0	1 (<0.1%)	0		0	0	0	
Epiglottitis	喉頭蓋炎	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Epstein-Barr virus infection	エプスタイン・バーウイルス感染	1 (<0.1%)	0	0		0	0	0	
Erysipelas	丹毒	2 (0.1%)	2 (0.1%)	0		4 (0.2%)	1 (<0.1%)	1 (<0.1%)	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Escherichia urinary tract infection	大腸菌性尿路感染	1 (<0.1%)	0	0		0	0	0	
Eye infection	眼感染	1 (<0.1%)	0	1 (<0.1%)		1 (<0.1%)	0	0	
Folliculitis	毛包炎	2 (0.1%)	0	0		0	1 (<0.1%)	0	
Fungal infection	真菌感染	0	1 (<0.1%)	0		0	0	0	
Fungal skin infection	皮膚真菌感染	2 (0.1%)	1 (<0.1%)	0		2 (0.1%)	0	0	
Furuncle	せつ	3 (0.2%)	0	0		1 (<0.1%)	0	0	
Gastroenteritis	胃腸炎	8 (0.5%)	4 (0.2%)	0		10 (0.6%)	7 (0.4%)	1 (<0.1%)	
Gastroenteritis viral	ウイルス性胃腸炎	4 (0.2%)	1 (<0.1%)	0		0	0	0	
Genital candidiasis	性器カンジダ症	1 (<0.1%)	0	0		0	0	0	
Genital infection fungal	真菌性性器感染	0	0	0		1 (<0.1%)	0	0	
Gingival infection	歯肉感染	2 (0.1%)	0	0		0	0	0	
Helicobacter gastritis	ヘリコバクター性胃炎	2 (0.1%)	0	0		0	0	0	
Helicobacter infection	ヘリコバクター感染	0	0	0		1 (<0.1%)	0	0	
Herpes simplex	単純ヘルペス	1 (<0.1%)	0	0		0	0	0	
Herpes zoster	帯状疱疹	5 (0.3%)	2 (0.1%)	0		2 (0.1%)	0	0	
Hordeolum	麦粒腫	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Incision site abscess	切開部位膿瘍	0	1 (<0.1%)	0		0	0	0	
Incision site infection	切開部位感染	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Infected cyst	感染性嚢腫	0	0	0		1 (<0.1%)	0	0	
Infected skin ulcer	感染性皮膚潰瘍	0	0	0		0	1 (<0.1%)	0	
Infection	感染	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Infective aneurysm	感染性動脈瘤	0	1 (<0.1%)	0		0	0	0	
Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	1 (<0.1%)	
Influenza	インフルエンザ	31 (1.8%)	7 (0.4%)	0		28 (1.6%)	9 (0.5%)	1 (<0.1%)	
Injection site infection	注射部位感染	0	0	0		1 (<0.1%)	0	0	
Kidney infection	腎感染	0	0	0		1 (<0.1%)	0	0	
Laryngitis	喉頭炎	1 (<0.1%)	0	0		0	0	0	
Lobar pneumonia	大葉性肺炎	0	1 (<0.1%)	0		2 (0.1%)	0	0	
Localised infection	限局性感染	6 (0.3%)	2 (0.1%)	0		5 (0.3%)	1 (<0.1%)	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Lower respiratory tract infection	下気道感染	4 (0.2%)	4 (0.2%)	0		0	5 (0.3%)	0	
Lung infection	肺感染	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Lymphangitis	リンパ管炎	0	0	0		1 (<0.1%)	0	0	
Mastitis	乳腺炎	0	0	0		0	0	1 (<0.1%)	
Mumps	ムンプス	0	0	0		1 (<0.1%)	0	0	
Myringitis	鼓膜炎	0	1 (<0.1%)	0		0	0	0	
Nail bed infection	爪床感染	0	0	0		0	1 (<0.1%)	0	
Nail infection	爪感染	1 (<0.1%)	0	0		0	0	0	
Nasopharyngitis	鼻咽頭炎	80 (4.7%)	12 (0.7%)	1 (<0.1%)		71 (4.1%)	13 (0.8%)	0	
Oesophageal candidiasis	食道カンジダ症	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Onychomycosis	爪真菌症	0	0	0		1 (<0.1%)	0	0	
Opisthorchiasis	タイ肝吸虫症	0	0	0		1 (<0.1%)	0	0	
Oral candidiasis	口腔カンジダ症	3 (0.2%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Oral fungal infection	口腔真菌感染	2 (0.1%)	0	0		0	1 (<0.1%)	0	
Oral herpes	口腔ヘルペス	3 (0.2%)	0	0		2 (0.1%)	0	0	
Oropharyngitis fungal	真菌性口腔咽頭炎	0	0	0		0	1 (<0.1%)	0	
Otitis externa	外耳炎	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Otitis media	中耳炎	2 (0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Paronychia	爪囲炎	2 (0.1%)	0	0		0	1 (<0.1%)	0	
Pharyngitis	咽頭炎	10 (0.6%)	0	0		2 (0.1%)	0	0	
Pharyngitis streptococcal	レンサ球菌性咽頭炎	1 (<0.1%)	0	0		0	0	0	
Pneumonia	肺炎	6 (0.3%)	7 (0.4%)	2 (0.1%)		5 (0.3%)	7 (0.4%)	8 (0.5%)	
Pneumonia bacterial	細菌性肺炎	0	0	0		0	0	2 (0.1%)	
Post procedural sepsis	処置後敗血症	0	0	0		0	0	1 (<0.1%)	
Postoperative wound infection	術後創感染	0	1 (<0.1%)	0		0	3 (0.2%)	0	
Pseudomembranous colitis	偽膜性大腸炎	0	0	0		1 (<0.1%)	0	0	
Pulmonary sepsis	肺敗血症	0	0	0		0	0	1 (<0.1%)	
Pulmonary tuberculosis	肺結核	0	1 (<0.1%)	0		0	2 (0.1%)	1 (<0.1%)	
Pyelonephritis	腎盂腎炎	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	2 (0.1%)	0	
Pyelonephritis acute	急性腎盂腎炎	0	0	0		1 (<0.1%)	0	0	
Rash pustular	膿疱性皮疹	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Renal abscess	腎膿瘍	1 (<0.1%)	0	0		0	0	0	
Respiratory tract infection	気道感染	8 (0.5%)	2 (0.1%)	0		3 (0.2%)	1 (<0.1%)	1 (<0.1%)	
Rhinitis	鼻炎	10 (0.6%)	0	0		6 (0.4%)	0	0	
Sepsis	敗血症	0	2 (0.1%)	2 (0.1%)		0	1 (<0.1%)	4 (0.2%)	
Septic shock	敗血症性ショック	0	0	1 (<0.1%)		0	2 (0.1%)	1 (<0.1%)	
Sinusitis	副鼻腔炎	11 (0.6%)	2 (0.1%)	0		5 (0.3%)	6 (0.4%)	0	
Skin infection	皮膚感染	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	2 (0.1%)	0	
Sputum purulent	膿性痰	0	0	0		0	1 (<0.1%)	0	
Staphylococcal skin infection	ブドウ球菌皮膚感染	1 (<0.1%)	0	0		0	0	0	
Strongyloidiasis	糞線虫症	0	0	0		1 (<0.1%)	0	0	
Subacute endocarditis	亜急性心内膜炎	0	1 (<0.1%)	0		0	0	0	
Tinea cruris	股部白癬	0	0	0		2 (0.1%)	0	0	
Tinea pedis	足部白癬	0	0	0		2 (0.1%)	0	0	
Tonsillitis	扁桃炎	0	0	0		1 (<0.1%)	0	0	
Tooth abscess	歯膿瘍	2 (0.1%)	0	0		3 (0.2%)	1 (<0.1%)	0	
Tooth infection	歯感染	2 (0.1%)	1 (<0.1%)	0		3 (0.2%)	0	0	
Tracheitis	気管炎	0	0	0		1 (<0.1%)	0	0	
Tracheobronchitis	気管気管支炎	0	0	1 (<0.1%)		1 (<0.1%)	0	0	
Upper respiratory tract infection	上気道感染	12 (0.7%)	3 (0.2%)	0		20 (1.2%)	4 (0.2%)	0	
Urinary tract infection	尿路感染	25 (1.5%)	10 (0.6%)	2 (0.1%)		23 (1.3%)	8 (0.5%)	1 (<0.1%)	
Vaginal infection	膣感染	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Vaginitis bacterial	細菌性膣炎	1 (<0.1%)	0	0		0	0	0	
Viral infection	ウイルス感染	4 (0.2%)	1 (<0.1%)	1 (<0.1%)		4 (0.2%)	2 (0.1%)	0	
Viral upper respiratory tract infection	ウイルス性上気道感染	4 (0.2%)	2 (0.1%)	0		4 (0.2%)	1 (<0.1%)	0	
Vulvovaginal candidiasis	外陰部膣カンジダ症	3 (0.2%)	0	0		0	0	0	
Vulvovaginal mycotic infection	外陰膣真菌感染	1 (<0.1%)	0	0		2 (0.1%)	0	0	
Wound abscess	創部膿瘍	0	0	1 (<0.1%)		0	0	0	
Wound infection	創傷感染	3 (0.2%)	1 (<0.1%)	0		0	2 (0.1%)	0	
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	116 (6.8%)	30 (1.7%)	9 (0.5%)		133 (7.8%)	38 (2.2%)	11 (0.6%)	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Accident	事故	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Accidental overdose	偶発的過量投与	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Alcohol poisoning	アルコール中毒	0	0	0		0	0	1 (<0.1%)	
Anaemia postoperative	術後貧血	0	0	0		1 (<0.1%)	0	0	
Animal bite	動物咬傷	3 (0.2%)	0	0		1 (<0.1%)	0	0	
Animal scratch	動物による引っかき傷	1 (<0.1%)	0	0		0	0	0	
Ankle fracture	足関節部骨折	0	0	0		0	0	1 (<0.1%)	
Arthropod bite	節足動物咬傷	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Arthropod sting	節足動物刺傷	0	1 (<0.1%)	0		2 (0.1%)	0	0	
Bursa injury	滑液包損傷	0	0	0		0	0	1 (<0.1%)	
Cartilage injury	軟骨損傷	0	0	0		0	0	1 (<0.1%)	
Concussion	脳振盪	0	0	0		0	1 (<0.1%)	0	
Contusion	挫傷	47 (2.7%)	6 (0.3%)	0		57 (3.3%)	9 (0.5%)	2 (0.1%)	
Crushing injury of trunk	体幹の圧挫損傷	1 (<0.1%)	0	0		0	0	0	
Drug exposure during pregnancy	妊娠時の薬物曝露	0	0	0		0	0	1 (<0.1%)	
Drug toxicity	薬物毒性	0	0	1 (<0.1%)		0	0	0	
Epicondylitis	上顆炎	0	0	0		1 (<0.1%)	0	0	
Eschar	焼痂	1 (<0.1%)	0	0		0	0	0	
Excoriation	擦過傷	4 (0.2%)	1 (<0.1%)	0		4 (0.2%)	0	0	
Eye injury	眼外傷	1 (<0.1%)	0	0		0	0	0	
Face injury	顔面損傷	0	0	0		1 (<0.1%)	0	0	
Facial bones fracture	顔面骨骨折	0	1 (<0.1%)	0		0	0	0	
Fall	転倒	6 (0.3%)	3 (0.2%)	1 (<0.1%)		6 (0.4%)	2 (0.1%)	1 (<0.1%)	
Femoral neck fracture	大腿骨頚部骨折	0	0	0		0	1 (<0.1%)	1 (<0.1%)	
Femur fracture	大腿骨骨折	0	0	0		0	1 (<0.1%)	0	
Foot fracture	足骨折	2 (0.1%)	0	0		1 (<0.1%)	0	0	
Forearm fracture	前腕骨折	0	0	0		0	0	1 (<0.1%)	
Gastroenteritis radiation	放射線胃腸炎	0	1 (<0.1%)	0		0	0	0	
Graft haemorrhage	移植部位出血	0	0	0		1 (<0.1%)	0	0	
Hand fracture	手骨折	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Humerus fracture	上腕骨骨折	0	0	1 (<0.1%)		0	1 (<0.1%)	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Induced abortion haemorrhage	人工流産による出血	0	0	1 (<0.1%)		0	0	0	
Inflammation of wound	創部炎症	1 (<0.1%)	0	0		0	0	0	
Injury	損傷	1 (<0.1%)	0	0		0	0	0	
Joint dislocation	関節脱臼	2 (0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Joint injury	関節損傷	1 (<0.1%)	1 (<0.1%)	0		0	3 (0.2%)	0	
Joint sprain	関節捻挫	7 (0.4%)	2 (0.1%)	0		6 (0.4%)	2 (0.1%)	0	
Ligament injury	靭帯損傷	0	0	0		0	0	1 (<0.1%)	
Ligament rupture	靭帯断裂	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Limb injury	四肢損傷	4 (0.2%)	0	0		2 (0.1%)	0	0	
Mouth injury	口腔内損傷	0	0	0		1 (<0.1%)	0	0	
Muscle rupture	筋断裂	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Muscle strain	筋挫傷	3 (0.2%)	1 (<0.1%)	1 (<0.1%)		2 (0.1%)	1 (<0.1%)	0	
Open wound	開放創	0	0	0		1 (<0.1%)	0	0	
Operative haemorrhage	術中出血	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Overdose	過量投与	1 (<0.1%)	0	1 (<0.1%)		1 (<0.1%)	1 (<0.1%)	0	
Pelvic fracture	骨盤骨折	0	0	0		0	1 (<0.1%)	0	
Periorbital haematoma	眼窩周囲血腫	2 (0.1%)	0	0		1 (<0.1%)	0	0	
Post procedural haematuria	処置後血尿	2 (0.1%)	0	0		0	0	0	
Post procedural haemorrhage	処置後出血	5 (0.3%)	1 (<0.1%)	1 (<0.1%)		5 (0.3%)	1 (<0.1%)	0	
Post procedural swelling	処置後腫脹	0	0	0		0	2 (0.1%)	0	
Post-traumatic pain	外傷後疼痛	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Postoperative hernia	術後ヘルニア	0	0	0		1 (<0.1%)	0	0	
Procedural pain	処置による疼痛	1 (<0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	1 (<0.1%)	
Radius fracture	橈骨骨折	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Rib fracture	肋骨骨折	2 (0.1%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Road traffic accident	交通事故	2 (0.1%)	0	0		1 (<0.1%)	0	0	
Scratch	引っかき傷	2 (0.1%)	0	0		0	0	0	
Skeletal injury	骨格損傷	3 (0.2%)	1 (<0.1%)	0		0	1 (<0.1%)	0	
Skin injury	皮膚損傷	0	0	0		1 (<0.1%)	0	0	
Skin laceration	皮膚裂傷	9 (0.5%)	1 (<0.1%)	0		4 (0.2%)	0	0	
Soft tissue injury	軟部組織損傷	0	0	0		1 (<0.1%)	1 (<0.1%)	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Spinal column injury	脊柱損傷	0	0	1 (<0.1%)		0	0	0	
Spinal compression fracture	脊椎圧迫骨折	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Stress fracture	ストレス骨折	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Subcutaneous haematoma	皮下血腫	9 (0.5%)	0	0		16 (0.9%)	1 (<0.1%)	0	
Synovial rupture	滑膜断裂	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Tendon injury	腱損傷	0	0	0		0	1 (<0.1%)	0	
Tendon rupture	腱断裂	0	0	0		0	1 (<0.1%)	0	
Therapeutic agent toxicity	治療薬毒性	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Thermal burn	熱傷	0	0	0		2 (0.1%)	0	0	
Thoracic vertebral fracture	胸椎骨折	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Tooth fracture	歯牙破折	0	2 (0.1%)	0		4 (0.2%)	1 (<0.1%)	0	
Tooth injury	歯牙損傷	1 (<0.1%)	0	0		0	0	0	
Traumatic fracture	外傷性骨折	0	0	0		1 (<0.1%)	0	0	
Traumatic haematoma	外傷性血腫	2 (0.1%)	1 (<0.1%)	0		4 (0.2%)	1 (<0.1%)	0	
Traumatic haemorrhage	外傷性出血	4 (0.2%)	0	0		1 (<0.1%)	0	0	
Ulna fracture	尺骨骨折	0	0	0		0	2 (0.1%)	0	
Upper limb fracture	上肢骨折	0	0	0		1 (<0.1%)	0	0	
Vascular pseudoaneurysm	血管偽動脈瘤	0	1 (<0.1%)	0		0	0	0	
Wound	創傷	4 (0.2%)	1 (<0.1%)	0		4 (0.2%)	2 (0.1%)	0	
Wound dehiscence	創し開	0	1 (<0.1%)	0		0	0	0	
Wound haemorrhage	創傷出血	18 (1.0%)	2 (0.1%)	0		21 (1.2%)	0	0	
Wrist fracture	手首関節骨折	0	0	0		0	1 (<0.1%)	0	
Investigations	臨床検査	59 (3.4%)	24 (1.4%)	3 (0.2%)		135 (7.9%)	38 (2.2%)	6 (0.4%)	
Activated partial thromboplastin time prolonged	活性化部分トロンボプラスチン時間延長	1 (<0.1%)	0	0		0	0	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	0	0		0	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	17 (1.0%)	3 (0.2%)	0		45 (2.6%)	7 (0.4%)	0	
Antiphospholipid antibodies positive	抗リン脂質抗体陽性	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	11 (0.6%)	1 (<0.1%)	0		15 (0.9%)	3 (0.2%)	0	
Bilirubin conjugated increased	抱合ビリルビン増加	2 (0.1%)	0	0		1 (<0.1%)	0	0	
Biopsy breast	乳房生検	0	0	0		2 (0.1%)	0	0	
Biopsy kidney	腎生検	1 (<0.1%)	0	1 (<0.1%)		0	0	0	
Biopsy lung	肺生検	1 (<0.1%)	0	0		0	0	0	
Biopsy prostate	前立腺生検	1 (<0.1%)	0	0		2 (0.1%)	0	0	
Biopsy stomach	胃生検	0	1 (<0.1%)	0		0	0	0	
Blood albumin increased	血中アルブミン増加	0	1 (<0.1%)	0		0	0	0	
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	4 (0.2%)	2 (0.1%)	0		6 (0.4%)	3 (0.2%)	0	
Blood amylase increased	血中アミラーゼ増加	1 (<0.1%)	0	0		3 (0.2%)	1 (<0.1%)	0	
Blood bilirubin increased	血中ビリルビン増加	3 (0.2%)	2 (0.1%)	0		2 (0.1%)	0	0	
Blood cholesterol increased	血中コレステロール増加	1 (<0.1%)	0	0		2 (0.1%)	0	0	
Blood creatinine increased	血中クレアチニン増加	1 (<0.1%)	0	0		0	0	0	
Blood folate decreased	血中葉酸減少	1 (<0.1%)	0	0		0	0	0	
Blood glucose decreased	血中ブドウ糖減少	1 (<0.1%)	0	0		0	0	0	
Blood glucose fluctuation	血中ブドウ糖変動	1 (<0.1%)	0	0		0	0	0	
Blood glucose increased	血中ブドウ糖増加	0	0	0		1 (<0.1%)	0	0	
Blood homocysteine increased	血中ホモシステイン増加	2 (0.1%)	0	0		1 (<0.1%)	0	0	
Blood potassium decreased	血中カリウム減少	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Blood potassium increased	血中カリウム増加	1 (<0.1%)	0	0		0	0	0	
Blood pressure increased	血圧上昇	1 (<0.1%)	1 (<0.1%)	0		2 (0.1%)	0	0	
Blood thromboplastin decreased	血中トロンボプラスチン減少	1 (<0.1%)	0	0		0	0	0	
Blood thyroid stimulating hormone increased	血中甲状腺刺激ホルモン増加	0	1 (<0.1%)	0		0	0	0	
Blood urine present	尿中血陽性	0	1 (<0.1%)	0		0	0	0	
Body temperature increased	体温上昇	1 (<0.1%)	0	0		0	0	0	
C-reactive protein increased	Ｃ－反応性蛋白増加	1 (<0.1%)	0	0		0	0	0	
Carbohydrate antigen 125 increased	糖鎖抗原１２５増加	0	0	0		1 (<0.1%)	0	0	
Carcinoembryonic antigen increased	癌胎児性抗原増加	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Chest X-ray abnormal	胸部X線異常	0	0	0		0	0	1 (<0.1%)	
Coagulation factor VII level decreased	凝固第ＶＩＩ因子量減少	1 (<0.1%)	0	0		0	0	0	
Coagulation factor VIII level increased	凝固第ＶＩＩＩ因子量増加	0	0	0		1 (<0.1%)	0	0	
Coagulation factor X level decreased	凝固第X因子量減少	1 (<0.1%)	0	0		0	0	0	
Colonoscopy	結腸内視鏡検査	2 (0.1%)	1 (<0.1%)	0		2 (0.1%)	0	0	
Computerised tomogram	コンピュータ断層撮影	0	0	0		1 (<0.1%)	0	0	
Computerised tomogram abdomen	腹部コンピュータ断層撮影	0	0	0		1 (<0.1%)	0	0	
Free prostate-specific antigen decreased	遊離前立腺特異性抗原減少	1 (<0.1%)	0	0		0	0	0	
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2 (0.1%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Glomerular filtration rate decreased	糸球体濾過率減少	0	0	0		1 (<0.1%)	0	0	
Haematocrit decreased	ヘマトクリット減少	0	0	0		1 (<0.1%)	0	0	
Haemoglobin decreased	ヘモグロビン減少	2 (0.1%)	3 (0.2%)	0		2 (0.1%)	1 (<0.1%)	0	
Heart rate decreased	心拍数減少	0	0	0		1 (<0.1%)	0	0	
Heart rate irregular	心拍数不整	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Hepatic enzyme increased	肝酵素上昇	0	1 (<0.1%)	0		10 (0.6%)	4 (0.2%)	1 (<0.1%)	
Influenza A virus test positive	A型インフルエンザウイルス検査陽性	0	0	0		0	1 (<0.1%)	0	
International normalised ratio abnormal	ＩＮＲ異常	0	0	0		0	1 (<0.1%)	1 (<0.1%)	
International normalised ratio decreased	ＩＮＲ減少	0	0	0		5 (0.3%)	0	0	
International normalised ratio fluctuation	ＩＮＲ変動	0	0	0		2 (0.1%)	0	0	
International normalised ratio increased	ＩＮＲ増加	0	1 (<0.1%)	0		25 (1.5%)	11 (0.6%)	2 (0.1%)	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Intraocular pressure increased	眼圧上昇	0	0	0		1 (<0.1%)	0	0	
Lipids increased	脂質増加	2 (0.1%)	0	0		0	0	0	
Lipoprotein (a) increased	リポ蛋白（ａ）増加	1 (<0.1%)	0	0		0	0	0	
Liver function test abnormal	肝機能検査異常	5 (0.3%)	1 (<0.1%)	1 (<0.1%)		15 (0.9%)	2 (0.1%)	2 (0.1%)	
Low density lipoprotein increased	低比重リポ蛋白増加	0	0	0		1 (<0.1%)	0	0	
Lymph node palpable	リンパ節触知	1 (<0.1%)	0	0		0	0	0	
Lymphocyte count increased	リンパ球数増加	0	0	0		1 (<0.1%)	0	0	
Neutrophil count decreased	好中球数減少	0	0	0		1 (<0.1%)	0	0	
Occult blood	便潜血	0	0	0		1 (<0.1%)	0	0	
Oesophagogastroduodenoscopy	食道胃十二指腸内視鏡検査	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Platelet count decreased	血小板数減少	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Platelet count increased	血小板数増加	1 (<0.1%)	0	0		0	0	0	
Prostatic specific antigen decreased	前立腺特異性抗原減少	1 (<0.1%)	0	0		0	0	0	
Prostatic specific antigen increased	前立腺特異性抗原増加	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Protein total increased	総蛋白増加	0	1 (<0.1%)	0		0	0	0	
Prothrombin time prolonged	プロトロンビン時間延長	0	0	0		0	1 (<0.1%)	0	
Red blood cell count decreased	赤血球数減少	0	0	0		0	1 (<0.1%)	0	
Red blood cells urine positive	尿中赤血球陽性	0	0	0		1 (<0.1%)	0	0	
Staphylococcus test positive	ブドウ球菌検査陽性	0	0	0		1 (<0.1%)	0	0	
Transaminases increased	トランスアミナーゼ上昇	1 (<0.1%)	2 (0.1%)	1 (<0.1%)		2 (0.1%)	0	0	
Troponin I increased	トロポニンＩ増加	0	1 (<0.1%)	0		0	0	0	
Troponin increased	トロポニン増加	0	0	0		1 (<0.1%)	0	0	
Tumour marker increased	腫瘍マーカー上昇	0	1 (<0.1%)	0		0	0	0	
Ultrasound Doppler	ドップラー超音波	0	0	0		1 (<0.1%)	0	0	
Ultrasound scan	超音波スキャン	1 (<0.1%)	0	0		0	0	0	
Urine ketone body present	尿中ケトン体陽性	0	0	0		1 (<0.1%)	0	0	
Urogram	尿路造影	1 (<0.1%)	0	0		0	0	0	
Vitamin B12 decreased	ビタミンＢ１２減少	0	0	0		1 (<0.1%)	0	0	
Weight decreased	体重減少	3 (0.2%)	1 (<0.1%)	0		1 (<0.1%)	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Weight increased	体重増加	0	0	0		4 (0.2%)	0	0	
White blood cell count decreased	白血球数減少	1 (<0.1%)	0	0		0	2 (0.1%)	0	
White blood cell count increased	白血球数増加	0	0	0		1 (<0.1%)	0	0	
White blood cells urine positive	尿中白血球陽性	0	0	0		1 (<0.1%)	0	0	
Metabolism and nutrition disorders	代謝および栄養障害	51 (3.0%)	25 (1.5%)	2 (0.1%)		59 (3.4%)	15 (0.9%)	5 (0.3%)	
Acidosis	アシドーシス	0	0	0		0	1 (<0.1%)	0	
Decreased appetite	食欲減退	6 (0.3%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Dehydration	脱水	0	1 (<0.1%)	0		2 (0.1%)	1 (<0.1%)	0	
Diabetes mellitus	糖尿病	4 (0.2%)	0	0		5 (0.3%)	3 (0.2%)	0	
Diabetic foot	糖尿病性足病変	0	0	0		1 (<0.1%)	0	0	
Diabetic ketoacidosis	糖尿病性ケトアシドーシス	0	1 (<0.1%)	0		0	0	0	
Dyslipidaemia	脂質異常症	0	0	0		1 (<0.1%)	0	0	
Electrolyte imbalance	電解質失調	0	0	0		0	0	1 (<0.1%)	
Failure to thrive	成長障害	0	0	1 (<0.1%)		0	0	0	
Folate deficiency	葉酸欠乏	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Gout	痛風	5 (0.3%)	8 (0.5%)	0		7 (0.4%)	4 (0.2%)	1 (<0.1%)	
Haemochromatosis	ヘモクロマトーシス	0	1 (<0.1%)	0		0	0	0	
Hypercalcaemia	高カルシウム血症	1 (<0.1%)	0	0		0	0	0	
Hypercholesterolaemia	高コレステロール血症	7 (0.4%)	1 (<0.1%)	0		8 (0.5%)	0	1 (<0.1%)	
Hyperglycaemia	高血糖	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Hyperhomocysteinaemia	高ホモシステイン血症	2 (0.1%)	0	0		4 (0.2%)	0	0	
Hyperinsulinaemia	高インスリン血症	0	0	0		1 (<0.1%)	0	0	
Hyperkalaemia	高カリウム血症	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Hyperlipidaemia	高脂血症	2 (0.1%)	0	0		6 (0.4%)	1 (<0.1%)	0	
Hypernatraemia	高ナトリウム血症	1 (<0.1%)	0	0		0	0	0	
Hyperproteinaemia	高蛋白血症	1 (<0.1%)	0	0		0	0	0	
Hypertriglyceridaemia	高トリグリセリド血症	0	0	0		1 (<0.1%)	0	0	
Hyperuricaemia	高尿酸血症	2 (0.1%)	0	0		1 (<0.1%)	0	0	
Hypoalbuminaemia	低アルブミン血症	1 (<0.1%)	3 (0.2%)	0		0	1 (<0.1%)	0	
Hypocalcaemia	低カルシウム血症	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Hypochloraemia	低クロール血症	1 (<0.1%)	0	0		0	0	0	
Hypoglycaemia	低血糖症	2 (0.1%)	1 (<0.1%)	1 (<0.1%)		2 (0.1%)	0	0	
Hypokalaemia	低カリウム血症	10 (0.6%)	0	0		11 (0.6%)	2 (0.1%)	0	
Hypolipidaemia	低脂血症	0	0	0		1 (<0.1%)	0	0	
Hypomagnesaemia	低マグネシウム血症	0	1 (<0.1%)	0		0	0	0	
Hyponatraemia	低ナトリウム血症	0	0	0		1 (<0.1%)	0	1 (<0.1%)	
Hypoproteinaemia	低蛋白血症	0	1 (<0.1%)	0		0	0	0	
Hypovitaminosis	ビタミン欠乏症	0	0	0		1 (<0.1%)	0	0	
Iron deficiency	鉄欠乏	2 (0.1%)	3 (0.2%)	0		0	0	0	
Lipid metabolism disorder	脂質代謝障害	0	1 (<0.1%)	0		0	0	0	
Malnutrition	栄養障害	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Metabolic acidosis	代謝性アシドーシス	0	0	0		0	0	1 (<0.1%)	
Metabolic disorder	代謝障害	0	0	0		0	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	3 (0.2%)	0	0		6 (0.4%)	0	0	
Obesity	肥満	0	0	0		1 (<0.1%)	0	0	
Tetany	テタニー	1 (<0.1%)	0	0		0	0	0	
Type 2 diabetes mellitus	２型糖尿病	2 (0.1%)	0	0		1 (<0.1%)	0	0	
Vitamin B12 deficiency	ビタミンＢ１２欠乏	1 (<0.1%)	2 (0.1%)	0		0	1 (<0.1%)	0	
Vitamin D deficiency	ビタミンＤ欠乏	3 (0.2%)	0	0		2 (0.1%)	0	0	
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	182 (10.6%)	63 (3.7%)	7 (0.4%)	1 (<0.1%)	156 (9.1%)	61 (3.6%)	11 (0.6%)	
Arthralgia	関節痛	33 (1.9%)	9 (0.5%)	1 (<0.1%)		25 (1.5%)	11 (0.6%)	2 (0.1%)	
Arthritis	関節炎	4 (0.2%)	1 (<0.1%)	0		8 (0.5%)	4 (0.2%)	1 (<0.1%)	
Back pain	背部痛	36 (2.1%)	12 (0.7%)	2 (0.1%)		22 (1.3%)	9 (0.5%)	0	
Bone pain	骨痛	2 (0.1%)	2 (0.1%)	0		1 (<0.1%)	0	0	
Bursitis	滑液包炎	2 (0.1%)	4 (0.2%)	0		1 (<0.1%)	2 (0.1%)	0	
Chondrocalcinosis	軟骨石灰化症	0	0	0		1 (<0.1%)	0	0	
Coccydynia	尾骨痛	1 (<0.1%)	0	0		0	0	0	
Costochondritis	肋軟骨炎	1 (<0.1%)	0	0		0	0	0	
Exostosis	外骨腫	1 (<0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Fistula discharge	瘻孔分泌物	0	1 (<0.1%)	0		0	0	0	
Flank pain	側腹部痛	0	0	0		2 (0.1%)	2 (0.1%)	0	
Foot deformity	足変形	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Gouty arthritis	痛風性関節炎	1 (<0.1%)	0	0		2 (0.1%)	0	0	
Groin pain	鼠径部痛	4 (0.2%)	4 (0.2%)	0		3 (0.2%)	2 (0.1%)	0	
Haemarthrosis	出血性関節症	0	0	0		0	3 (0.2%)	1 (<0.1%)	
Intervertebral disc disorder	椎間板障害	1 (<0.1%)	0	0		0	0	0	
Intervertebral disc protrusion	椎間板突出	0	1 (<0.1%)	0		1 (<0.1%)	0	1 (<0.1%)	
Jaw cyst	顎骨嚢胞	0	0	0		1 (<0.1%)	0	0	
Joint effusion	関節滲出液	1 (<0.1%)	0	0		0	2 (0.1%)	0	
Joint range of motion decreased	関節可動域減少	1 (<0.1%)	0	0		0	0	0	
Joint stiffness	関節硬直	0	0	0		1 (<0.1%)	0	0	
Joint swelling	関節腫脹	7 (0.4%)	1 (<0.1%)	0	1 (<0.1%)	5 (0.3%)	0	0	
Juvenile arthritis	若年性関節炎	0	0	0		0	0	1 (<0.1%)	
Kyphosis	脊柱後弯症	1 (<0.1%)	0	0		0	0	0	
Ligament pain	靭帯痛	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Limb discomfort	四肢不快感	2 (0.1%)	0	0		6 (0.4%)	1 (<0.1%)	0	
Lower extremity mass	下肢腫瘤	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Medial tibial stress syndrome	脛骨内側過労性症候群	1 (<0.1%)	0	0		0	0	0	
Monarthritis	単関節炎	0	0	0		0	1 (<0.1%)	0	
Muscle atrophy	筋萎縮	0	0	0		1 (<0.1%)	0	0	
Muscle contracture	筋拘縮	1 (<0.1%)	0	0		0	0	0	
Muscle fatigue	筋肉疲労	2 (0.1%)	0	0		0	0	0	
Muscle haemorrhage	筋肉内出血	0	0	0		1 (<0.1%)	1 (<0.1%)	3 (0.2%)	
Muscle rigidity	筋固縮	1 (<0.1%)	0	0		0	0	0	
Muscle spasms	筋痙縮	21 (1.2%)	1 (<0.1%)	1 (<0.1%)		13 (0.8%)	1 (<0.1%)	0	
Muscle tightness	筋緊張	0	0	0		1 (<0.1%)	0	0	
Muscle twitching	筋攣縮	1 (<0.1%)	0	0		0	0	0	
Muscular weakness	筋力低下	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Musculoskeletal chest pain	筋骨格系胸痛	4 (0.2%)	0	0		2 (0.1%)	1 (<0.1%)	0	
Musculoskeletal discomfort	筋骨格不快感	1 (<0.1%)	1 (<0.1%)	0		2 (0.1%)	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Musculoskeletal pain	筋骨格痛	5 (0.3%)	3 (0.2%)	0		13 (0.8%)	3 (0.2%)	0	
Musculoskeletal stiffness	筋骨格硬直	2 (0.1%)	0	0		2 (0.1%)	0	0	
Myalgia	筋肉痛	8 (0.5%)	3 (0.2%)	0		4 (0.2%)	1 (<0.1%)	0	
Myosclerosis	筋硬化症	0	1 (<0.1%)	0		0	0	0	
Myositis	筋炎	1 (<0.1%)	0	0		0	0	0	
Neck mass	頚部腫瘤	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Neck pain	頚部痛	2 (0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Osteitis	骨炎	1 (<0.1%)	0	0		2 (0.1%)	0	0	
Osteoarthritis	変形性関節症	4 (0.2%)	1 (<0.1%)	1 (<0.1%)		7 (0.4%)	0	0	
Osteoarthropathy	骨関節障害	1 (<0.1%)	0	0		0	0	0	
Osteopenia	骨減少症	0	0	0		1 (<0.1%)	0	0	
Osteoporosis	骨粗鬆症	3 (0.2%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Pain in extremity	四肢痛	56 (3.3%)	18 (1.0%)	2 (0.1%)		48 (2.8%)	16 (0.9%)	2 (0.1%)	
Pain in jaw	顎痛	1 (<0.1%)	0	0		1 (<0.1%)	2 (0.1%)	0	
Pathological fracture	病的骨折	0	1 (<0.1%)	0		0	0	0	
Periarthritis	関節周囲炎	0	1 (<0.1%)	0		0	0	0	
Plantar fasciitis	足底筋膜炎	1 (<0.1%)	0	0		3 (0.2%)	0	0	
Polymyalgia rheumatica	リウマチ性多発筋痛	1 (<0.1%)	0	0		0	0	0	
Rotator cuff syndrome	肩回旋筋腱板症候群	2 (0.1%)	0	0		2 (0.1%)	1 (<0.1%)	0	
Sacroiliitis	仙腸骨炎	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Scoliosis	側弯症	0	1 (<0.1%)	0		0	0	0	
Spinal osteoarthritis	変形性脊椎症	5 (0.3%)	1 (<0.1%)	0		2 (0.1%)	1 (<0.1%)	0	
Spondylitis	脊椎炎	0	0	0		1 (<0.1%)	0	0	
Synovial cyst	滑液嚢腫	1 (<0.1%)	2 (0.1%)	0		4 (0.2%)	0	0	
Synovitis	滑膜炎	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Systemic lupus erythematosus	全身性エリテマトーデス	0	1 (<0.1%)	0		0	0	0	
Tendon pain	腱痛	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Tendonitis	腱炎	5 (0.3%)	1 (<0.1%)	0		5 (0.3%)	1 (<0.1%)	0	
Tenosynovitis	腱鞘炎	0	0	0		0	1 (<0.1%)	0	
Torticollis	斜頚	1 (<0.1%)	0	0		0	0	0	
Upper extremity mass	上肢腫瘤	1 (<0.1%)	0	0		0	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
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）	13 (0.8%)	17 (1.0%)	39 (2.3%)		21 (1.2%)	16 (0.9%)	32 (1.9%)	
Acute leukaemia	急性白血病	0	0	0		0	0	1 (<0.1%)	
Acute lymphocytic leukaemia	急性リンパ性白血病	0	0	1 (<0.1%)		0	0	0	
Adenocarcinoma	腺癌	0	0	1 (<0.1%)		0	0	0	
Adenoma benign	良性腺腫	1 (<0.1%)	0	0		0	0	0	
Adrenal adenoma	副腎腺腫	1 (<0.1%)	0	0		2 (0.1%)	0	0	
Angiomyolipoma	血管筋脂肪腫	1 (<0.1%)	0	0		0	0	0	
B-cell lymphoma	Ｂ細胞性リンパ腫	0	1 (<0.1%)	0		0	0	0	
Basal cell carcinoma	基底細胞癌	1 (<0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	0	
Benign lung neoplasm	肺の良性新生物	0	0	0		1 (<0.1%)	0	0	
Benign mediastinal neoplasm	縦隔の良性新生物	0	0	0		1 (<0.1%)	0	0	
Bladder cancer	膀胱癌	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Bladder transitional cell carcinoma stage I	膀胱移行上皮癌第１期	0	0	0		0	1 (<0.1%)	0	
Breast cancer	乳癌	0	1 (<0.1%)	2 (0.1%)		0	0	1 (<0.1%)	
Breast cancer metastatic	転移性乳癌	0	1 (<0.1%)	0		0	0	0	
Cervix cancer metastatic	転移性子宮頚部癌	0	1 (<0.1%)	0		0	0	0	
Cervix carcinoma	子宮頚部癌	0	0	2 (0.1%)		0	1 (<0.1%)	4 (0.2%)	
Cervix carcinoma stage III	子宮頚部癌第３期	0	0	1 (<0.1%)		0	0	0	
Colon cancer	結腸癌	0	1 (<0.1%)	2 (0.1%)		0	1 (<0.1%)	3 (0.2%)	
Colorectal cancer	結腸直腸癌	0	0	2 (0.1%)		0	0	0	
Ear neoplasm malignant	耳の悪性新生物	0	0	0		0	0	1 (<0.1%)	
Endometrial cancer	子宮内膜癌	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Erythroplasia	紅色肥厚症	0	0	0		1 (<0.1%)	0	0	
Fibroadenoma of breast	乳腺線維腺腫	0	0	0		1 (<0.1%)	0	0	
Fibroma	線維腫	0	0	0		1 (<0.1%)	0	0	
Gastric cancer	胃癌	0	0	1 (<0.1%)		0	0	1 (<0.1%)	
Gastric cancer recurrent	再発胃癌	0	0	1 (<0.1%)		0	0	0	
Glioblastoma	神経膠芽細胞腫	1 (<0.1%)	0	0		0	0	0	
Haemangioma of liver	肝臓血管腫	2 (0.1%)	0	0		2 (0.1%)	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Hepatic cancer metastatic	転移性肝癌	0	0	1 (<0.1%)		0	0	0	
Hepatic neoplasm malignant	肝の悪性新生物	0	0	2 (0.1%)		0	0	2 (0.1%)	
Hodgkin's disease	ホジキン病	0	0	0		0	1 (<0.1%)	0	
Large cell carcinoma of the respiratory tract stage unspecified	呼吸器大細胞癌、病期不明	0	0	0		0	0	1 (<0.1%)	
Large intestine carcinoma	大腸癌	0	0	1 (<0.1%)		0	0	0	
Lipoma	脂肪腫	3 (0.2%)	0	0		2 (0.1%)	0	0	
Lung adenocarcinoma	肺腺癌	0	0	0		0	1 (<0.1%)	2 (0.1%)	
Lung cancer metastatic	転移性肺癌	0	0	1 (<0.1%)		0	0	0	
Lung carcinoma cell type unspecified recurrent	再発肺癌、細胞タイプ不明	0	0	1 (<0.1%)		0	0	0	
Lung neoplasm	肺新生物	0	2 (0.1%)	0		4 (0.2%)	1 (<0.1%)	1 (<0.1%)	
Lung neoplasm malignant	肺の悪性新生物	1 (<0.1%)	0	1 (<0.1%)		0	0	2 (0.1%)	
Lymphoma	リンパ腫	0	1 (<0.1%)	2 (0.1%)		0	0	1 (<0.1%)	
Lymphoma cutis	皮膚型リンパ腫	0	1 (<0.1%)	0		0	0	0	
Malignant melanoma	悪性黒色腫	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Malignant melanoma in situ	表皮内悪性黒色腫	0	1 (<0.1%)	0		0	0	0	
Meningioma	髄膜腫	0	0	0		1 (<0.1%)	0	0	
Metastases to abdominal cavity	腹腔内転移	0	0	0		0	1 (<0.1%)	0	
Metastases to central nervous system	中枢神経系転移	0	0	1 (<0.1%)		0	0	0	
Metastases to liver	肝転移	0	1 (<0.1%)	1 (<0.1%)		1 (<0.1%)	1 (<0.1%)	2 (0.1%)	
Metastases to lung	肺転移	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Metastases to lymph nodes	リンパ節転移	0	2 (0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Metastases to spine	脊椎転移	0	0	0		0	1 (<0.1%)	0	
Metastatic neoplasm	転移性新生物	0	0	2 (0.1%)		0	0	0	
Metastatic squamous cell carcinoma	転移性扁平上皮癌	0	0	0		0	0	1 (<0.1%)	
Non-Hodgkin's lymphoma	非ホジキンリンパ腫	0	0	2 (0.1%)		0	0	0	
Oesophageal adenocarcinoma	食道腺癌	0	0	1 (<0.1%)		0	0	0	
Oesophageal carcinoma	食道癌	0	0	0		0	0	1 (<0.1%)	
Ovarian cancer	卵巣癌	0	0	1 (<0.1%)		0	1 (<0.1%)	1 (<0.1%)	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Ovarian cancer metastatic	転移性卵巣癌	0	0	0		0	0	1 (<0.1%)	
Ovarian cancer recurrent	再発卵巣癌	0	0	0		0	0	1 (<0.1%)	
Ovarian epithelial cancer	卵巣上皮癌	0	0	0		0	0	1 (<0.1%)	
Pancreatic carcinoma	膵癌	0	0	2 (0.1%)		0	0	0	
Pelvic neoplasm	骨盤新生物	0	0	1 (<0.1%)		0	0	0	
Penis carcinoma	陰茎癌	0	0	0		0	0	1 (<0.1%)	
Pleural neoplasm	胸膜新生物	1 (<0.1%)	0	0		0	0	0	
Polycythaemia vera	真性多血症	0	0	0		0	1 (<0.1%)	0	
Prostate cancer	前立腺癌	0	0	1 (<0.1%)		1 (<0.1%)	1 (<0.1%)	0	
Prostate cancer metastatic	転移性前立腺癌	0	0	0		0	1 (<0.1%)	0	
Pyogenic granuloma	化膿性肉芽腫	0	0	0		1 (<0.1%)	0	0	
Rectal adenoma	直腸腺腫	0	0	0		1 (<0.1%)	0	0	
Rectal cancer	直腸癌	0	1 (<0.1%)	0		0	1 (<0.1%)	1 (<0.1%)	
Rectal cancer recurrent	再発直腸癌	0	0	1 (<0.1%)		0	0	0	
Renal cell carcinoma	腎細胞癌	0	1 (<0.1%)	0		0	0	0	
Renal cell carcinoma recurrent	再発腎細胞癌	0	0	0		0	0	1 (<0.1%)	
Renal neoplasm	腎新生物	0	1 (<0.1%)	0		0	0	1 (<0.1%)	
Retroperitoneal neoplasm	後腹膜新生物	0	0	0		0	0	1 (<0.1%)	
Rhabdomyosarcoma	横紋筋肉腫	0	0	1 (<0.1%)		0	0	0	
Seborrhoeic keratosis	脂漏性角化症	1 (<0.1%)	0	0		0	0	0	
Skin cancer	皮膚癌	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Small cell lung cancer metastatic	転移性小細胞肺癌	0	0	1 (<0.1%)		0	0	0	
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Superficial spreading melanoma stage unspecified	表在拡大型黒色腫、病期不明	0	1 (<0.1%)	0		0	0	0	
Uterine leiomyoma	子宮平滑筋腫	2 (0.1%)	1 (<0.1%)	0		2 (0.1%)	1 (<0.1%)	0	
Uterine neoplasm	子宮新生物	0	1 (<0.1%)	0		0	0	0	
Waldenstrom's macroglobulinaemia	ワルデンストローム・マクログロブリン血症	0	0	1 (<0.1%)		0	0	0	
Nervous system disorders	神経系障害	141 (8.2%)	45 (2.6%)	12 (0.7%)		88 (5.1%)	35 (2.0%)	10 (0.6%)	
Amnesia	健忘	0	0	0		2 (0.1%)	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Aphonia	失声症	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Ataxia	運動失調	1 (<0.1%)	0	0		0	0	0	
Balance disorder	平衡障害	0	0	0		1 (<0.1%)	0	0	
Brain injury	脳損傷	0	0	0		1 (<0.1%)	0	0	
Burning sensation	灼熱感	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Carpal tunnel syndrome	手根管症候群	0	0	0		0	1 (<0.1%)	0	
Cerebral arteriosclerosis	脳動脈硬化症	0	1 (<0.1%)	0		0	0	0	
Cerebral atrophy	大脳萎縮	0	0	0		1 (<0.1%)	0	0	
Cerebral haemorrhage	脳出血	0	0	1 (<0.1%)		0	0	1 (<0.1%)	
Cervical root pain	頚髄神経根痛	0	1 (<0.1%)	0		0	0	0	
Cervicobrachial syndrome	頚腕症候群	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Cognitive disorder	認知障害	0	0	1 (<0.1%)		0	0	0	
Complex regional pain syndrome	複合性局所疼痛症候群	0	0	0		0	2 (0.1%)	0	
Convulsion	痙攣	0	0	0		0	1 (<0.1%)	0	
Dementia	認知症	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Diabetic neuropathy	糖尿病性ニューロパチー	0	0	0		1 (<0.1%)	0	0	
Dizziness	浮動性めまい	30 (1.7%)	8 (0.5%)	0		20 (1.2%)	2 (0.1%)	0	
Dizziness postural	体位性めまい	0	0	0		1 (<0.1%)	0	0	
Dysaesthesia	異常感覚	1 (<0.1%)	0	0		0	0	0	
Dysgeusia	味覚異常	3 (0.2%)	0	0		0	0	0	
Epilepsy	てんかん	0	1 (<0.1%)	1 (<0.1%)		0	0	0	
Facial neuralgia	顔面部神経痛	0	0	0		0	0	1 (<0.1%)	
Haemorrhage intracranial	頭蓋内出血	0	0	1 (<0.1%)		0	1 (<0.1%)	1 (<0.1%)	
Head discomfort	頭部不快感	1 (<0.1%)	0	0		0	0	0	
Headache	頭痛	74 (4.3%)	15 (0.9%)	2 (0.1%)		52 (3.0%)	16 (0.9%)	0	
Hyperaesthesia	知覚過敏	0	1 (<0.1%)	0		0	0	0	
Hypoaesthesia	感覚鈍麻	3 (0.2%)	0	0		6 (0.4%)	1 (<0.1%)	0	
Hypoglycaemic coma	低血糖昏睡	0	0	1 (<0.1%)		0	0	0	
IIIrd nerve paresis	第３脳神経不全麻痺	0	0	0		0	1 (<0.1%)	0	
Ischaemic stroke	虚血性脳卒中	0	2 (0.1%)	1 (<0.1%)		0	0	5 (0.3%)	
Lethargy	嗜眠	4 (0.2%)	1 (<0.1%)	0		2 (0.1%)	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Meralgia paraesthetica	感覚異常性大腿神経痛	0	1 (<0.1%)	0		0	0	0	
Metabolic encephalopathy	代謝性脳症	0	0	1 (<0.1%)		0	0	0	
Migraine	片頭痛	0	1 (<0.1%)	1 (<0.1%)		0	1 (<0.1%)	0	
Mononeuritis	単神経炎	0	1 (<0.1%)	0		0	0	0	
Motor dysfunction	運動機能障害	0	0	0		0	1 (<0.1%)	0	
Movement disorder	運動障害	0	0	0		0	1 (<0.1%)	0	
Multiple sclerosis	多発性硬化症	0	1 (<0.1%)	0		0	0	0	
Muscle contractions involuntary	不随意性筋収縮	0	0	0		1 (<0.1%)	0	0	
Myelitis	脊髄炎	0	0	0		0	1 (<0.1%)	0	
Nerve compression	神経圧迫	0	0	0		1 (<0.1%)	0	0	
Neuralgia	神経痛	0	1 (<0.1%)	0		1 (<0.1%)	0	1 (<0.1%)	
Neuritis cranial	脳神経炎	0	0	0		1 (<0.1%)	0	0	
Neuropathy peripheral	末梢性ニューロパチー	1 (<0.1%)	1 (<0.1%)	0		2 (0.1%)	0	1 (<0.1%)	
Paraesthesia	錯感覚	16 (0.9%)	1 (<0.1%)	0		6 (0.4%)	1 (<0.1%)	0	
Parkinson's disease	パーキンソン病	0	0	1 (<0.1%)		0	0	0	
Parkinsonism	パーキンソニズム	0	0	0		0	1 (<0.1%)	0	
Peripheral nerve palsy	末梢神経麻痺	1 (<0.1%)	0	0		0	0	0	
Peripheral sensorimotor neuropathy	末梢性感覚運動ニューロパチー	0	1 (<0.1%)	0		0	0	0	
Polyneuropathy	多発ニューロパチー	1 (<0.1%)	0	0		0	0	0	
Post herpetic neuralgia	ヘルペス後神経痛	1 (<0.1%)	0	0		0	0	0	
Presyncope	失神寸前の状態	3 (0.2%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Pseudoradicular syndrome	偽性根症候群	1 (<0.1%)	0	0		0	0	0	
Restless legs syndrome	下肢静止不能症候群	2 (0.1%)	0	0		0	0	0	
Sciatica	坐骨神経痛	4 (0.2%)	4 (0.2%)	0		1 (<0.1%)	2 (0.1%)	0	
Senile dementia	老年認知症	0	0	0		1 (<0.1%)	0	0	
Sensory disturbance	感覚障害	2 (0.1%)	0	0		0	0	0	
Somnolence	傾眠	2 (0.1%)	2 (0.1%)	0		0	0	0	
Spinal cord compression	脊髄圧迫	0	1 (<0.1%)	0		0	0	0	
Syncope	失神	8 (0.5%)	1 (<0.1%)	1 (<0.1%)		4 (0.2%)	2 (0.1%)	0	
Tension headache	緊張性頭痛	1 (<0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Transient ischaemic attack	一過性脳虚血発作	1 (<0.1%)	0	0		1 (<0.1%)	3 (0.2%)	0	
Tremor	振戦	1 (<0.1%)	1 (<0.1%)	0		2 (0.1%)	0	0	
Vascular encephalopathy	血管性脳症	0	0	0		1 (<0.1%)	0	0	
Vertebrobasilar insufficiency	椎骨脳底動脈不全	0	0	0		0	1 (<0.1%)	0	
Pregnancy, puerperium and perinatal conditions	妊娠、産褥および周産期の状態	2 (0.1%)	0	0		2 (0.1%)	0	0	
Post abortion haemorrhage	流産後の出血	1 (<0.1%)	0	0		0	0	0	
Pregnancy	妊娠	1 (<0.1%)	0	0		2 (0.1%)	0	0	
Psychiatric disorders	精神障害	56 (3.3%)	14 (0.8%)	4 (0.2%)		39 (2.3%)	14 (0.8%)	3 (0.2%)	
Acute psychosis	急性精神病	0	0	0		0	0	1 (<0.1%)	
Affective disorder	感情障害	1 (<0.1%)	0	0		0	0	0	
Agitation	激越	1 (<0.1%)	0	0		0	0	0	
Alcohol abuse	アルコール乱用	0	0	0		1 (<0.1%)	0	0	
Alcohol withdrawal syndrome	アルコール離脱症候群	0	0	0		0	1 (<0.1%)	0	
Anxiety	不安	15 (0.9%)	9 (0.5%)	0		10 (0.6%)	1 (<0.1%)	0	
Attention deficit/hyperactivity disorder	注意欠陥多動性障害	0	0	0		0	1 (<0.1%)	0	
Completed suicide	自殺既遂	0	0	0		0	0	1 (<0.1%)	
Confusional state	錯乱状態	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Delirium	譫妄	0	0	0		0	1 (<0.1%)	0	
Depressed mood	抑うつ気分	2 (0.1%)	0	0		1 (<0.1%)	0	0	
Depression	うつ病	12 (0.7%)	5 (0.3%)	3 (0.2%)		6 (0.4%)	4 (0.2%)	0	
Insomnia	不眠症	25 (1.5%)	3 (0.2%)	0		15 (0.9%)	3 (0.2%)	0	
Libido decreased	リビドー減退	2 (0.1%)	0	0		0	0	0	
Major depression	大うつ病	0	1 (<0.1%)	0		0	0	0	
Mood swings	気分動揺	1 (<0.1%)	0	0		0	0	0	
Panic attack	パニック発作	2 (0.1%)	0	0		0	1 (<0.1%)	1 (<0.1%)	
Psychotic disorder	精神病性障害	0	0	1 (<0.1%)		0	0	0	
Restlessness	落ち着きのなさ	0	0	0		1 (<0.1%)	0	0	
Senile psychosis	老人性精神病	0	0	0		1 (<0.1%)	0	0	
Sleep disorder	睡眠障害	2 (0.1%)	0	0		4 (0.2%)	1 (<0.1%)	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Stress	ストレス	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Suicide attempt	自殺企図	0	0	1 (<0.1%)		0	0	0	
Renal and urinary disorders	腎および尿路障害	50 (2.9%)	16 (0.9%)	5 (0.3%)		52 (3.0%)	22 (1.3%)	4 (0.2%)	
Acute prerenal failure	急性腎前性腎不全	1 (<0.1%)	0	0		0	0	0	
Anuria	無尿	0	0	1 (<0.1%)		1 (<0.1%)	0	0	
Bladder diverticulum	膀胱憩室	0	0	0		1 (<0.1%)	0	0	
Calculus ureteric	尿管結石	0	2 (0.1%)	0		0	0	0	
Calculus urinary	尿路結石	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Chromaturia	着色尿	0	0	0		2 (0.1%)	0	0	
Cystitis haemorrhagic	出血性膀胱炎	0	0	1 (<0.1%)		0	0	0	
Cystitis noninfective	非感染性膀胱炎	0	0	0		1 (<0.1%)	0	0	
Dysuria	排尿困難	2 (0.1%)	0	0		2 (0.1%)	1 (<0.1%)	0	
Glomerulonephritis chronic	慢性糸球体腎炎	1 (<0.1%)	0	0		0	0	0	
Haematuria	血尿	29 (1.7%)	9 (0.5%)	1 (<0.1%)		28 (1.6%)	13 (0.8%)	0	
Hydronephrosis	水腎症	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Lupus nephritis	ループス腎炎	0	1 (<0.1%)	0		0	0	0	
Nephrolithiasis	腎結石症	3 (0.2%)	0	0		6 (0.4%)	0	1 (<0.1%)	
Nephropathy	腎症	1 (<0.1%)	0	0		2 (0.1%)	0	0	
Nephrotic syndrome	ネフローゼ症候群	0	1 (<0.1%)	0		0	0	0	
Nocturia	夜間頻尿	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Pollakiuria	頻尿	3 (0.2%)	0	0		0	0	0	
Pyelocaliectasis	腎盂腎杯拡張症	1 (<0.1%)	0	0		0	0	0	
Renal colic	腎仙痛	0	0	0		0	1 (<0.1%)	1 (<0.1%)	
Renal cyst	腎嚢胞	9 (0.5%)	0	0		11 (0.6%)	1 (<0.1%)	0	
Renal failure	腎不全	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)		0	0	1 (<0.1%)	
Renal failure acute	急性腎不全	0	1 (<0.1%)	1 (<0.1%)		2 (0.1%)	3 (0.2%)	1 (<0.1%)	
Renal failure chronic	慢性腎不全	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Residual urine	残尿	1 (<0.1%)	0	0		0	0	0	
Urethral haemorrhage	尿道出血	0	0	0		1 (<0.1%)	0	0	
Urinary incontinence	尿失禁	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Urinary retention	尿閉	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Urinary tract obstruction	尿路閉塞	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Urine odour abnormal	尿臭異常	0	0	0		1 (<0.1%)	0	0	
Reproductive system and breast disorders	生殖系および乳房障害	69 (4.0%)	40 (2.3%)	6 (0.3%)		45 (2.6%)	18 (1.1%)	2 (0.1%)	
Adenomyosis	腺筋症	1 (<0.1%)	0	0		0	0	0	
Adnexa uteri cyst	子宮付属器嚢胞	0	1 (<0.1%)	0		0	0	0	
Benign prostatic hyperplasia	良性前立腺肥大症	6 (0.3%)	0	0		10 (0.6%)	0	0	
Breast engorgement	乳房うっ滞	0	0	0		0	1 (<0.1%)	0	
Breast hyperplasia	乳房過形成	1 (<0.1%)	0	0		0	0	0	
Breast mass	乳房腫瘤	1 (<0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	0	
Breast pain	乳房痛	1 (<0.1%)	0	0		0	0	0	
Cervical polyp	子宮頚管ポリープ	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Dysfunctional uterine bleeding	機能障害性子宮出血	0	1 (<0.1%)	0		0	0	0	
Dysmenorrhoea	月経困難症	3 (0.2%)	0	0		6 (0.4%)	0	0	
Endometrial hyperplasia	子宮内膜増殖症	0	1 (<0.1%)	0		0	0	0	
Epididymitis	精巣上体炎	0	0	0		1 (<0.1%)	0	0	
Erectile dysfunction	勃起不全	3 (0.2%)	0	0		3 (0.2%)	0	0	
Fibrocystic breast disease	線維嚢胞性乳腺疾患	1 (<0.1%)	0	0		0	0	0	
Genital cyst	生殖器嚢胞	1 (<0.1%)	0	0		0	0	0	
Genital discharge	性器分泌物	0	0	0		1 (<0.1%)	0	0	
Genital pain	生殖器痛	0	0	0		1 (<0.1%)	0	0	
Gynaecomastia	女性化乳房	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Haemorrhagic ovarian cyst	出血性卵巣嚢胞	1 (<0.1%)	0	0		0	0	0	
Menometrorrhagia	機能性子宮出血	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Menorrhagia	月経過多	24 (1.4%)	21 (1.2%)	4 (0.2%)		10 (0.6%)	8 (0.5%)	1 (<0.1%)	
Menstrual disorder	月経障害	2 (0.1%)	0	0		0	0	0	
Menstruation irregular	不規則月経	1 (<0.1%)	0	0		0	0	0	
Metrorrhagia	不正子宮出血	8 (0.5%)	2 (0.1%)	0		2 (0.1%)	1 (<0.1%)	0	
Oedema genital	性器浮腫	1 (<0.1%)	0	0		0	0	0	
Oligomenorrhoea	希発月経	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Ovarian cyst	卵巣嚢胞	2 (0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Ovarian mass	卵巣腫瘤	1 (<0.1%)	0	0		0	0	0	
Penile haemorrhage	陰茎出血	0	0	0		1 (<0.1%)	0	0	
Penile swelling	陰茎腫脹	0	0	0		0	0	1 (<0.1%)	
Postmenopausal haemorrhage	閉経後出血	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Premenstrual syndrome	月経前症候群	0	0	0		0	1 (<0.1%)	0	
Prostatitis	前立腺炎	0	0	1 (<0.1%)		2 (0.1%)	0	0	
Prostatomegaly	前立腺腫大	1 (<0.1%)	0	0		0	0	0	
Pruritus genital	陰部そう痒症	0	0	0		1 (<0.1%)	0	0	
Scrotal swelling	陰嚢腫脹	0	0	0		0	1 (<0.1%)	1 (<0.1%)	
Uterine enlargement	子宮肥大	1 (<0.1%)	0	0		0	0	0	
Uterine haemorrhage	子宮出血	0	0	0		1 (<0.1%)	0	0	
Uterine polyp	子宮ポリープ	0	1 (<0.1%)	0		0	0	0	
Vaginal discharge	膣分泌物	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Vaginal haemorrhage	膣出血	17 (1.0%)	10 (0.6%)	1 (<0.1%)		7 (0.4%)	4 (0.2%)	0	
Vulvovaginal pain	外陰膣痛	0	0	0		1 (<0.1%)	0	0	
Vulvovaginal pruritus	外陰膣そう痒症	0	0	0		1 (<0.1%)	0	0	
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	189 (11.0%)	37 (2.2%)	8 (0.5%)		161 (9.4%)	37 (2.2%)	8 (0.5%)	
Acute respiratory failure	急性呼吸不全	0	0	0		0	1 (<0.1%)	0	
Allergic pharyngitis	アレルギー性咽頭炎	0	0	0		1 (<0.1%)	0	0	
Asthma	喘息	2 (0.1%)	1 (<0.1%)	1 (<0.1%)		0	2 (0.1%)	2 (0.1%)	
Atelectasis	無気肺	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Bronchitis chronic	慢性気管支炎	2 (0.1%)	0	0		0	0	0	
Bronchospasm	気管支痙攣	1 (<0.1%)	0	0		3 (0.2%)	0	0	
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	2 (0.1%)	3 (0.2%)	0		0	2 (0.1%)	1 (<0.1%)	
Cough	咳嗽	63 (3.7%)	8 (0.5%)	1 (<0.1%)		46 (2.7%)	5 (0.3%)	0	
Dysphonia	発声障害	3 (0.2%)	0	0		1 (<0.1%)	0	0	
Dyspnoea	呼吸困難	27 (1.6%)	5 (0.3%)	1 (<0.1%)		22 (1.3%)	14 (0.8%)	1 (<0.1%)	
Dyspnoea at rest	安静時呼吸困難	0	1 (<0.1%)	0		0	0	0	
Dyspnoea exertional	労作性呼吸困難	6 (0.3%)	1 (<0.1%)	0		4 (0.2%)	2 (0.1%)	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Emphysema	肺気腫	1 (<0.1%)	0	0		0	0	0	
Epistaxis	鼻出血	78 (4.5%)	10 (0.6%)	1 (<0.1%)		68 (4.0%)	4 (0.2%)	2 (0.1%)	
Haemoptysis	喀血	15 (0.9%)	4 (0.2%)	0		15 (0.9%)	2 (0.1%)	0	
Haemothorax	血胸	0	0	0		0	0	1 (<0.1%)	
Hiccups	しゃっくり	1 (<0.1%)	0	0		0	0	0	
Hyperventilation	過換気	0	0	0		0	1 (<0.1%)	0	
Hypoxia	低酸素症	0	0	0		0	1 (<0.1%)	0	
Increased upper airway secretion	上気道分泌増加	1 (<0.1%)	0	0		0	0	0	
Interstitial lung disease	間質性肺疾患	0	0	0		0	0	1 (<0.1%)	
Lung consolidation	肺硬化	0	0	0		1 (<0.1%)	0	0	
Lung disorder	肺障害	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Nasal congestion	鼻閉	3 (0.2%)	0	0		2 (0.1%)	0	0	
Oropharyngeal blistering	口腔咽頭水疱形成	0	0	0		1 (<0.1%)	0	0	
Oropharyngeal pain	口腔咽頭痛	15 (0.9%)	1 (<0.1%)	0		4 (0.2%)	2 (0.1%)	0	
Orthopnoea	起坐呼吸	1 (<0.1%)	0	0		0	0	0	
Painful respiration	呼吸時疼痛	1 (<0.1%)	0	0		0	0	0	
Paranasal cyst	副鼻腔嚢胞	1 (<0.1%)	0	0		0	0	0	
Pharyngeal inflammation	咽頭の炎症	1 (<0.1%)	0	0		0	0	0	
Pleural effusion	胸水	3 (0.2%)	1 (<0.1%)	0		2 (0.1%)	2 (0.1%)	0	
Pleural fibrosis	胸膜線維症	0	0	0		1 (<0.1%)	0	0	
Pleurisy	胸膜炎	0	0	0		0	1 (<0.1%)	0	
Pleuritic pain	胸膜痛	0	0	0		0	1 (<0.1%)	0	
Postnasal drip	後鼻漏	0	0	0		1 (<0.1%)	0	0	
Productive cough	湿性咳嗽	2 (0.1%)	1 (<0.1%)	0		3 (0.2%)	0	0	
Pulmonary embolism	肺塞栓症	0	0	1 (<0.1%)		0	0	1 (<0.1%)	
Pulmonary fibrosis	肺線維症	0	1 (<0.1%)	0		0	0	0	
Pulmonary hypertension	肺高血圧症	0	0	0		1 (<0.1%)	2 (0.1%)	0	
Pulmonary infarction	肺梗塞	0	0	0		1 (<0.1%)	0	0	
Pulmonary mass	肺腫瘤	0	0	1 (<0.1%)		0	0	0	
Pulmonary oedema	肺水腫	0	0	0		0	1 (<0.1%)	0	
Rales	ラ音	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Respiratory distress	呼吸窮迫	0	0	0		0	1 (<0.1%)	0	
Respiratory failure	呼吸不全	0	0	2 (0.1%)		0	0	0	
Respiratory tract congestion	気道うっ血	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Respiratory tract inflammation	気道の炎症	0	0	0		1 (<0.1%)	0	0	
Rhinitis allergic	アレルギー性鼻炎	0	0	0		2 (0.1%)	1 (<0.1%)	0	
Rhinitis atrophic	萎縮性鼻炎	1 (<0.1%)	0	0		0	0	0	
Rhinorrhoea	鼻漏	2 (0.1%)	0	0		6 (0.4%)	1 (<0.1%)	0	
Sinus congestion	副鼻腔うっ血	0	1 (<0.1%)	0		2 (0.1%)	0	0	
Sleep apnoea syndrome	睡眠時無呼吸症候群	0	0	0		1 (<0.1%)	0	0	
Sputum retention	痰貯留	1 (<0.1%)	0	0		0	0	0	
Tachypnoea	頻呼吸	1 (<0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	1 (<0.1%)	
Throat irritation	咽喉刺激感	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Upper airway obstruction	上気道閉塞	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Wegener's granulomatosis	ウェゲナー肉芽腫症	0	1 (<0.1%)	0		0	0	0	
Wheezing	喘鳴	2 (0.1%)	0	0		1 (<0.1%)	0	0	
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	125 (7.3%)	23 (1.3%)	1 (<0.1%)		127 (7.4%)	33 (1.9%)	3 (0.2%)	
Acne	ざ瘡	1 (<0.1%)	0	0		0	0	0	
Actinic keratosis	日光性角化症	0	0	0		1 (<0.1%)	0	0	
Alopecia	脱毛症	8 (0.5%)	2 (0.1%)	0		11 (0.6%)	3 (0.2%)	0	
Blister	水疱	1 (<0.1%)	0	0		2 (0.1%)	0	0	
Blood blister	血性水疱	0	0	0		1 (<0.1%)	0	0	
Decubitus ulcer	褥瘡性潰瘍	2 (0.1%)	1 (<0.1%)	0		2 (0.1%)	0	0	
Dermal cyst	皮膚嚢腫	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Dermatitis	皮膚炎	4 (0.2%)	0	0		5 (0.3%)	1 (<0.1%)	0	
Dermatitis allergic	アレルギー性皮膚炎	0	1 (<0.1%)	0		1 (<0.1%)	0	1 (<0.1%)	
Dermatitis contact	接触性皮膚炎	2 (0.1%)	0	0		2 (0.1%)	0	0	
Dermatitis exfoliative	剥脱性皮膚炎	0	0	0		0	2 (0.1%)	0	
Dermatitis herpetiformis	疱疹状皮膚炎	1 (<0.1%)	0	0		0	0	0	
Dermatosis	皮膚症	0	0	0		0	1 (<0.1%)	0	
Drug eruption	薬疹	1 (<0.1%)	0	0		2 (0.1%)	1 (<0.1%)	0	
Dry skin	皮膚乾燥	6 (0.3%)	0	0		10 (0.6%)	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Ecchymosis	斑状出血	2 (0.1%)	0	1 (<0.1%)		6 (0.4%)	0	1 (<0.1%)	
Eczema	湿疹	6 (0.3%)	0	0		7 (0.4%)	0	1 (<0.1%)	
Ephelides	雀卵斑	1 (<0.1%)	0	0		0	0	0	
Erythema	紅斑	4 (0.2%)	0	0		7 (0.4%)	3 (0.2%)	0	
Erythema multiforme	多形紅斑	0	0	0		1 (<0.1%)	0	0	
Exfoliative rash	剥脱性発疹	1 (<0.1%)	0	0		0	0	0	
Generalised erythema	全身紅斑	0	1 (<0.1%)	0		0	0	0	
Haemorrhage subcutaneous	皮下出血	1 (<0.1%)	0	0		0	0	0	
Haemorrhagic urticaria	出血性蕁麻疹	0	0	0		1 (<0.1%)	0	0	
Henoch-Schonlein purpura	ヘノッホ・シェーンライン紫斑病	0	0	0		0	1 (<0.1%)	0	
Hyperhidrosis	多汗症	4 (0.2%)	2 (0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Hypoaesthesia facial	顔面感覚鈍麻	1 (<0.1%)	0	0		0	0	0	
Increased tendency to bruise	挫傷発生の増加傾向	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Leukocytoclastic vasculitis	白血球破砕性血管炎	0	0	0		0	1 (<0.1%)	0	
Livedo reticularis	網状皮斑	0	0	0		1 (<0.1%)	0	0	
Nail bed bleeding	爪床出血	1 (<0.1%)	0	0		0	0	0	
Nail bed inflammation	爪床の炎症	0	0	0		1 (<0.1%)	0	0	
Night sweats	寝汗	7 (0.4%)	0	0		3 (0.2%)	2 (0.1%)	0	
Onychoclasis	爪破損	1 (<0.1%)	0	0		0	0	0	
Panniculitis	脂肪織炎	1 (<0.1%)	0	0		0	0	0	
Petechiae	点状出血	2 (0.1%)	0	0		6 (0.4%)	0	0	
Photosensitivity allergic reaction	アレルギー性光線過敏性反応	1 (<0.1%)	0	0		0	0	0	
Pigmentation disorder	色素沈着障害	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Pruritus	そう痒症	27 (1.6%)	2 (0.1%)	0		26 (1.5%)	5 (0.3%)	0	
Pruritus allergic	アレルギー性そう痒症	0	0	0		1 (<0.1%)	0	0	
Pruritus generalised	全身性そう痒症	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Psoriasis	乾癬	2 (0.1%)	0	0		1 (<0.1%)	0	0	
Purpura	紫斑	0	0	0		3 (0.2%)	0	0	
Rash	発疹	19 (1.1%)	7 (0.4%)	0		24 (1.4%)	3 (0.2%)	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Rash erythematous	紅斑性皮疹	0	0	0		2 (0.1%)	0	0	
Rash generalised	全身性皮疹	0	0	0		0	1 (<0.1%)	0	
Rash macular	斑状皮疹	0	0	0		1 (<0.1%)	0	0	
Rash papular	丘疹	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Rash pruritic	そう痒性皮疹	0	0	0		2 (0.1%)	0	0	
Scab	痂皮	1 (<0.1%)	0	0		0	0	0	
Scar	瘢痕	0	0	0		0	1 (<0.1%)	0	
Seborrhoeic dermatitis	脂漏性皮膚炎	1 (<0.1%)	0	0		0	0	0	
Skin discolouration	皮膚変色	3 (0.2%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Skin disorder	皮膚障害	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Skin exfoliation	皮膚剥脱	1 (<0.1%)	0	0		0	0	0	
Skin fragility	皮膚脆弱性	0	1 (<0.1%)	0		0	0	0	
Skin haemorrhage	皮膚出血	7 (0.4%)	2 (0.1%)	0		6 (0.4%)	1 (<0.1%)	0	
Skin hyperpigmentation	皮膚色素過剰	1 (<0.1%)	0	0		0	0	0	
Skin induration	皮膚硬結	1 (<0.1%)	0	0		0	0	0	
Skin irritation	皮膚刺激	0	0	0		2 (0.1%)	0	0	
Skin lesion	皮膚病変	4 (0.2%)	1 (<0.1%)	0		3 (0.2%)	0	0	
Skin mass	皮膚腫瘤	0	0	0		1 (<0.1%)	0	0	
Skin oedema	皮膚浮腫	0	0	0		0	1 (<0.1%)	0	
Skin striae	皮膚線条	0	0	0		1 (<0.1%)	0	0	
Skin swelling	皮膚腫脹	0	0	0		1 (<0.1%)	0	0	
Skin ulcer	皮膚潰瘍	6 (0.3%)	1 (<0.1%)	0		6 (0.4%)	3 (0.2%)	0	
Skin ulcer haemorrhage	出血性皮膚潰瘍	0	0	0		1 (<0.1%)	0	0	
Spider naevus	くも状母斑	1 (<0.1%)	0	0		0	0	0	
Stasis dermatitis	うっ滞性皮膚炎	0	0	0		1 (<0.1%)	0	0	
Telangiectasia	毛細血管拡張症	0	0	0		1 (<0.1%)	0	0	
Urticaria	蕁麻疹	4 (0.2%)	1 (<0.1%)	0		2 (0.1%)	1 (<0.1%)	0	
Surgical and medical procedures	外科および内科処置	9 (0.5%)	3 (0.2%)	0		9 (0.5%)	2 (0.1%)	0	
Abortion induced	人工流産	0	0	0		1 (<0.1%)	0	0	
Bariatric gastric balloon insertion	肥満症に対する胃内バルーン挿入	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Bladder catheter removal	膀胱カテーテル除去	0	1 (<0.1%)	0		0	0	0	
Cataract operation	白内障手術	1 (<0.1%)	0	0		0	0	0	
Cerumen removal	耳垢除去	1 (<0.1%)	0	0		0	0	0	
Colon polypectomy	結腸ポリープ切除	0	0	0		1 (<0.1%)	0	0	
Dental cleaning	歯牙清掃	1 (<0.1%)	0	0		0	0	0	
Dental implantation	歯科インプラント埋込み	2 (0.1%)	0	0		0	0	0	
Ear tube insertion	耳チューブ挿入	1 (<0.1%)	0	0		0	0	0	
High frequency ablation	高周波アブレーション	1 (<0.1%)	0	0		0	0	0	
Ileostomy closure	回腸瘻閉鎖	1 (<0.1%)	0	0		0	0	0	
Incisional hernia repair	瘢痕ヘルニア修復	1 (<0.1%)	0	0		0	0	0	
Intervertebral disc operation	椎間板手術	0	0	0		0	1 (<0.1%)	0	
Intestinal polypectomy	腸ポリープ切除	0	0	0		1 (<0.1%)	0	0	
Intra-uterine contraceptive device insertion	子宮内避妊具挿入	1 (<0.1%)	0	0		0	0	0	
Knee operation	膝手術	0	1 (<0.1%)	0		0	0	0	
Meniscus operation	半月板手術	0	1 (<0.1%)	0		0	0	0	
Removal of internal fixation	内固定除去	0	0	0		1 (<0.1%)	0	0	
Sinus operation	副鼻腔手術	1 (<0.1%)	0	0		0	0	0	
Skin neoplasm excision	皮膚新生物切除	0	0	0		1 (<0.1%)	0	0	
Tooth extraction	抜歯	0	0	0		1 (<0.1%)	0	0	
Transurethral prostatectomy	経尿道的前立腺摘除	0	0	0		0	1 (<0.1%)	0	
Uterine polypectomy	子宮ポリープ切除	0	0	0		1 (<0.1%)	0	0	
Vasectomy	精管切除	1 (<0.1%)	0	0		0	0	0	
Vena cava filter insertion	大静脈フィルター挿入	0	0	0		1 (<0.1%)	0	0	
Vascular disorders	血管障害	97 (5.6%)	35 (2.0%)	5 (0.3%)		127 (7.4%)	35 (2.0%)	10 (0.6%)	
Angiosclerosis	血管硬化	1 (<0.1%)	0	0		0	0	0	
Aortic aneurysm	大動脈瘤	0	1 (<0.1%)	0		0	3 (0.2%)	0	
Aortic arteriosclerosis	大動脈硬化症	2 (0.1%)	2 (0.1%)	0		1 (<0.1%)	0	0	
Aortic stenosis	大動脈狭窄	1 (<0.1%)	0	0		0	0	0	
Arterial haemorrhage	動脈出血	0	0	0		1 (<0.1%)	0	0	
Arterial thrombosis limb	四肢動脈血栓症	0	0	1 (<0.1%)		0	1 (<0.1%)	0	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Arteriosclerosis	動脈硬化症	0	2 (0.1%)	0		1 (<0.1%)	3 (0.2%)	0	
Arteriosclerosis obliterans	閉塞性動脈硬化症	0	0	0		0	0	1 (<0.1%)	
Bleeding varicose vein	出血性静脈瘤	2 (0.1%)	0	0		0	0	0	
Blue toe syndrome	青趾症候群	0	0	0		1 (<0.1%)	0	0	
Circulatory collapse	循環虚脱	1 (<0.1%)	0	0		0	0	0	
Collateral circulation	側副血行	4 (0.2%)	0	0		6 (0.4%)	0	0	
Essential hypertension	本態性高血圧症	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Extremity necrosis	四肢壊死	0	0	0		0	1 (<0.1%)	0	
Femoral artery occlusion	大腿動脈閉塞	0	1 (<0.1%)	0		0	0	0	
Haematoma	血腫	30 (1.7%)	7 (0.4%)	0		50 (2.9%)	8 (0.5%)	1 (<0.1%)	
Hot flush	ほてり	2 (0.1%)	0	0		2 (0.1%)	0	0	
Hypertension	高血圧	21 (1.2%)	16 (0.9%)	1 (<0.1%)		30 (1.8%)	9 (0.5%)	1 (<0.1%)	
Hypertensive crisis	高血圧クリーゼ	0	0	0		0	0	1 (<0.1%)	
Hypotension	低血圧	3 (0.2%)	0	1 (<0.1%)		6 (0.4%)	1 (<0.1%)	0	
Iliac artery stenosis	腸骨動脈狭窄	0	0	0		0	0	1 (<0.1%)	
Intermittent claudication	間欠性跛行	1 (<0.1%)	0	0		0	0	0	
Jugular vein thrombosis	頚静脈血栓症	0	0	0		0	1 (<0.1%)	0	
Lymphoedema	リンパ浮腫	0	1 (<0.1%)	0		0	0	0	
Lymphorrhoea	リンパ漏	0	0	0		1 (<0.1%)	0	0	
May-Thurner syndrome	マイ・トゥルナー症候群	0	0	0		0	0	1 (<0.1%)	
Neovascularisation	血管新生	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Orthostatic hypotension	起立性低血圧	3 (0.2%)	0	0		1 (<0.1%)	0	0	
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	0	2 (0.1%)	1 (<0.1%)		1 (<0.1%)	1 (<0.1%)	0	
Peripheral artery aneurysm	末梢動脈瘤	0	1 (<0.1%)	0		0	0	0	
Peripheral coldness	末梢冷感	2 (0.1%)	1 (<0.1%)	0		0	0	0	
Peripheral embolism	末梢血管塞栓症	0	0	0		0	0	1 (<0.1%)	
Peripheral ischaemia	末梢性虚血	0	0	1 (<0.1%)		1 (<0.1%)	0	0	
Peripheral vascular disorder	末梢血管障害	1 (<0.1%)	0	0		0	0	1 (<0.1%)	
Phlebitis	静脈炎	1 (<0.1%)	0	0		0	2 (0.1%)	0	
Phlebitis superficial	表在性静脈炎	1 (<0.1%)	0	0		0	0	1 (<0.1%)	

表 2.7.4.7-4 重症度別の TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing N=1718 (100%)	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Post thrombotic syndrome	血栓後症候群	10 (0.6%)	0	0		7 (0.4%)	2 (0.1%)	1 (<0.1%)	
Raynaud's phenomenon	レイノー現象	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Shock haemorrhagic	出血性ショック	0	0	0		0	0	1 (<0.1%)	
Superficial vein prominence	表在静脈隆起	1 (<0.1%)	0	0		0	0	0	
Thrombophlebitis	血栓性静脈炎	0	0	0		3 (0.2%)	0	0	
Thrombophlebitis migrans	遊走性血栓静脈炎	0	0	0		1 (<0.1%)	0	0	
Thrombophlebitis superficial	表在性血栓性静脈炎	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Thrombosis	血栓症	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Varicose ulceration	静脈瘤性潰瘍	0	0	0		0	1 (<0.1%)	0	
Varicose vein	静脈瘤	6 (0.3%)	0	0		7 (0.4%)	1 (<0.1%)	0	
Vasodilatation	血管拡張	3 (0.2%)	0	0		1 (<0.1%)	0	0	
Vasospasm	血管痙攣	0	0	0		0	1 (<0.1%)	0	
Vein pain	静脈痛	1 (<0.1%)	0	0		3 (0.2%)	0	0	
Venous insufficiency	静脈不全	2 (0.1%)	2 (0.1%)	0		8 (0.5%)	0	0	
Venous thrombosis limb	四肢静脈血栓症	1 (<0.1%)	0	0		0	0	0	

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Only the most severe intensity is counted for multiple occurrences of the same AE in each subject.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-3-4.sas erjli 21MAR2013 10:09
End of table

表 2.7.4.7-5 重症度別の TEAE（試験 11702-PE、安全性解析対象集団）

Primary System Organ Class Preferred Term MedDRA version{14.1}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Number of subjects (%) with at least one adverse event		993 (41.2%)	683 (28.3%)	260 (10.8%)	1 (<0.1%)	1029 (42.8%)	642 (26.7%)	229 (9.5%)	1 (<0.1%)
Blood and lymphatic system disorders	血液およびリンパ系障害	35 (1.5%)	35 (1.5%)	15 (0.6%)		43 (1.8%)	25 (1.0%)	10 (0.4%)	
Anaemia	貧血	21 (0.9%)	23 (1.0%)	9 (0.4%)		20 (0.8%)	13 (0.5%)	4 (0.2%)	
Anaemia folate deficiency	葉酸欠乏性貧血	0	0	1 (<0.1%)		1 (<0.1%)	0	0	
Anaemia of chronic disease	慢性疾患の貧血	0	1 (<0.1%)	0		0	0	0	
Coagulopathy	凝血異常	0	0	0		0	0	2 (<0.1%)	
Eosinophilia	好酸球増加症	0	0	0		0	2 (<0.1%)	0	
Febrile neutropenia	発熱性好中球減少症	0	1 (<0.1%)	0		0	0	0	
Haemolytic anaemia	溶血性貧血	0	0	1 (<0.1%)		0	0	0	
Haemorrhagic anaemia	出血性貧血	0	1 (<0.1%)	0		0	1 (<0.1%)	1 (<0.1%)	
Haemorrhagic diathesis	出血性素因	1 (<0.1%)	0	0		0	0	0	
Heparin-induced thrombocytopenia	ヘパリン起因性血小板減少症	0	1 (<0.1%)	0		0	0	0	
Hypercoagulation	凝固亢進	0	0	1 (<0.1%)		1 (<0.1%)	2 (<0.1%)	0	
Hypochromic anaemia	低色素性貧血	0	0	0		0	1 (<0.1%)	0	
Hypocoagulable state	凝固低下状態	0	0	0		0	0	1 (<0.1%)	
Idiopathic thrombocytopenic purpura	特発性血小板減少性紫斑病	0	0	0		0	1 (<0.1%)	0	
Iron deficiency anaemia	鉄欠乏性貧血	4 (0.2%)	1 (<0.1%)	0		6 (0.2%)	2 (<0.1%)	0	
Leukocytosis	白血球増加症	0	0	0		2 (<0.1%)	2 (<0.1%)	0	
Leukopenia	白血球減少症	2 (<0.1%)	0	0		1 (<0.1%)	2 (<0.1%)	0	
Lymph node fibrosis	リンパ節線維症	1 (<0.1%)	0	0		0	0	0	
Lymph node pain	リンパ節痛	0	1 (<0.1%)	0		0	0	0	
Lymphadenopathy	リンパ節症	0	4 (0.2%)	0		4 (0.2%)	1 (<0.1%)	0	
Lymphadenopathy mediastinal	縦隔リンパ節腫脹	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Lymphocytosis	リンパ球増加症	0	0	0		1 (<0.1%)	0	0	
Microcytic anaemia	小球性貧血	0	1 (<0.1%)	0		0	0	0	
Neutropenia	好中球減少症	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	1 (<0.1%)	
Normochromic normocytic anaemia	正色素性正球性貧血	1 (<0.1%)	0	0		0	0	0	
Pernicious anaemia	悪性貧血	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Spleen disorder	脾臓障害	1 (<0.1%)	0	0		0	0	0	
Splenic haemorrhage	脾臓出血	0	0	0		0	0	1 (<0.1%)	
Splenic infarction	脾臓梗塞	0	0	0		0	0	1 (<0.1%)	
Splenic lesion	脾臓病変	0	0	0		1 (<0.1%)	0	0	
Splenomegaly	脾腫	3 (0.1%)	0	0		1 (<0.1%)	0	0	
Spontaneous haematoma	特発性血腫	0	0	0		1 (<0.1%)	0	0	
Thrombocytopenia	血小板減少症	0	0	3 (0.1%)		2 (<0.1%)	4 (0.2%)	1 (<0.1%)	
Thrombocytosis	血小板増加症	1 (<0.1%)	1 (<0.1%)	0		2 (<0.1%)	0	0	
Cardiac disorders	心臓障害	113 (4.7%)	72 (3.0%)	22 (0.9%)		118 (4.9%)	58 (2.4%)	21 (0.9%)	
Acute coronary syndrome	急性冠動脈症候群	0	0	0		0	1 (<0.1%)	0	
Acute left ventricular failure	急性左室不全	0	0	1 (<0.1%)		0	0	0	
Acute myocardial infarction	急性心筋梗塞	1 (<0.1%)	1 (<0.1%)	3 (0.1%)		1 (<0.1%)	5 (0.2%)	5 (0.2%)	
Angina pectoris	狭心症	6 (0.2%)	2 (<0.1%)	0		2 (<0.1%)	2 (<0.1%)	0	
Angina unstable	不安定狭心症	3 (0.1%)	4 (0.2%)	2 (<0.1%)		2 (<0.1%)	1 (<0.1%)	0	
Aortic valve incompetence	大動脈弁閉鎖不全症	8 (0.3%)	2 (<0.1%)	0		6 (0.2%)	0	0	
Arrhythmia	不整脈	2 (<0.1%)	1 (<0.1%)	0		3 (0.1%)	1 (<0.1%)	0	
Arteriosclerosis coronary artery	冠動脈硬化症	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Atrial fibrillation	心房細動	9 (0.4%)	11 (0.5%)	1 (<0.1%)		8 (0.3%)	13 (0.5%)	3 (0.1%)	
Atrial flutter	心房粗動	0	1 (<0.1%)	0		3 (0.1%)	1 (<0.1%)	0	
Atrial tachycardia	心房頻脈	0	1 (<0.1%)	0		0	0	0	
Atrial thrombosis	心房血栓症	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Atrioventricular block	房室ブロック	0	0	0		0	0	1 (<0.1%)	
Bradycardia	徐脈	2 (<0.1%)	2 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Bundle branch block left	左脚ブロック	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Bundle branch block right	右脚ブロック	0	0	0		1 (<0.1%)	0	0	
Cardiac aneurysm	心臓瘤	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Cardiac disorder	心障害	1 (<0.1%)	0	0		0	0	0	
Cardiac failure	心不全	1 (<0.1%)	6 (0.2%)	5 (0.2%)		6 (0.2%)	8 (0.3%)	1 (<0.1%)	
Cardiac failure acute	急性心不全	0	1 (<0.1%)	2 (<0.1%)		1 (<0.1%)	1 (<0.1%)	0	
Cardiac failure chronic	慢性心不全	0	2 (<0.1%)	0		2 (<0.1%)	0	0	
Cardiac failure congestive	うっ血性心不全	0	2 (<0.1%)	3 (0.1%)		3 (0.1%)	2 (<0.1%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Cardiac hypertrophy	心肥大	0	2 (<0.1%)	0		0	0	0	
Cardiac valve disease	心臓弁膜疾患	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Cardio-respiratory arrest	心肺停止	0	0	1 (<0.1%)		0	0	0	
Cardiomegaly	心拡大	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Cardiomyopathy	心筋症	0	0	0		2 (<0.1%)	0	1 (<0.1%)	
Cardiovascular disorder	心血管障害	0	0	0		1 (<0.1%)	0	0	
Cardiovascular insufficiency	心血管不全	1 (<0.1%)	0	0		0	0	0	
Congestive cardiomyopathy	うっ血性心筋症	0	0	2 (<0.1%)		0	0	0	
Cor pulmonale	肺性心	1 (<0.1%)	0	2 (<0.1%)		1 (<0.1%)	1 (<0.1%)	0	
Cor pulmonale acute	急性肺性心	0	0	1 (<0.1%)		0	0	0	
Cor pulmonale chronic	慢性肺性心	0	1 (<0.1%)	0		0	0	1 (<0.1%)	
Coronary artery disease	冠動脈疾患	0	2 (<0.1%)	0		2 (<0.1%)	2 (<0.1%)	4 (0.2%)	
Coronary artery dissection	冠動脈解離	0	0	0		0	1 (<0.1%)	0	
Coronary artery occlusion	冠動脈閉塞	0	1 (<0.1%)	0		0	0	0	
Coronary artery stenosis	冠動脈狭窄	0	0	0		0	2 (<0.1%)	0	
Cyanosis	チアノーゼ	6 (0.2%)	0	0		0	0	0	
Diastolic dysfunction	拡張機能障害	3 (0.1%)	0	0		0	0	0	
Dilatation ventricular	心室拡張	2 (<0.1%)	0	0		2 (<0.1%)	2 (<0.1%)	0	
Extrasystoles	期外収縮	3 (0.1%)	0	0		3 (0.1%)	0	0	
Hepatojugular reflux	肝頚静脈逆流	1 (<0.1%)	0	0		0	0	0	
Hypertensive heart disease	高血圧性心疾患	2 (<0.1%)	0	0		0	0	0	
Hypertrophic cardiomyopathy	肥大型心筋症	0	1 (<0.1%)	0		0	0	0	
Ischaemic cardiomyopathy	虚血性心筋症	0	0	0		0	1 (<0.1%)	0	
Left atrial dilatation	左房拡張	6 (0.2%)	1 (<0.1%)	0		2 (<0.1%)	1 (<0.1%)	0	
Left ventricular dysfunction	左室機能不全	2 (<0.1%)	1 (<0.1%)	0		0	0	0	
Left ventricular failure	左室不全	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Left ventricular hypertrophy	左室肥大	3 (0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Mitral valve incompetence	僧帽弁閉鎖不全症	17 (0.7%)	7 (0.3%)	0		20 (0.8%)	2 (<0.1%)	0	
Myocardial infarction	心筋梗塞	0	0	0		0	0	1 (<0.1%)	
Myocardial ischaemia	心筋虚血	0	0	0		2 (<0.1%)	0	1 (<0.1%)	
Myocarditis	心筋炎	0	0	0		0	1 (<0.1%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Palpitations	動悸	14 (0.6%)	5 (0.2%)	1 (<0.1%)		24 (1.0%)	3 (0.1%)	0	
Paroxysmal arrhythmia	発作性不整脈	0	0	0		1 (<0.1%)	0	0	
Pericardial effusion	心嚢液貯留	0	2 (<0.1%)	0		3 (0.1%)	2 (<0.1%)	0	
Pericardial haemorrhage	心嚢内出血	0	0	0		0	0	2 (<0.1%)	
Pericarditis	心膜炎	0	3 (0.1%)	0		0	0	0	
Right atrial dilatation	右房拡張	1 (<0.1%)	0	0		0	0	0	
Right ventricular dysfunction	右室機能不全	0	0	0		1 (<0.1%)	0	0	
Right ventricular failure	右室不全	1 (<0.1%)	2 (<0.1%)	1 (<0.1%)		0	0	0	
Sick sinus syndrome	洞不全症候群	0	0	0		0	1 (<0.1%)	0	
Sinus bradycardia	洞性徐脈	2 (<0.1%)	0	0		0	0	0	
Sinus tachycardia	洞性頻脈	4 (0.2%)	0	0		4 (0.2%)	2 (<0.1%)	0	
Supraventricular extrasystoles	上室性期外収縮	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Supraventricular tachycardia	上室性頻脈	1 (<0.1%)	2 (<0.1%)	0		2 (<0.1%)	1 (<0.1%)	3 (0.1%)	
Tachyarrhythmia	頻脈性不整脈	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Tachycardia	頻脈	36 (1.5%)	10 (0.4%)	0		32 (1.3%)	6 (0.2%)	0	
Tricuspid valve incompetence	三尖弁閉鎖不全症	7 (0.3%)	0	0		10 (0.4%)	1 (<0.1%)	0	
Ventricular extrasystoles	心室性期外収縮	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Ventricular hypertrophy	心室肥大	3 (0.1%)	1 (<0.1%)	0		3 (0.1%)	0	0	
Ventricular hypokinesia	心室壁運動低下	0	0	0		1 (<0.1%)	0	0	
Ventricular tachycardia	心室性頻脈	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)		2 (<0.1%)	2 (<0.1%)	0	
Congenital, familial and genetic disorders	先天性、家族性および遺伝性障害	22 (0.9%)	7 (0.3%)	0		17 (0.7%)	3 (0.1%)	0	
Anomalous pulmonary venous connection	肺静脈還流異常	0	1 (<0.1%)	0		0	0	0	
Antithrombin III deficiency	アンチトロンビンＩＩＩ欠乏症	1 (<0.1%)	0	0		0	0	0	
Atrial septal defect	心房中隔欠損症	1 (<0.1%)	0	0		0	0	0	
Cardiac septal defect	心中隔欠損	0	1 (<0.1%)	0		0	0	0	
Coagulation factor mutation	凝固因子変異	1 (<0.1%)	0	0		0	0	0	
Congenital cystic kidney disease	先天性嚢胞性腎疾患	0	0	0		1 (<0.1%)	0	0	
Congenital renal cyst	先天性腎嚢胞	0	0	0		2 (<0.1%)	0	0	
Double ureter	重複尿管	1 (<0.1%)	0	0		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Eisenmenger's syndrome	アイゼンメンゲル症候群	0	1 (<0.1%)	0		0	0	0	
Factor II mutation	第ＩＩ因子突然変異	2 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Factor V Leiden mutation	第Ⅴ因子ライデン変異	11 (0.5%)	1 (<0.1%)	0		10 (0.4%)	2 (<0.1%)	0	
Gene mutation	遺伝子突然変異	3 (0.1%)	0	0		2 (<0.1%)	0	0	
Hydrocele	陰嚢水瘤	0	2 (<0.1%)	0		0	0	0	
Kidney duplex	重複腎	0	0	0		1 (<0.1%)	0	0	
Phimosis	包茎	0	0	0		0	1 (<0.1%)	0	
Platelet glycoprotein gene mutation	血小板糖蛋白遺伝子突然変異	0	0	0		1 (<0.1%)	0	0	
Protein C deficiency	プロテインＣ欠乏症	1 (<0.1%)	0	0		0	0	0	
Protein S deficiency	プロテインＳ欠乏症	2 (<0.1%)	0	0		0	0	0	
Type V hyperlipidaemia	５型高脂血症	0	1 (<0.1%)	0		0	0	0	
Ear and labyrinth disorders	耳および迷路障害	57 (2.4%)	11 (0.5%)	2 (<0.1%)		55 (2.3%)	10 (0.4%)	2 (<0.1%)	
Auricular perichondritis	耳介軟骨膜炎	0	1 (<0.1%)	0		0	0	0	
Deafness	難聴	2 (<0.1%)	0	0		0	0	0	
Deafness unilateral	片耳難聴	0	0	0		0	0	1 (<0.1%)	
Ear canal erythema	外耳道紅斑	0	0	0		1 (<0.1%)	0	0	
Ear discomfort	耳不快感	1 (<0.1%)	0	0		4 (0.2%)	0	0	
Ear disorder	耳の障害	0	0	0		1 (<0.1%)	0	0	
Ear haemorrhage	耳出血	2 (<0.1%)	0	0		6 (0.2%)	3 (0.1%)	0	
Ear pain	耳痛	0	0	0		5 (0.2%)	0	0	
Ear pruritus	耳そう痒症	0	0	0		2 (<0.1%)	0	0	
Eustachian tube obstruction	耳管閉塞	0	1 (<0.1%)	0		0	0	0	
Hypoacusis	聴力低下	2 (<0.1%)	0	0		3 (0.1%)	1 (<0.1%)	0	
Meniere's disease	メニエール病	0	1 (<0.1%)	0		0	0	0	
Otosalpingitis	耳管炎	0	1 (<0.1%)	0		0	0	0	
Sudden hearing loss	突発難聴	0	1 (<0.1%)	0		0	0	1 (<0.1%)	
Tinnitus	耳鳴	15 (0.6%)	2 (<0.1%)	0		6 (0.2%)	0	0	
Tympanic membrane perforation	鼓膜穿孔	0	0	0		0	1 (<0.1%)	0	
Vertigo	回転性めまい	33 (1.4%)	5 (0.2%)	1 (<0.1%)		33 (1.4%)	5 (0.2%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Vertigo positional	頭位性回転性めまい	2 (<0.1%)	0	1 (<0.1%)		1 (<0.1%)	0	0	
Endocrine disorders	内分泌障害	14 (0.6%)	6 (0.2%)	1 (<0.1%)		15 (0.6%)	7 (0.3%)	2 (<0.1%)	
Addison's disease	アジソン病	0	0	1 (<0.1%)		0	0	0	
Adrenal haemorrhage	副腎出血	0	0	1 (<0.1%)		0	0	1 (<0.1%)	
Adrenal insufficiency	副腎機能不全	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Adrenal mass	副腎腫瘤	2 (<0.1%)	0	0		2 (<0.1%)	0	0	
Autoimmune thyroiditis	自己免疫性甲状腺炎	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Basedow's disease	バセドウ病	0	1 (<0.1%)	0		0	0	0	
Diabetes insipidus	尿崩症	0	0	0		0	0	1 (<0.1%)	
Goitre	甲状腺腫	3 (0.1%)	0	0		4 (0.2%)	0	0	
Hyperparathyroidism	副甲状腺機能亢進症	0	0	0		0	1 (<0.1%)	0	
Hyperthyroidism	甲状腺機能亢進症	1 (<0.1%)	3 (0.1%)	0		3 (0.1%)	3 (0.1%)	0	
Hypothyroidism	甲状腺機能低下症	5 (0.2%)	1 (<0.1%)	0		4 (0.2%)	1 (<0.1%)	0	
Inappropriate antidiuretic hormone secretion	抗利尿ホルモン不適合分泌	0	0	0		0	1 (<0.1%)	0	
Steroid withdrawal syndrome	ステロイド離脱症候群	0	1 (<0.1%)	0		0	0	0	
Thyroid cyst	甲状腺嚢腫	2 (<0.1%)	0	0		0	1 (<0.1%)	0	
Thyroid mass	甲状腺腫瘤	0	0	0		1 (<0.1%)	0	0	
Eye disorders	眼障害	81 (3.4%)	15 (0.6%)	2 (<0.1%)		71 (3.0%)	18 (0.7%)	5 (0.2%)	1 (<0.1%)
Abnormal sensation in eye	眼の異常感	1 (<0.1%)	0	0		0	0	0	
Age-related macular degeneration	加齢黄斑変性	1 (<0.1%)	0	0		0	0	1 (<0.1%)	
Amaurosis	黒内障	0	0	0		0	1 (<0.1%)	0	
Arteriosclerotic retinopathy	動脈硬化性網膜症	0	0	0		1 (<0.1%)	0	0	
Blepharitis	眼瞼炎	0	0	0		1 (<0.1%)	0	0	
Cataract	白内障	8 (0.3%)	2 (<0.1%)	0		3 (0.1%)	4 (0.2%)	0	
Conjunctival haemorrhage	結膜出血	25 (1.0%)	2 (<0.1%)	0		23 (1.0%)	3 (0.1%)	0	
Conjunctival hyperaemia	結膜充血	1 (<0.1%)	0	0		0	0	0	
Conjunctivitis	結膜炎	6 (0.2%)	3 (0.1%)	0		6 (0.2%)	1 (<0.1%)	0	1 (<0.1%)
Conjunctivitis allergic	アレルギー性結膜炎	0	0	0		1 (<0.1%)	0	0	
Diplopia	複視	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Dry eye	眼乾燥	6 (0.2%)	0	0		2 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Eye allergy	眼のアレルギー	0	0	0		1 (<0.1%)	0	0	
Eye disorder	眼の障害	0	0	0		0	1 (<0.1%)	0	
Eye haemorrhage	眼出血	7 (0.3%)	0	0		10 (0.4%)	2 (<0.1%)	1 (<0.1%)	
Eye inflammation	眼の炎症	2 (<0.1%)	0	0		2 (<0.1%)	0	0	
Eye irritation	眼刺激	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Eye pain	眼痛	0	2 (<0.1%)	0		3 (0.1%)	1 (<0.1%)	0	
Eye pruritus	眼そう痒症	0	0	1 (<0.1%)		2 (<0.1%)	0	0	
Eyelid bleeding	眼瞼出血	1 (<0.1%)	0	0		0	0	0	
Eyelid oedema	眼瞼浮腫	3 (0.1%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Eyelid pain	眼瞼痛	1 (<0.1%)	0	0		0	0	0	
Eyelid skin dryness	眼瞼皮膚乾燥	1 (<0.1%)	0	0		0	0	0	
Eyelids pruritus	眼瞼そう痒症	2 (<0.1%)	0	0		0	0	0	
Foreign body sensation in eyes	眼の異物感	1 (<0.1%)	0	0		0	0	0	
Glaucoma	緑内障	1 (<0.1%)	2 (<0.1%)	0		3 (0.1%)	1 (<0.1%)	0	
Heterophoria	眼球斜位	1 (<0.1%)	0	0		0	0	0	
Keratitis	角膜炎	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Lacrimal haemorrhage	涙器出血	0	0	0		1 (<0.1%)	0	0	
Lacrimation increased	流涙増加	2 (<0.1%)	0	0		0	0	0	
Lens disorder	水晶体障害	1 (<0.1%)	0	0		0	0	0	
Lenticular opacities	水晶体混濁	0	1 (<0.1%)	0		0	0	0	
Myopia	近視	0	0	0		1 (<0.1%)	0	0	
Ocular hyperaemia	眼充血	2 (<0.1%)	0	0		5 (0.2%)	0	0	
Ocular hypertension	高眼圧症	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Optic disc hyperaemia	視神経乳頭充血	0	1 (<0.1%)	0		0	0	0	
Optic ischaemic neuropathy	虚血性視神経症	0	1 (<0.1%)	0		0	0	0	
Panophthalmitis	全眼球炎	0	0	0		1 (<0.1%)	0	0	
Papilloedema	視神経乳頭浮腫	0	1 (<0.1%)	0		0	0	0	
Photopsia	光視症	0	0	0		1 (<0.1%)	0	1 (<0.1%)	
Presbyopia	老視	0	0	0		1 (<0.1%)	0	0	
Pupils unequal	瞳孔不同	0	0	0		0	0	1 (<0.1%)	
Retinal degeneration	網膜変性	0	0	0		0	0	1 (<0.1%)	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Retinal detachment	網膜剥離	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Retinal haemorrhage	網膜出血	0	0	0		0	0	1 (<0.1%)	
Retinopathy hypertensive	高血圧性網膜症	1 (<0.1%)	0	0		0	0	0	
Scleral haemorrhage	強膜出血	1 (<0.1%)	0	0		0	0	0	
Scleral hyperaemia	強膜充血	2 (<0.1%)	0	0		0	0	0	
Scleritis	強膜炎	1 (<0.1%)	0	0		0	0	0	
Scotoma	暗点	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Vision blurred	霧視	3 (0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	1 (<0.1%)	
Visual acuity reduced	視力低下	5 (0.2%)	0	0		0	1 (<0.1%)	0	
Visual impairment	視力障害	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Vitreous detachment	硝子体剥離	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Vitreous floaters	硝子体浮遊物	0	0	0		2 (<0.1%)	0	0	
Vitreous haemorrhage	硝子体出血	0	0	1 (<0.1%)		0	0	0	
Gastrointestinal disorders	胃腸障害	541 (22.4%)	164 (6.8%)	31 (1.3%)	1 (<0.1%)	518 (21.5%)	124 (5.2%)	30 (1.2%)	
Abdominal discomfort	腹部不快感	13 (0.5%)	3 (0.1%)	0		13 (0.5%)	2 (<0.1%)	0	
Abdominal distension	腹部膨満	8 (0.3%)	3 (0.1%)	0		4 (0.2%)	0	0	
Abdominal hernia	腹部ヘルニア	0	1 (<0.1%)	0		0	0	0	
Abdominal mass	腹部腫瘤	0	0	0		1 (<0.1%)	0	0	
Abdominal pain	腹痛	24 (1.0%)	19 (0.8%)	2 (<0.1%)		25 (1.0%)	8 (0.3%)	5 (0.2%)	
Abdominal pain lower	下腹部痛	2 (<0.1%)	1 (<0.1%)	0		6 (0.2%)	0	0	
Abdominal pain upper	上腹部痛	36 (1.5%)	17 (0.7%)	0		34 (1.4%)	6 (0.2%)	1 (<0.1%)	
Abdominal tenderness	腹部圧痛	1 (<0.1%)	0	0		0	0	0	
Abdominal wall haematoma	腹壁血腫	0	0	0		5 (0.2%)	0	2 (<0.1%)	
Abdominal wall mass	腹壁腫瘤	0	0	0		1 (<0.1%)	0	0	
Aerophagia	空気嚥下	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Anal fissure	裂肛	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Anal haemorrhage	肛門出血	5 (0.2%)	0	0		3 (0.1%)	0	0	
Anal inflammation	肛門の炎症	0	0	0		1 (<0.1%)	0	0	
Anal prolapse	肛門脱	0	0	0		0	1 (<0.1%)	0	
Anal pruritus	肛門そう痒症	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Anorectal disorder	肛門直腸障害	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Aphthous stomatitis	アフタ性口内炎	2 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Apical granuloma	根尖肉芽腫	0	0	0		0	0	1 (<0.1%)	
Ascites	腹水	1 (<0.1%)	2 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Barrett's oesophagus	バレット食道	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Breath odour	呼気臭	1 (<0.1%)	0	0		0	0	0	
Change of bowel habit	便習慣変化	0	1 (<0.1%)	0		0	0	0	
Chapped lips	口唇のひび割れ	1 (<0.1%)	0	0		0	0	0	
Cheilitis	口唇炎	1 (<0.1%)	0	0		0	0	0	
Coeliac artery stenosis	腹腔動脈狭窄	0	1 (<0.1%)	0		0	0	0	
Coeliac disease	セリアック病	2 (<0.1%)	0	0		0	0	0	
Colitis	大腸炎	1 (<0.1%)	0	1 (<0.1%)		0	2 (<0.1%)	0	
Colitis ischaemic	虚血性大腸炎	0	0	1 (<0.1%)		0	0	0	
Colitis ulcerative	潰瘍性大腸炎	0	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Colonic polyp	結腸ポリープ	8 (0.3%)	5 (0.2%)	1 (<0.1%)		12 (0.5%)	1 (<0.1%)	0	
Colonic stenosis	結腸狭窄	0	0	1 (<0.1%)		0	0	0	
Constipation	便秘	125 (5.2%)	14 (0.6%)	0		111 (4.6%)	20 (0.8%)	0	
Dental caries	齲歯	7 (0.3%)	2 (<0.1%)	0		7 (0.3%)	2 (<0.1%)	0	
Diarrhoea	下痢	99 (4.1%)	22 (0.9%)	4 (0.2%)		100 (4.2%)	24 (1.0%)	0	
Diarrhoea haemorrhagic	血性下痢	0	2 (<0.1%)	0		1 (<0.1%)	0	0	
Disbacteriosis	細菌叢異常症	0	0	0		2 (<0.1%)	0	0	
Diverticular perforation	憩室穿孔	0	1 (<0.1%)	0		0	0	0	
Diverticulum	憩室	4 (0.2%)	0	0		6 (0.2%)	2 (<0.1%)	0	
Diverticulum gastric	胃憩室	0	0	0		1 (<0.1%)	0	0	
Diverticulum intestinal	腸憩室	13 (0.5%)	1 (<0.1%)	1 (<0.1%)		6 (0.2%)	0	0	
Dry mouth	口内乾燥	9 (0.4%)	1 (<0.1%)	0		4 (0.2%)	0	0	
Duodenal ulcer	十二指腸潰瘍	0	1 (<0.1%)	1 (<0.1%)		1 (<0.1%)	1 (<0.1%)	0	
Duodenitis	十二指腸炎	2 (<0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	0	
Duodenogastric reflux	十二指腸胃逆流	1 (<0.1%)	0	0		0	0	0	
Dyspepsia	消化不良	36 (1.5%)	6 (0.2%)	0		36 (1.5%)	3 (0.1%)	1 (<0.1%)	
Dysphagia	嚥下障害	0	2 (<0.1%)	2 (<0.1%)		5 (0.2%)	0	0	
Enteritis	小腸炎	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Enterocolitis	腸炎	0	0	0		0	1 (<0.1%)	0	
Epigastric discomfort	心窩部不快感	0	0	0		3 (0.1%)	1 (<0.1%)	0	
Erosive duodenitis	びらん性十二指腸炎	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Eructation	おくび	0	0	0		2 (<0.1%)	0	0	
Faecal incontinence	便失禁	1 (<0.1%)	0	0		0	0	0	
Faecaloma	糞塊	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Faeces discoloured	変色便	0	0	0		1 (<0.1%)	0	0	
Flatulence	鼓腸	4 (0.2%)	1 (<0.1%)	0		4 (0.2%)	0	0	
Food poisoning	食中毒	0	2 (<0.1%)	0		0	1 (<0.1%)	0	
Frequent bowel movements	排便回数増加	0	0	0		1 (<0.1%)	0	0	
Gastric disorder	胃障害	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Gastric haemorrhage	胃出血	0	0	0		0	0	1 (<0.1%)	
Gastric mucosa erythema	胃粘膜紅斑	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Gastric mucosal hypertrophy	胃粘膜肥厚	0	0	0		1 (<0.1%)	0	0	
Gastric perforation	胃穿孔	0	0	1 (<0.1%)		0	0	0	
Gastric polyps	胃ポリープ	4 (0.2%)	0	0		2 (<0.1%)	0	0	
Gastric ulcer	胃潰瘍	3 (0.1%)	2 (<0.1%)	0		2 (<0.1%)	0	0	
Gastric ulcer haemorrhage	出血性胃潰瘍	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Gastric varices	胃静脈瘤	1 (<0.1%)	0	0		0	0	0	
Gastritis	胃炎	19 (0.8%)	4 (0.2%)	1 (<0.1%)		14 (0.6%)	7 (0.3%)	0	
Gastritis erosive	びらん性胃炎	8 (0.3%)	2 (<0.1%)	0		3 (0.1%)	0	0	
Gastritis haemorrhagic	出血性胃炎	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Gastroduodenitis	胃十二指腸炎	1 (<0.1%)	0	0		0	0	0	
Gastrointestinal disorder	胃腸障害	5 (0.2%)	3 (0.1%)	0		1 (<0.1%)	0	0	
Gastrointestinal dysplasia	胃腸異形成	0	1 (<0.1%)	0		0	0	0	
Gastrointestinal fistula	胃腸管瘻	0	0	0		1 (<0.1%)	0	0	
Gastrointestinal haemorrhage	胃腸出血	6 (0.2%)	4 (0.2%)	2 (<0.1%)		1 (<0.1%)	1 (<0.1%)	3 (0.1%)	
Gastrointestinal pain	消化器痛	0	0	0		2 (<0.1%)	1 (<0.1%)	0	
Gastrointestinal telangiectasia	胃腸毛細血管拡張症	1 (<0.1%)	0	0		0	0	0	
Gastrointestinal tract mucosal discolouration	消化管粘膜変色	1 (<0.1%)	0	0		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Gastrointestinal ulcer	胃腸潰瘍	0	0	0		0	1 (<0.1%)	0	
Gastrooesophageal reflux disease	胃食道逆流性疾患	22 (0.9%)	4 (0.2%)	3 (0.1%)		22 (0.9%)	6 (0.2%)	0	
Gastrooesophageal sphincter insufficiency	胃食道括約筋機能不全	1 (<0.1%)	0	0		0	0	0	
Gingival bleeding	歯肉出血	53 (2.2%)	4 (0.2%)	0		75 (3.1%)	1 (<0.1%)	0	
Gingival disorder	歯肉障害	1 (<0.1%)	0	0		0	0	0	
Gingival oedema	歯肉浮腫	0	0	0		1 (<0.1%)	0	0	
Gingival pain	歯肉痛	2 (<0.1%)	0	0		2 (<0.1%)	0	0	
Gingivitis	歯肉炎	9 (0.4%)	1 (<0.1%)	0		2 (<0.1%)	0	0	
Glossitis	舌炎	1 (<0.1%)	0	0		0	0	0	
Glossodynia	舌痛	1 (<0.1%)	0	0		0	0	0	
Haematemesis	吐血	3 (0.1%)	6 (0.2%)	2 (<0.1%)		4 (0.2%)	2 (<0.1%)	0	
Haematochezia	血便排泄	10 (0.4%)	0	0		12 (0.5%)	0	0	
Haemorrhoidal haemorrhage	痔出血	22 (0.9%)	4 (0.2%)	0		11 (0.5%)	1 (<0.1%)	0	
Haemorrhoids	痔核	15 (0.6%)	5 (0.2%)	0		15 (0.6%)	3 (0.1%)	0	
Hiatus hernia	裂孔ヘルニア	18 (0.7%)	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	10 (0.4%)	1 (<0.1%)	0	
Hyperchlorhydria	胃酸過多	1 (<0.1%)	0	0		0	0	0	
Hypoaesthesia oral	口の感覚鈍麻	3 (0.1%)	0	0		0	0	0	
Ileus	イレウス	0	0	0		0	1 (<0.1%)	0	
Ileus paralytic	麻痺性イレウス	0	0	0		0	1 (<0.1%)	1 (<0.1%)	
Impaired gastric emptying	胃排出不全	0	0	0		0	1 (<0.1%)	0	
Inflammatory bowel disease	炎症性腸疾患	0	0	0		1 (<0.1%)	0	0	
Infrequent bowel movements	排便回数減少	2 (<0.1%)	0	0		0	0	0	
Inguinal hernia	鼠径ヘルニア	1 (<0.1%)	1 (<0.1%)	0		2 (<0.1%)	1 (<0.1%)	0	
Intestinal haemorrhage	腸出血	2 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	3 (0.1%)	
Intestinal infarction	腸梗塞	0	0	1 (<0.1%)		0	0	0	
Intestinal obstruction	腸閉塞	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Intestinal polyp	腸管ポリープ	1 (<0.1%)	0	0		3 (0.1%)	0	0	
Irritable bowel syndrome	過敏性腸症候群	3 (0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	0	
Large intestinal haemorrhage	大腸出血	0	0	0		1 (<0.1%)	0	0	
Large intestinal obstruction	大腸閉塞	0	0	1 (<0.1%)		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Large intestine perforation	大腸穿孔	1 (<0.1%)	0	0		0	1 (<0.1%)	1 (<0.1%)	
Lip dry	口唇乾燥	1 (<0.1%)	0	0		0	0	0	
Lip haematoma	口唇血腫	1 (<0.1%)	0	0		0	0	0	
Lip haemorrhage	口唇出血	2 (<0.1%)	1 (<0.1%)	0		2 (<0.1%)	0	0	
Lip pain	口唇痛	1 (<0.1%)	0	0		0	0	0	
Loose tooth	弛緩歯	1 (<0.1%)	0	0		0	0	0	
Lower gastrointestinal haemorrhage	下部消化管出血	8 (0.3%)	1 (<0.1%)	0		9 (0.4%)	1 (<0.1%)	0	
Lumbar hernia	腰ヘルニア	0	1 (<0.1%)	0		0	0	0	
Melaena	メレナ	3 (0.1%)	5 (0.2%)	0		6 (0.2%)	6 (0.2%)	2 (<0.1%)	
Mouth haemorrhage	口腔内出血	7 (0.3%)	0	0		4 (0.2%)	0	0	
Mouth ulceration	口腔内潰瘍形成	4 (0.2%)	0	0		4 (0.2%)	0	1 (<0.1%)	
Nausea	悪心	84 (3.5%)	21 (0.9%)	1 (<0.1%)		101 (4.2%)	20 (0.8%)	1 (<0.1%)	
Odynophagia	嚥下痛	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Oesophageal disorder	食道障害	1 (<0.1%)	0	0		0	0	0	
Oesophageal irritation	食道刺激症状	1 (<0.1%)	0	0		0	0	0	
Oesophageal pain	食道痛	1 (<0.1%)	0	0		0	0	0	
Oesophageal ulcer	食道潰瘍	0	0	1 (<0.1%)		0	0	0	
Oesophageal ulcer haemorrhage	食道潰瘍出血	0	0	0		0	0	1 (<0.1%)	
Oesophagitis	食道炎	8 (0.3%)	3 (0.1%)	0		4 (0.2%)	0	0	
Oesophagitis ulcerative	潰瘍性食道炎	0	1 (<0.1%)	0		0	0	0	
Oral discomfort	口腔内不快感	0	0	0		1 (<0.1%)	0	0	
Oral pain	口腔内痛	1 (<0.1%)	0	0		0	0	0	
Pancreas lipomatosis	膵脂肪腫症	5 (0.2%)	0	0		10 (0.4%)	0	0	
Pancreatic atrophy	膵萎縮	1 (<0.1%)	0	0		0	0	0	
Pancreatic cyst	膵嚢胞	1 (<0.1%)	0	0		0	0	0	
Pancreatitis	膵炎	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Pancreatitis acute	急性膵炎	0	0	0		0	0	1 (<0.1%)	
Papilla of Vater stenosis	ファーター乳頭狭窄	0	1 (<0.1%)	0		0	0	0	
Paraesthesia oral	口の錯感覚	0	0	0		2 (<0.1%)	0	0	
Parotid gland enlargement	耳下腺腫大	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Peptic ulcer	消化性潰瘍	2 (<0.1%)	0	0		0	1 (<0.1%)	0	
Periodontitis	歯周炎	3 (0.1%)	0	0		0	0	0	
Peritoneal cyst	腹膜嚢胞	1 (<0.1%)	0	0		0	0	0	
Plicated tongue	ひだ舌	1 (<0.1%)	0	0		0	0	0	
Poor dental condition	歯状態不良	0	1 (<0.1%)	1 (<0.1%)		0	0	0	
Portal hypertensive gastropathy	門脈圧亢進性胃障害	1 (<0.1%)	0	0		0	0	0	
Post-tussive vomiting	咳嗽後嘔吐	0	0	0		0	2 (<0.1%)	0	
Proctalgia	肛門周囲痛	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Proctitis	直腸炎	0	1 (<0.1%)	0		0	0	0	
Rectal haemorrhage	直腸出血	45 (1.9%)	11 (0.5%)	1 (<0.1%)		30 (1.2%)	8 (0.3%)	3 (0.1%)	
Rectal polyp	直腸ポリープ	3 (0.1%)	0	0		5 (0.2%)	0	0	
Rectal prolapse	直腸脱	3 (0.1%)	0	0		0	0	0	
Rectal tenesmus	直腸しぶり	1 (<0.1%)	0	0		0	0	0	
Retroperitoneal haematoma	後腹膜血腫	0	0	0		1 (<0.1%)	0	1 (<0.1%)	
Salivary gland enlargement	唾液腺腫大	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Sigmoiditis	Ｓ状結腸炎	0	2 (<0.1%)	0		0	0	0	
Small intestinal obstruction	小腸閉塞	0	1 (<0.1%)	0		0	0	1 (<0.1%)	
Stomatitis	口内炎	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Subileus	亜イレウス	0	0	1 (<0.1%)		0	2 (<0.1%)	0	
Submaxillary gland enlargement	顎下腺腫大	0	0	0		1 (<0.1%)	0	0	
Swollen tongue	舌腫脹	2 (<0.1%)	0	0		0	0	0	
Tongue disorder	舌障害	1 (<0.1%)	0	0		0	0	0	
Tongue haemorrhage	舌出血	2 (<0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	0	
Tongue ulceration	舌潰瘍	0	0	0		1 (<0.1%)	0	0	
Tooth crowding	叢生歯列	0	1 (<0.1%)	0		0	0	0	
Tooth discolouration	変色歯	2 (<0.1%)	0	0		0	0	0	
Tooth impacted	埋伏歯	1 (<0.1%)	0	0		0	0	0	
Tooth loss	歯の脱落	1 (<0.1%)	0	1 (<0.1%)		0	0	0	
Toothache	歯痛	24 (1.0%)	7 (0.3%)	0		20 (0.8%)	3 (0.1%)	0	
Umbilical hernia	臍ヘルニア	1 (<0.1%)	3 (0.1%)	0		1 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Upper gastrointestinal haemorrhage	上部消化管出血	0	0	2 (<0.1%)		1 (<0.1%)	0	2 (<0.1%)	
Varices oesophageal	食道静脈瘤	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Vomiting	嘔吐	33 (1.4%)	15 (0.6%)	3 (0.1%)		59 (2.5%)	15 (0.6%)	0	
General disorders and administration site conditions	一般・全身障害および投与部位の状態	348 (14.4%)	125 (5.2%)	28 (1.2%)	1 (<0.1%)	337 (14.0%)	128 (5.3%)	15 (0.6%)	
Adverse drug reaction	医薬品副作用	0	0	0		0	1 (<0.1%)	0	
Application site erythema	適用部位紅斑	0	0	0		1 (<0.1%)	0	0	
Application site rash	適用部位発疹	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Asthenia	無力症	40 (1.7%)	10 (0.4%)	1 (<0.1%)		42 (1.7%)	10 (0.4%)	1 (<0.1%)	
Axillary pain	腋窩痛	2 (<0.1%)	0	0		0	1 (<0.1%)	0	
Catheter site haemorrhage	カテーテル留置部位出血	1 (<0.1%)	1 (<0.1%)	0		3 (0.1%)	0	0	
Catheter site inflammation	カテーテル留置部位炎症	0	0	0		1 (<0.1%)	0	0	
Catheter site pain	カテーテル留置部位疼痛	0	0	0		0	0	1 (<0.1%)	
Catheter site phlebitis	カテーテル留置部位静脈炎	2 (<0.1%)	0	0		0	0	0	
Catheter site swelling	カテーテル留置部位腫脹	0	0	0		0	1 (<0.1%)	0	
Chest discomfort	胸部不快感	15 (0.6%)	5 (0.2%)	0		15 (0.6%)	2 (<0.1%)	0	
Chest pain	胸痛	122 (5.1%)	48 (2.0%)	12 (0.5%)	1 (<0.1%)	122 (5.1%)	58 (2.4%)	5 (0.2%)	
Chills	悪寒	7 (0.3%)	0	0		2 (<0.1%)	2 (<0.1%)	0	
Cyst	嚢胞	3 (0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Death	死亡	0	0	4 (0.2%)		0	0	2 (<0.1%)	
Device breakage	医療機器破損	0	0	0		1 (<0.1%)	0	0	
Device deposit issue	医療機器沈着物の問題	0	0	0		0	1 (<0.1%)	0	
Discomfort	不快感	1 (<0.1%)	0	0		0	0	0	
Drug intolerance	薬物不耐性	0	0	0		0	1 (<0.1%)	0	
Drug withdrawal syndrome	薬剤離脱症候群	0	0	0		0	2 (<0.1%)	0	
Exercise tolerance decreased	運動耐性低下	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Face oedema	顔面浮腫	1 (<0.1%)	0	0		0	0	0	
Facial pain	顔面痛	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Fatigue	疲労	50 (2.1%)	15 (0.6%)	1 (<0.1%)		42 (1.7%)	10 (0.4%)	1 (<0.1%)	
Feeling cold	冷感	5 (0.2%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Feeling hot	熱感	3 (0.1%)	0	0		0	0	0	
Feeling of body temperature change	体温変動感	2 (<0.1%)	0	0		0	0	0	
Gait disturbance	歩行障害	0	2 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
General physical health deterioration	全身健康状態低下	2 (<0.1%)	2 (<0.1%)	0		2 (<0.1%)	0	1 (<0.1%)	
Generalised oedema	全身性浮腫	0	0	0		1 (<0.1%)	0	0	
Granuloma	肉芽腫	0	0	0		0	0	1 (<0.1%)	
Gravitational oedema	重力性浮腫	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Haemorrhagic cyst	出血性嚢胞	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Hyperthermia	高熱	2 (<0.1%)	1 (<0.1%)	0		3 (0.1%)	0	0	
Hypothermia	低体温	1 (<0.1%)	0	0		0	0	0	
Impaired healing	治癒不良	1 (<0.1%)	0	0		0	0	0	
Implant site thrombosis	埋込み部位血栓	0	0	0		0	1 (<0.1%)	0	
Inflammation	炎症	3 (0.1%)	1 (<0.1%)	1 (<0.1%)		0	0	0	
Influenza like illness	インフルエンザ様疾患	15 (0.6%)	1 (<0.1%)	0		17 (0.7%)	2 (<0.1%)	0	
Infusion site extravasation	注入部位血管外漏出	1 (<0.1%)	0	0		0	0	0	
Infusion site inflammation	注入部位炎症	1 (<0.1%)	0	0		0	0	0	
Injection site discomfort	注射部位不快感	0	0	0		0	1 (<0.1%)	0	
Injection site eczema	注射部位湿疹	1 (<0.1%)	0	0		0	0	0	
Injection site erythema	注射部位紅斑	0	0	0		1 (<0.1%)	0	0	
Injection site extravasation	注射部位血管外漏出	0	0	0		0	1 (<0.1%)	0	
Injection site haematoma	注射部位血腫	3 (0.1%)	1 (<0.1%)	0		12 (0.5%)	1 (<0.1%)	0	
Injection site haemorrhage	注射部位出血	1 (<0.1%)	0	0		3 (0.1%)	0	0	
Injection site pain	注射部位疼痛	0	0	0		1 (<0.1%)	0	0	
Injection site rash	注射部位発疹	0	0	0		1 (<0.1%)	0	0	
Injection site reaction	注射部位反応	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Localised oedema	限局性浮腫	2 (<0.1%)	0	0		0	1 (<0.1%)	0	
Malaise	倦怠感	9 (0.4%)	3 (0.1%)	0		5 (0.2%)	3 (0.1%)	0	
Mass	腫瘤	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Medical device complication	医療機器合併症	0	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Mucosal inflammation	粘膜の炎症	0	1 (<0.1%)	0		0	0	0	
Non-cardiac chest pain	非心臓性胸痛	3 (0.1%)	5 (0.2%)	2 (<0.1%)		4 (0.2%)	4 (0.2%)	1 (<0.1%)	
Oedema	浮腫	14 (0.6%)	4 (0.2%)	0		19 (0.8%)	3 (0.1%)	0	
Oedema peripheral	末梢性浮腫	64 (2.7%)	20 (0.8%)	3 (0.1%)	0	73 (3.0%)	21 (0.9%)	0	
Pain	疼痛	8 (0.3%)	6 (0.2%)	1 (<0.1%)		4 (0.2%)	4 (0.2%)	0	
Pelvic mass	骨盤腔内腫瘤	1 (<0.1%)	0	0		0	0	0	
Polyp	ポリープ	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Pyrexia	発熱	57 (2.4%)	10 (0.4%)	0		54 (2.2%)	15 (0.6%)	1 (<0.1%)	
Sensation of pressure	圧迫感	0	0	0		1 (<0.1%)	0	0	
Sudden death	突然死	0	0	3 (0.1%)		0	0	1 (<0.1%)	
Tenderness	圧痛	0	0	0		1 (<0.1%)	0	0	
Thirst	口渇	2 (<0.1%)	0	0		0	0	0	
Thrombosis in device	医療機器内血栓	1 (<0.1%)	0	0		0	0	0	
Vessel puncture site haematoma	血管穿刺部位血腫	0	0	0		3 (0.1%)	0	0	
Vessel puncture site haemorrhage	血管穿刺部位出血	4 (0.2%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Hepatobiliary disorders	肝胆道系障害	63 (2.6%)	19 (0.8%)	6 (0.2%)		91 (3.8%)	5 (0.2%)	5 (0.2%)	
Bile duct stone	胆管結石	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Biliary cirrhosis primary	原発性胆汁性肝硬変	0	0	0		0	1 (<0.1%)	0	
Biliary colic	胆道仙痛	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Biliary dilatation	胆管拡張	0	0	0		1 (<0.1%)	0	0	
Cholangitis	胆管炎	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Cholangitis sclerosing	硬化性胆管炎	0	0	1 (<0.1%)		0	0	0	
Cholecystitis	胆嚢炎	0	2 (<0.1%)	0		2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Cholecystitis acute	急性胆嚢炎	0	0	0		2 (<0.1%)	0	1 (<0.1%)	
Cholecystitis chronic	慢性胆嚢炎	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Cholelithiasis	胆石症	13 (0.5%)	6 (0.2%)	1 (<0.1%)		25 (1.0%)	1 (<0.1%)	1 (<0.1%)	
Cholestasis	胆汁うっ滞	0	2 (<0.1%)	0		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Cytolytic hepatitis	肝細胞融解性肝炎	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Gallbladder polyp	胆嚢ポリープ	3 (0.1%)	0	0		0	0	0	
Haemorrhagic hepatic cyst	出血性肝嚢胞	1 (<0.1%)	0	0		0	0	0	
Hepatic cirrhosis	肝硬変	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Hepatic congestion	肝臓うっ血	0	1 (<0.1%)	0		0	0	0	
Hepatic cyst	肝嚢胞	7 (0.3%)	0	0		9 (0.4%)	0	0	
Hepatic failure	肝不全	0	0	1 (<0.1%)		0	0	1 (<0.1%)	
Hepatic function abnormal	肝機能異常	3 (0.1%)	2 (<0.1%)	0		11 (0.5%)	0	1 (<0.1%)	
Hepatic mass	肝腫瘤	0	0	0		1 (<0.1%)	0	0	
Hepatic pain	肝臓痛	0	1 (<0.1%)	0		0	0	0	
Hepatic steatosis	脂肪肝	36 (1.5%)	3 (0.1%)	0		41 (1.7%)	1 (<0.1%)	0	
Hepatic vein dilatation	肝静脈拡張	0	0	0		1 (<0.1%)	0	0	
Hepatitis	肝炎	0	0	0		0	1 (<0.1%)	0	
Hepatitis acute	急性肝炎	0	0	1 (<0.1%)		0	0	0	
Hepatitis chronic active	慢性活動性肝炎	0	0	1 (<0.1%)		0	0	0	
Hepatomegaly	肝腫大	7 (0.3%)	0	0		8 (0.3%)	0	0	
Hyperbilirubinaemia	高ビリルビン血症	0	0	0		2 (<0.1%)	0	0	
Hypertransaminasaemia	高トランスアミナーゼ血症	0	0	0		1 (<0.1%)	0	0	
Ischaemic hepatitis	虚血性肝炎	0	0	1 (<0.1%)		0	0	0	
Jaundice	黄疸	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Liver disorder	肝障害	0	0	0		2 (<0.1%)	0	0	
Liver injury	肝損傷	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Immune system disorders	免疫系障害	25 (1.0%)	13 (0.5%)	0		19 (0.8%)	4 (0.2%)	2 (<0.1%)	
Allergy to arthropod sting	節足動物刺傷アレルギー	1 (<0.1%)	0	0		0	0	0	
Allergy to chemicals	化学物質アレルギー	0	0	0		1 (<0.1%)	0	0	
Antiphospholipid syndrome	抗リン脂質抗体症候群	2 (<0.1%)	2 (<0.1%)	0		1 (<0.1%)	0	1 (<0.1%)	
Contrast media allergy	造影剤アレルギー	0	0	0		0	1 (<0.1%)	0	
Drug hypersensitivity	薬物過敏症	2 (<0.1%)	5 (0.2%)	0		6 (0.2%)	1 (<0.1%)	1 (<0.1%)	
Food allergy	食物アレルギー	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Hypersensitivity	過敏症	4 (0.2%)	2 (<0.1%)	0		2 (<0.1%)	0	0	
Latex allergy	ラテックスアレルギー	1 (<0.1%)	0	0		0	0	0	
Sarcoidosis	サルコイドーシス	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Seasonal allergy	季節性アレルギー	14 (0.6%)	2 (<0.1%)	0		9 (0.4%)	2 (<0.1%)	0	
Infections and infestations	感染症および寄生虫症	501 (20.8%)	205 (8.5%)	40 (1.7%)		514 (21.4%)	198 (8.2%)	28 (1.2%)	
Abdominal infection	腹部感染	0	0	0		0	1 (<0.1%)	0	
Abdominal wall abscess	腹壁膿瘍	0	1 (<0.1%)	0		0	0	0	
Abscess jaw	顎膿瘍	1 (<0.1%)	0	0		0	0	0	
Abscess limb	四肢膿瘍	0	0	0		0	2 (<0.1%)	0	
Abscess oral	口腔膿瘍	1 (<0.1%)	0	0		0	0	0	
Abscess soft tissue	軟部組織膿瘍	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Acarodermatitis	ダニ皮膚炎	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Acute tonsillitis	急性扁桃炎	3 (0.1%)	0	0		4 (0.2%)	0	0	
Anal abscess	肛門膿瘍	0	0	1 (<0.1%)		0	0	0	
Appendiceal abscess	虫垂膿瘍	0	0	0		0	0	1 (<0.1%)	
Appendicitis	虫垂炎	0	0	0		0	2 (<0.1%)	0	
Arthritis infective	感染性関節炎	0	0	0		1 (<0.1%)	0	0	
Bacteraemia	菌血症	0	1 (<0.1%)	0		0	0	1 (<0.1%)	
Bacterial infection	細菌感染	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Bacteriuria	細菌尿	0	0	0		1 (<0.1%)	0	0	
Biliary sepsis	胆道性敗血症	0	0	0		0	1 (<0.1%)	0	
Biliary tract infection bacterial	細菌性胆道感染	0	1 (<0.1%)	0		0	0	0	
Blastocystis infection	ブラストシスティス感染	0	0	0		0	1 (<0.1%)	0	
Bone abscess	骨膿瘍	0	1 (<0.1%)	0		0	0	0	
Borrelia infection	ボレリア感染	0	1 (<0.1%)	0		0	0	0	
Bronchitis	気管支炎	69 (2.9%)	37 (1.5%)	2 (<0.1%)		63 (2.6%)	24 (1.0%)	2 (<0.1%)	
Bronchitis viral	ウイルス性気管支炎	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Bronchopneumonia	気管支肺炎	2 (<0.1%)	2 (<0.1%)	1 (<0.1%)		2 (<0.1%)	4 (0.2%)	1 (<0.1%)	
Bronchopulmonary aspergillosis	気管支肺アスペルギルス症	0	1 (<0.1%)	1 (<0.1%)		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Burn infection	熱傷部感染	0	0	0		0	1 (<0.1%)	0	
Campylobacter infection	カンピロバクター感染	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Candidiasis	カンジダ症	5 (0.2%)	0	0		3 (0.1%)	0	0	
Catheter site infection	カテーテル留置部位感染	1 (<0.1%)	0	0		0	0	0	
Cellulitis	蜂巣炎	3 (0.1%)	5 (0.2%)	2 (<0.1%)		11 (0.5%)	10 (0.4%)	0	
Cervicitis	子宮頚管炎	1 (<0.1%)	0	0		0	0	0	
Chlamydial infection	クラミジア感染	0	0	0		1 (<0.1%)	0	0	
Chronic sinusitis	慢性副鼻腔炎	0	0	0		1 (<0.1%)	0	0	
Clostridial infection	クロストリジウム感染	0	0	0		1 (<0.1%)	0	0	
Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	0	1 (<0.1%)	0		0	0	0	
Conjunctivitis infective	感染性結膜炎	0	0	0		1 (<0.1%)	0	0	
Conjunctivitis viral	ウイルス性結膜炎	2 (<0.1%)	0	0		0	0	0	
Cystitis	膀胱炎	10 (0.4%)	4 (0.2%)	0		20 (0.8%)	7 (0.3%)	2 (<0.1%)	
Cytomegalovirus infection	サイトメガロウイルス感染	0	1 (<0.1%)	0		0	0	0	
Dacryocanaliculitis	涙小管炎	0	0	0		0	1 (<0.1%)	0	
Dental gangrene	歯組織の壊疽	1 (<0.1%)	0	0		0	0	0	
Device related infection	医療機器関連感染	0	1 (<0.1%)	0		0	0	0	
Diarrhoea infectious	感染性下痢	0	1 (<0.1%)	0		0	0	0	
Diverticulitis	憩室炎	1 (<0.1%)	2 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Dysentery	赤痢	0	0	0		1 (<0.1%)	0	0	
Ear infection	耳感染	6 (0.2%)	3 (0.1%)	0		3 (0.1%)	0	0	
Endocarditis	心内膜炎	0	1 (<0.1%)	0		0	0	0	
Endocarditis bacterial	細菌性心内膜炎	0	0	1 (<0.1%)		0	0	0	
Enterocolitis infectious	感染性小腸結腸炎	0	0	0		1 (<0.1%)	0	0	
Erysipelas	丹毒	3 (0.1%)	0	0		3 (0.1%)	4 (0.2%)	0	
Eye infection	眼感染	2 (<0.1%)	0	0		4 (0.2%)	1 (<0.1%)	0	
Folliculitis	毛包炎	8 (0.3%)	0	0		2 (<0.1%)	0	0	
Fungal infection	真菌感染	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Fungal oesophagitis	真菌性食道炎	0	0	0		0	1 (<0.1%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Fungal skin infection	皮膚真菌感染	4 (0.2%)	0	0		3 (0.1%)	0	0	
Furuncle	せつ	2 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Gastroenteritis	胃腸炎	19 (0.8%)	7 (0.3%)	2 (<0.1%)		28 (1.2%)	9 (0.4%)	0	
Gastroenteritis norovirus	ノロウイルス性胃腸炎	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Gastroenteritis salmonella	サルモネラ菌性胃腸炎	0	1 (<0.1%)	0		0	0	0	
Gastroenteritis viral	ウイルス性胃腸炎	2 (<0.1%)	1 (<0.1%)	0		4 (0.2%)	0	0	
Gastrointestinal infection	消化管感染	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Genital candidiasis	性器カンジダ症	0	0	0		1 (<0.1%)	0	0	
Genital herpes	陰部ヘルペス	1 (<0.1%)	0	0		0	0	0	
Genital infection fungal	真菌性性器感染	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Genitourinary tract infection	泌尿生殖器感染	1 (<0.1%)	0	0		0	0	0	
Giardiasis	ジアルジア症	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Gingival abscess	歯肉膿瘍	1 (<0.1%)	0	0		0	0	0	
Gingival infection	歯肉感染	0	0	0		2 (<0.1%)	0	0	
Groin abscess	鼠径部膿瘍	0	0	0		2 (<0.1%)	0	0	
Groin infection	鼠径部感染	0	0	0		1 (<0.1%)	0	0	
H1N1 influenza	Ｈ１Ｎ１インフルエンザ	0	0	0		0	2 (<0.1%)	0	
Haematoma infection	血腫感染	0	1 (<0.1%)	0		0	0	0	
Helicobacter gastritis	ヘリコバクター性胃炎	2 (<0.1%)	1 (<0.1%)	0		2 (<0.1%)	0	0	
Helicobacter infection	ヘリコバクター感染	2 (<0.1%)	1 (<0.1%)	0		2 (<0.1%)	1 (<0.1%)	0	
Hepatitis A	Ａ型肝炎	0	0	0		0	1 (<0.1%)	0	
Hepatitis C	Ｃ型肝炎	1 (<0.1%)	0	0		0	0	0	
Herpes dermatitis	ヘルペス性皮膚炎	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Herpes simplex	単純ヘルペス	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Herpes virus infection	ヘルペスウイルス感染	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Herpes zoster	帯状疱疹	5 (0.2%)	3 (0.1%)	0		6 (0.2%)	5 (0.2%)	0	
Hordeolum	麦粒腫	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Impetigo	膿痂疹	2 (<0.1%)	1 (<0.1%)	0		0	0	0	
Infected bites	咬傷感染	0	1 (<0.1%)	0		0	0	0	
Infected dermal cyst	感染性皮膚嚢腫	0	1 (<0.1%)	0		0	1 (<0.1%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Infected skin ulcer	感染性皮膚潰瘍	0	1 (<0.1%)	0		2 (<0.1%)	0	0	
Infection	感染	2 (<0.1%)	0	0		3 (0.1%)	0	0	
Infectious peritonitis	感染性腹膜炎	0	1 (<0.1%)	2 (<0.1%)		0	0	0	
Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪	0	2 (<0.1%)	0		2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Infective glossitis	感染性舌炎	1 (<0.1%)	0	0		0	0	0	
Influenza	インフルエンザ	46 (1.9%)	11 (0.5%)	1 (<0.1%)		46 (1.9%)	5 (0.2%)	0	
Injection site infection	注射部位感染	1 (<0.1%)	0	0		0	0	0	
Intervertebral discitis	椎間板炎	0	1 (<0.1%)	1 (<0.1%)		0	0	0	
Intraspinal abscess	脊髄内膿瘍	0	1 (<0.1%)	0		0	0	0	
Joint abscess	関節膿瘍	0	0	1 (<0.1%)		0	0	0	
Kidney infection	腎感染	2 (<0.1%)	1 (<0.1%)	0		0	0	0	
Laryngitis	喉頭炎	8 (0.3%)	1 (<0.1%)	0		5 (0.2%)	1 (<0.1%)	0	
Laryngitis viral	ウイルス性喉頭炎	0	0	0		1 (<0.1%)	0	0	
Listeriosis	リステリア症	1 (<0.1%)	0	0		0	0	0	
Liver abscess	肝膿瘍	0	0	0		0	1 (<0.1%)	0	
Lobar pneumonia	大葉性肺炎	0	2 (<0.1%)	1 (<0.1%)		1 (<0.1%)	0	0	
Localised infection	限局性感染	10 (0.4%)	3 (0.1%)	0		2 (<0.1%)	4 (0.2%)	0	
Lower respiratory tract infection	下気道感染	10 (0.4%)	7 (0.3%)	1 (<0.1%)		14 (0.6%)	15 (0.6%)	1 (<0.1%)	
Lung abscess	肺膿瘍	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Lung infection	肺感染	11 (0.5%)	9 (0.4%)	2 (<0.1%)		11 (0.5%)	6 (0.2%)	1 (<0.1%)	
Lyme disease	ライム病	0	0	0		1 (<0.1%)	0	0	
Mastitis	乳腺炎	1 (<0.1%)	0	0		0	0	0	
Nasopharyngitis	鼻咽頭炎	157 (6.5%)	23 (1.0%)	1 (<0.1%)		172 (7.2%)	17 (0.7%)	0	
Oesophageal candidiasis	食道カンジダ症	2 (<0.1%)	2 (<0.1%)	0		1 (<0.1%)	0	0	
Onychomycosis	爪真菌症	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Oral candidiasis	口腔カンジダ症	6 (0.2%)	1 (<0.1%)	0		9 (0.4%)	0	0	
Oral fungal infection	口腔真菌感染	3 (0.1%)	0	0		3 (0.1%)	0	0	
Oral herpes	口腔ヘルペス	5 (0.2%)	1 (<0.1%)	0		5 (0.2%)	0	0	
Oropharyngeal candidiasis	中咽頭カンジダ症	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Oropharyngitis fungal	真菌性口腔咽頭炎	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Osteomyelitis	骨髄炎	0	0	0		0	1 (<0.1%)	1 (<0.1%)	
Otitis externa	外耳炎	2 (<0.1%)	0	0		2 (<0.1%)	1 (<0.1%)	0	
Otitis media	中耳炎	0	4 (0.2%)	0		3 (0.1%)	2 (<0.1%)	0	
Paronychia	爪囲炎	2 (<0.1%)	1 (<0.1%)	0		0	0	0	
Pericoronitis	歯冠周囲炎	0	0	0		1 (<0.1%)	0	0	
Pertussis	百日咳	0	0	0		0	1 (<0.1%)	0	
Pharyngitis	咽頭炎	8 (0.3%)	6 (0.2%)	0		10 (0.4%)	2 (<0.1%)	0	
Pharyngitis streptococcal	レンサ球菌性咽頭炎	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Pilonidal cyst	毛巣嚢胞	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Pneumonia	肺炎	9 (0.4%)	16 (0.7%)	9 (0.4%)		13 (0.5%)	21 (0.9%)	10 (0.4%)	
Pneumonia bacterial	細菌性肺炎	0	1 (<0.1%)	0		0	0	0	
Pneumonia mycoplasmal	マイコプラズマ性肺炎	0	0	0		0	1 (<0.1%)	0	
Pneumonia necrotising	壊死性肺炎	0	1 (<0.1%)	0		0	0	0	
Pneumonia primary atypical	原発性異型肺炎	0	0	0		0	0	1 (<0.1%)	
Post procedural infection	処置後感染	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Postoperative wound infection	術後創感染	0	1 (<0.1%)	0		2 (<0.1%)	1 (<0.1%)	0	
Prostate infection	前立腺感染	0	0	0		0	1 (<0.1%)	0	
Pseudofolliculitis barbae	偽須毛包炎	0	0	0		1 (<0.1%)	0	0	
Pseudomembranous colitis	偽膜性大腸炎	0	1 (<0.1%)	0		0	0	0	
Pulmonary mycosis	肺真菌症	0	0	0		2 (<0.1%)	0	0	
Pulpitis dental	歯髄炎	0	0	0		1 (<0.1%)	0	0	
Pyelonephritis	腎盂腎炎	1 (<0.1%)	4 (0.2%)	0		1 (<0.1%)	2 (<0.1%)	1 (<0.1%)	
Pyelonephritis acute	急性腎盂腎炎	0	0	0		0	1 (<0.1%)	0	
Respiratory tract infection	気道感染	13 (0.5%)	9 (0.4%)	1 (<0.1%)		19 (0.8%)	6 (0.2%)	0	
Respiratory tract infection viral	ウイルス性気道感染	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Rhinitis	鼻炎	16 (0.7%)	1 (<0.1%)	0		19 (0.8%)	2 (<0.1%)	1 (<0.1%)	
Salpingitis	卵管炎	0	0	0		1 (<0.1%)	0	0	
Salpingo-oophoritis	卵管卵巣炎	1 (<0.1%)	0	0		0	0	0	
Scrotal abscess	陰嚢膿瘍	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Scrotal infection	陰嚢感染	0	1 (<0.1%)	0		0	0	0	
Sepsis	敗血症	0	1 (<0.1%)	8 (0.3%)		0	1 (<0.1%)	2 (<0.1%)	
Sepsis syndrome	敗血症症候群	0	1 (<0.1%)	0		0	0	0	
Sinobronchitis	副鼻腔気管支炎	0	0	0		1 (<0.1%)	0	0	
Sinusitis	副鼻腔炎	24 (1.0%)	10 (0.4%)	1 (<0.1%)		21 (0.9%)	9 (0.4%)	0	
Skin bacterial infection	皮膚細菌感染	0	0	0		2 (<0.1%)	0	0	
Skin graft infection	植皮感染	0	1 (<0.1%)	0		0	0	0	
Skin infection	皮膚感染	3 (0.1%)	1 (<0.1%)	0		2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Soft tissue infection	軟部組織感染	1 (<0.1%)	0	0		0	0	0	
Staphylococcal infection	ブドウ球菌感染	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Strongyloidiasis	糞線虫症	0	0	0		1 (<0.1%)	0	0	
Subcutaneous abscess	皮下組織膿瘍	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Subdiaphragmatic abscess	横隔膜下膿瘍	0	1 (<0.1%)	0		0	0	0	
Syphilis	梅毒	0	0	0		1 (<0.1%)	0	0	
Tinea infection	白癬感染	0	0	0		1 (<0.1%)	0	0	
Tinea manuum	手白癬	0	0	0		1 (<0.1%)	0	0	
Tinea pedis	足部白癬	3 (0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Tinea versicolour	癜風	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Tonsillitis	扁桃炎	1 (<0.1%)	2 (<0.1%)	0		7 (0.3%)	2 (<0.1%)	0	
Tooth abscess	歯膿瘍	8 (0.3%)	4 (0.2%)	0		6 (0.2%)	3 (0.1%)	0	
Tooth infection	歯感染	8 (0.3%)	3 (0.1%)	0		5 (0.2%)	3 (0.1%)	0	
Tracheitis	気管炎	5 (0.2%)	1 (<0.1%)	0		2 (<0.1%)	0	0	
Tracheobronchitis	気管気管支炎	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Upper respiratory tract infection	上気道感染	40 (1.7%)	8 (0.3%)	0		37 (1.5%)	7 (0.3%)	0	
Urethritis	尿道炎	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Urinary tract infection	尿路感染	69 (2.9%)	23 (1.0%)	1 (<0.1%)		76 (3.2%)	18 (0.7%)	1 (<0.1%)	
Urinary tract infection fungal	真菌性尿路感染	0	0	0		1 (<0.1%)	0	0	
Urosepsis	尿路性敗血症	0	1 (<0.1%)	1 (<0.1%)		0	0	1 (<0.1%)	
Vaginal abscess	膣膿瘍	1 (<0.1%)	0	0		0	0	0	
Vaginal infection	膣感染	5 (0.2%)	2 (<0.1%)	0		2 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Vestibular neuronitis	前庭神経炎	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Viraemia	ウイルス血症	0	0	0		2 (<0.1%)	0	0	
Viral corneal ulcer	ウイルス性角膜潰瘍	1 (<0.1%)	0	0		0	0	0	
Viral diarrhoea	ウイルス性下痢	1 (<0.1%)	0	0		0	0	0	
Viral infection	ウイルス感染	7 (0.3%)	2 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Viral myocarditis	ウイルス性心筋炎	0	0	0		1 (<0.1%)	0	0	
Viral rash	ウイルス性発疹	0	0	0		0	1 (<0.1%)	0	
Viral rhinitis	ウイルス性鼻炎	1 (<0.1%)	0	0		0	0	0	
Viral tracheitis	ウイルス性気管炎	1 (<0.1%)	0	0		0	0	0	
Viral upper respiratory tract infection	ウイルス性上気道感染	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Vulvitis	外陰部炎	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Vulvovaginal candidiasis	外陰部腟カンジダ症	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Vulvovaginal mycotic infection	外陰腟真菌感染	8 (0.3%)	2 (<0.1%)	0		2 (<0.1%)	2 (<0.1%)	0	
Wound infection	創傷感染	5 (0.2%)	4 (0.2%)	0		3 (0.1%)	0	0	
Wound infection bacterial	細菌性創感染	1 (<0.1%)	0	0		0	0	0	
Wound infection staphylococcal	ブドウ球菌性創感染	0	1 (<0.1%)	0		0	0	0	
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	209 (8.7%)	79 (3.3%)	13 (0.5%)		247 (10.3%)	91 (3.8%)	20 (0.8%)	
Accidental overdose	偶発的過量投与	0	0	0		1 (<0.1%)	0	0	
Alcohol poisoning	アルコール中毒	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Anaemia postoperative	術後貧血	0	0	0		0	2 (<0.1%)	0	
Animal bite	動物咬傷	0	0	0		2 (<0.1%)	0	0	
Ankle fracture	足関節部骨折	2 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Arthropod bite	節足動物咬傷	6 (0.2%)	0	0		2 (<0.1%)	0	0	
Arthropod sting	節足動物刺傷	1 (<0.1%)	0	0		0	0	0	
Back injury	背部損傷	0	1 (<0.1%)	0		0	0	0	
Bladder injury	膀胱損傷	0	0	0		1 (<0.1%)	0	0	
Brain contusion	脳挫傷	0	0	0		0	0	1 (<0.1%)	
Burn oesophageal	食道熱傷	1 (<0.1%)	0	0		0	0	0	
Cardiac valve replacement complication	心臓弁置換合併症	0	0	0		0	0	1 (<0.1%)	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Cartilage injury	軟骨損傷	0	1 (<0.1%)	0		0	0	0	
Cerebral haemorrhage traumatic	外傷性脳出血	0	0	1 (<0.1%)		0	0	0	
Cervical vertebral fracture	頚椎骨折	0	0	0		0	0	2 (<0.1%)	
Chest injury	胸部損傷	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Complications of transplant surgery	移植手術における合併症	0	0	0		1 (<0.1%)	0	0	
Compression fracture	圧迫骨折	0	0	1 (<0.1%)		0	0	0	
Concussion	脳振盪	1 (<0.1%)	0	0		0	2 (<0.1%)	0	
Contusion	挫傷	77 (3.2%)	15 (0.6%)	0		108 (4.5%)	18 (0.7%)	3 (0.1%)	
Corneal abrasion	角膜擦過傷	0	1 (<0.1%)	0		0	0	0	
Craniocerebral injury	頭蓋脳損傷	0	0	0		1 (<0.1%)	0	0	
Epicondylitis	上顆炎	2 (<0.1%)	0	0		2 (<0.1%)	0	0	
Eschar	焼痂	0	0	0		1 (<0.1%)	0	0	
Excoriation	擦過傷	3 (0.1%)	0	0		3 (0.1%)	0	0	
Exposure during breast feeding	母乳保育時の曝露	1 (<0.1%)	0	0		0	0	0	
Facial bones fracture	顔面骨骨折	0	2 (<0.1%)	0		0	2 (<0.1%)	0	
Fall	転倒	11 (0.5%)	8 (0.3%)	0		15 (0.6%)	3 (0.1%)	1 (<0.1%)	
Femoral neck fracture	大腿骨頚部骨折	0	0	1 (<0.1%)		0	0	0	
Femur fracture	大腿骨骨折	0	1 (<0.1%)	0		0	0	0	
Fibula fracture	腓骨骨折	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Foot fracture	足骨折	2 (<0.1%)	1 (<0.1%)	0		0	3 (0.1%)	0	
Foreign body in eye	眼内異物	0	0	0		0	1 (<0.1%)	0	
Graft haemorrhage	移植部位出血	1 (<0.1%)	0	0		0	0	0	
Haematuria traumatic	外傷性血尿	1 (<0.1%)	0	0		0	0	0	
Hand fracture	手骨折	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Head injury	頭部損傷	2 (<0.1%)	1 (<0.1%)	0		2 (<0.1%)	0	0	
Hip fracture	股関節部骨折	0	1 (<0.1%)	0		0	0	0	
Humerus fracture	上腕骨骨折	0	0	0		0	2 (<0.1%)	1 (<0.1%)	
Incision site haemorrhage	切開部位出血	1 (<0.1%)	0	0		2 (<0.1%)	2 (<0.1%)	1 (<0.1%)	
Inflammation of wound	創部炎症	0	0	0		1 (<0.1%)	0	0	
Injury	損傷	1 (<0.1%)	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Joint dislocation	関節脱臼	1 (<0.1%)	1 (<0.1%)	0		0	0	1 (<0.1%)	
Joint injury	関節損傷	5 (0.2%)	2 (<0.1%)	0		6 (0.2%)	3 (0.1%)	0	
Kidney rupture	腎臓破裂	0	0	0		1 (<0.1%)	0	0	
Laceration	裂傷	5 (0.2%)	2 (<0.1%)	0		6 (0.2%)	2 (<0.1%)	0	
Ligament rupture	靭帯断裂	3 (0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Ligament sprain	靭帯捻挫	8 (0.3%)	4 (0.2%)	0		9 (0.4%)	2 (<0.1%)	0	
Limb crushing injury	四肢圧挫損傷	0	1 (<0.1%)	0		0	0	0	
Limb injury	四肢損傷	4 (0.2%)	0	1 (<0.1%)		6 (0.2%)	3 (0.1%)	0	
Lip injury	口唇損傷	1 (<0.1%)	0	0		0	0	0	
Lower limb fracture	下肢骨折	1 (<0.1%)	0	0		0	0	0	
Lumbar vertebral fracture	腰椎骨折	0	1 (<0.1%)	0		0	0	0	
Maternal exposure during pregnancy	妊娠時の母体の曝露	0	0	0		1 (<0.1%)	0	0	
Meniscus lesion	半月板障害	2 (<0.1%)	0	0		1 (<0.1%)	2 (<0.1%)	0	
Multiple injuries	多発性外傷	0	0	0		0	0	1 (<0.1%)	
Muscle rupture	筋断裂	1 (<0.1%)	0	0		0	0	0	
Muscle strain	肉離れ	4 (0.2%)	1 (<0.1%)	0		5 (0.2%)	4 (0.2%)	0	
Operative haemorrhage	術中出血	2 (<0.1%)	2 (<0.1%)	0		0	2 (<0.1%)	0	
Overdose	過量投与	1 (<0.1%)	2 (<0.1%)	0		8 (0.3%)	4 (0.2%)	1 (<0.1%)	
Pelvic fracture	骨盤骨折	0	0	0		1 (<0.1%)	0	0	
Periorbital haematoma	眼窩周囲血腫	2 (<0.1%)	0	0		2 (<0.1%)	1 (<0.1%)	0	
Perirenal haematoma	腎周囲血腫	0	0	0		0	1 (<0.1%)	0	
Post gastric surgery syndrome	胃手術後症候群	1 (<0.1%)	0	0		0	0	0	
Post procedural haematoma	処置後血腫	2 (<0.1%)	0	0		2 (<0.1%)	1 (<0.1%)	0	
Post procedural haemorrhage	処置後出血	6 (0.2%)	3 (0.1%)	2 (<0.1%)		8 (0.3%)	1 (<0.1%)	1 (<0.1%)	
Post-traumatic neck syndrome	外傷後頚部症候群	0	0	0		1 (<0.1%)	0	0	
Post-traumatic pain	外傷後疼痛	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Postoperative ileus	術後イレウス	0	1 (<0.1%)	0		0	0	0	
Procedural hypertension	処置による高血圧	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Procedural nausea	処置による悪心	0	0	0		0	1 (<0.1%)	0	
Procedural pain	処置による疼痛	2 (<0.1%)	2 (<0.1%)	0		4 (0.2%)	4 (0.2%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Radiation skin injury	放射線皮膚損傷	1 (<0.1%)	0	0		0	0	0	
Radius fracture	橈骨骨折	2 (<0.1%)	0	0		0	1 (<0.1%)	0	
Repetitive strain injury	反復性挫傷	0	0	0		1 (<0.1%)	0	0	
Rib fracture	肋骨骨折	4 (0.2%)	4 (0.2%)	0		2 (<0.1%)	3 (0.1%)	0	
Road traffic accident	交通事故	1 (<0.1%)	0	0		0	1 (<0.1%)	1 (<0.1%)	
Scratch	引っかき傷	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Scrotal haematoma	陰嚢血腫	0	0	0		0	1 (<0.1%)	0	
Skeletal injury	骨格損傷	3 (0.1%)	2 (<0.1%)	0		3 (0.1%)	0	0	
Skin injury	皮膚損傷	1 (<0.1%)	0	0		0	0	0	
Soft tissue injury	軟部組織損傷	2 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Spinal compression fracture	脊椎圧迫骨折	0	1 (<0.1%)	1 (<0.1%)		1 (<0.1%)	1 (<0.1%)	0	
Splenic haematoma	脾血腫	0	0	0		0	0	1 (<0.1%)	
Sternal fracture	胸骨骨折	0	0	0		0	1 (<0.1%)	0	
Stress fracture	ストレス骨折	1 (<0.1%)	0	0		0	0	0	
Subcutaneous haematoma	皮下血腫	25 (1.0%)	7 (0.3%)	1 (<0.1%)		32 (1.3%)	9 (0.4%)	2 (<0.1%)	
Subdural haematoma	硬膜下血腫	0	0	1 (<0.1%)		1 (<0.1%)	0	2 (<0.1%)	
Subdural haemorrhage	硬膜下出血	0	0	0		0	0	2 (<0.1%)	
Sunburn	サンバーン	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Tendon injury	腱損傷	1 (<0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	0	
Tendon rupture	腱断裂	0	2 (<0.1%)	1 (<0.1%)		1 (<0.1%)	0	0	
Thermal burn	熱傷	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Thoracic vertebral fracture	胸椎骨折	0	0	0		0	2 (<0.1%)	0	
Tibia fracture	脛骨骨折	0	1 (<0.1%)	0		0	0	0	
Tobacco poisoning	タバコ中毒	0	0	0		1 (<0.1%)	0	0	
Tooth avulsion	歯の完全脱臼	1 (<0.1%)	0	0		0	0	0	
Tooth fracture	歯牙破折	0	1 (<0.1%)	0		4 (0.2%)	0	0	
Tooth injury	歯牙損傷	1 (<0.1%)	2 (<0.1%)	0		0	0	0	
Toxicity to various agents	各種物質毒性	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Transfusion-related immunomodulation reaction	輸血に伴う免疫修飾反応	0	0	0		0	1 (<0.1%)	0	
Traumatic fracture	外傷性骨折	1 (<0.1%)	0	0		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Traumatic haematoma	外傷性血腫	7 (0.3%)	0	0		9 (0.4%)	3 (0.1%)	0	
Traumatic haemorrhage	外傷性出血	6 (0.2%)	3 (0.1%)	0		2 (<0.1%)	6 (0.2%)	0	
Ulna fracture	尺骨骨折	0	0	0		1 (<0.1%)	0	0	
Upper limb fracture	上肢骨折	0	0	1 (<0.1%)		1 (<0.1%)	3 (0.1%)	1 (<0.1%)	
Vascular graft complication	移植血管合併症	0	0	0		1 (<0.1%)	0	0	
Vascular pseudoaneurysm	血管偽動脈瘤	0	0	0		2 (<0.1%)	0	0	
Venous injury	静脈損傷	0	0	0		0	1 (<0.1%)	0	
Wound	創傷	6 (0.2%)	0	1 (<0.1%)		4 (0.2%)	0	0	
Wound complication	創合併症	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Wound dehiscence	創し開	0	0	0		1 (<0.1%)	0	0	
Wound haematoma	創傷血腫	0	0	0		0	1 (<0.1%)	0	
Wound haemorrhage	創傷出血	31 (1.3%)	8 (0.3%)	0		44 (1.8%)	0	0	
Wrist fracture	手首関節骨折	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Investigations	臨床検査	156 (6.5%)	61 (2.5%)	12 (0.5%)		221 (9.2%)	85 (3.5%)	10 (0.4%)	
Activated partial thromboplastin time prolonged	活性化部分トロンボプラスチン時間延長	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)		0	0	0	
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	43 (1.8%)	8 (0.3%)	1 (<0.1%)		62 (2.6%)	12 (0.5%)	3 (0.1%)	
Angiotensin converting enzyme increased	アンギオテンシン変換酵素増加	1 (<0.1%)	0	0		0	0	0	
Anti-thyroid antibody positive	抗甲状腺抗体陽性	0	0	0		1 (<0.1%)	0	0	
Anticonvulsant drug level decreased	抗痙攣剤濃度減少	0	0	0		0	1 (<0.1%)	0	
Antinuclear antibody positive	抗核抗体陽性	1 (<0.1%)	0	0		0	0	0	
Antiphospholipid antibodies positive	抗リン脂質抗体陽性	7 (0.3%)	1 (<0.1%)	0		0	1 (<0.1%)	0	
Arthroscopy	関節鏡検査	0	1 (<0.1%)	0		0	0	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	17 (0.7%)	3 (0.1%)	0		17 (0.7%)	9 (0.4%)	0	
Bacterial test positive	細菌検査陽性	2 (<0.1%)	0	0		0	0	0	
Bilirubin conjugated increased	抱合ビリルビン増加	3 (0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Biopsy liver	肝生検	0	0	0		1 (<0.1%)	0	0	
Biopsy lung	肺生検	0	0	0		0	1 (<0.1%)	0	
Biopsy prostate	前立腺生検	1 (<0.1%)	0	0		0	0	0	
Blood alkaline phosphatase decreased	血中アルカリホスファターゼ減少	1 (<0.1%)	0	0		0	0	0	
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	8 (0.3%)	1 (<0.1%)	1 (<0.1%)		9 (0.4%)	3 (0.1%)	0	
Blood amylase increased	血中アミラーゼ増加	6 (0.2%)	1 (<0.1%)	0		4 (0.2%)	1 (<0.1%)	0	
Blood bilirubin increased	血中ビリルビン増加	6 (0.2%)	3 (0.1%)	0		3 (0.1%)	1 (<0.1%)	0	
Blood cholesterol increased	血中コレステロール増加	3 (0.1%)	0	0		4 (0.2%)	0	0	
Blood creatinine increased	血中クレアチニン増加	1 (<0.1%)	0	0		4 (0.2%)	2 (<0.1%)	0	
Blood follicle stimulating hormone increased	血中卵胞刺激ホルモン増加	0	0	0		1 (<0.1%)	0	0	
Blood glucose decreased	血中ブドウ糖減少	0	0	0		0	1 (<0.1%)	0	
Blood glucose increased	血中ブドウ糖増加	5 (0.2%)	4 (0.2%)	0		1 (<0.1%)	0	0	
Blood homocysteine increased	血中ホモシステイン増加	1 (<0.1%)	0	0		3 (0.1%)	0	0	
Blood immunoglobulin M increased	血中免疫グロブリンM増加	0	0	0		1 (<0.1%)	0	0	
Blood iron decreased	血中鉄減少	3 (0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Blood iron increased	血中鉄増加	1 (<0.1%)	0	0		0	0	0	
Blood magnesium decreased	血中マグネシウム減少	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Blood phosphorus decreased	血中リン減少	0	0	0		0	1 (<0.1%)	0	
Blood potassium decreased	血中カリウム減少	5 (0.2%)	0	0		2 (<0.1%)	0	0	
Blood potassium increased	血中カリウム増加	0	1 (<0.1%)	0		0	0	0	
Blood pressure decreased	血圧低下	0	1 (<0.1%)	0		0	0	0	
Blood pressure increased	血圧上昇	4 (0.2%)	2 (<0.1%)	0		2 (<0.1%)	0	0	
Blood pressure systolic increased	収縮期血圧上昇	0	0	0		0	1 (<0.1%)	0	
Blood thyroid stimulating hormone increased	血中甲状腺刺激ホルモン増加	0	0	0		1 (<0.1%)	1 (<0.1%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Blood triglycerides increased	血中トリグリセリド増加	0	0	0		0	1 (<0.1%)	0	
Blood urea increased	血中尿素増加	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Blood urine present	尿中血陽性	2 (<0.1%)	0	0		2 (<0.1%)	0	0	
Body temperature increased	体温上昇	2 (<0.1%)	0	0		0	0	0	
Brain scan abnormal	脳スキャン異常	0	0	0		1 (<0.1%)	0	0	
Breath sounds abnormal	呼吸音異常	0	0	0		0	1 (<0.1%)	0	
C-reactive protein increased	Ｃ－反応性蛋白増加	2 (<0.1%)	1 (<0.1%)	0		2 (<0.1%)	0	0	
Carbohydrate antigen 125 increased	糖鎖抗原１２５増加	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Carbohydrate antigen 19-9 increased	糖鎖抗原１９－９増加	2 (<0.1%)	0	0		0	0	0	
Carbon dioxide increased	二酸化炭素増加	1 (<0.1%)	0	0		0	0	0	
Cardiac murmur	心雑音	0	0	0		1 (<0.1%)	0	0	
Cardiolipin antibody positive	カルジオリピン抗体陽性	1 (<0.1%)	0	0		0	0	0	
Coagulation factor V level decreased	凝固第Ｖ因子量減少	1 (<0.1%)	0	0		0	0	0	
Coagulation factor VIII level increased	凝固第ＶＩＩＩ因子量増加	0	0	0		1 (<0.1%)	0	0	
Coagulation factor X level decreased	凝固第Ｘ因子量減少	1 (<0.1%)	0	0		0	0	0	
Coagulation time prolonged	凝固時間延長	0	0	0		3 (0.1%)	1 (<0.1%)	0	
Coagulation time shortened	凝固時間短縮	0	0	0		1 (<0.1%)	0	0	
Colonoscopy	結腸内視鏡検査	0	0	0		2 (<0.1%)	0	0	
Creatinine renal clearance decreased	腎クレアチニン・クリアランス減少	1 (<0.1%)	0	0		0	0	0	
Cytomegalovirus test positive	サイトメガロウイルス検査陽性	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Ejection fraction decreased	駆出率減少	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Electrocardiogram	心電図	1 (<0.1%)	0	0		0	0	0	

表 2.7.4.7-5　重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Electrocardiogram ST-T segment abnormal	心電図ＳＴ－Ｔ部分異常	1 (<0.1%)	0	0		0	0	0	
Electrocardiogram T wave amplitude decreased	心電図Ｔ波振幅減少	0	1 (<0.1%)	0		0	0	0	
Electrophoresis protein abnormal	蛋白電気泳動異常	1 (<0.1%)	0	0		0	0	0	
Endoscopy upper gastrointestinal tract	上部消化管内視鏡検査	1 (<0.1%)	0	0		0	0	0	
Epidermal growth factor receptor decreased	上皮増殖因子受容体減少	0	0	0		1 (<0.1%)	0	0	
Epidermal growth factor receptor increased	上皮増殖因子受容体増加	0	0	0		1 (<0.1%)	0	0	
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	0		0	0	0	
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	4 (0.2%)	1 (<0.1%)	0		0	3 (0.1%)	0	
Gastric pH decreased	胃内ｐＨ低下	0	0	0		1 (<0.1%)	0	0	
Grip strength decreased	握力低下	1 (<0.1%)	0	0		0	0	0	
HIV test positive	ＨＩＶ検査陽性	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Haemoglobin decreased	ヘモグロビン減少	5 (0.2%)	1 (<0.1%)	1 (<0.1%)		1 (<0.1%)	2 (<0.1%)	0	
Haemoglobin increased	ヘモグロビン増加	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Heart rate increased	心拍数増加	0	0	0		0	1 (<0.1%)	0	
Heart rate irregular	心拍数不整	1 (<0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	0	
Hepatic enzyme increased	肝酵素上昇	5 (0.2%)	3 (0.1%)	3 (0.1%)		4 (0.2%)	3 (0.1%)	1 (<0.1%)	
Hepatitis A virus test positive	Ａ型肝炎ウイルス検査陽性	1 (<0.1%)	0	0		0	0	0	
Herpes simplex serology positive	単純ヘルペス血清学的検査陽性	0	0	0		1 (<0.1%)	0	0	
International normalised ratio abnormal	ＩＮＲ異常	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
International normalised ratio decreased	ＩＮＲ減少	0	0	0		20 (0.8%)	3 (0.1%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
International normalised ratio fluctuation	ＩＮＲ変動	0	0	0		0	1 (<0.1%)	0	
International normalised ratio increased	ＩＮＲ増加	3 (0.1%)	3 (0.1%)	0		57 (2.4%)	20 (0.8%)	5 (0.2%)	
Lipids abnormal	脂質異常	0	0	0		1 (<0.1%)	0	0	
Lipids increased	脂質増加	0	0	0		2 (<0.1%)	0	0	
Liver function test abnormal	肝機能検査異常	15 (0.6%)	7 (0.3%)	3 (0.1%)		28 (1.2%)	8 (0.3%)	1 (<0.1%)	
Low density lipoprotein increased	低比重リポ蛋白増加	0	0	0		0	1 (<0.1%)	0	
Lumbar puncture	腰椎穿刺	0	0	0		1 (<0.1%)	0	0	
Medical observation	医学的観察	0	1 (<0.1%)	0		0	0	0	
Neutrophil count decreased	好中球数減少	0	0	0		0	1 (<0.1%)	0	
Occult blood positive	便潜血陽性	8 (0.3%)	1 (<0.1%)	0		4 (0.2%)	1 (<0.1%)	0	
Platelet count decreased	血小板数減少	0	2 (<0.1%)	0		0	0	0	
Platelet count increased	血小板数増加	1 (<0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	0	
Prostatic specific antigen increased	前立腺特異性抗原増加	6 (0.2%)	1 (<0.1%)	0		3 (0.1%)	1 (<0.1%)	0	
Prothrombin level decreased	プロトロンビン量減少	1 (<0.1%)	0	0		0	0	0	
Prothrombin time ratio decreased	プロトロンビン時間比減少	1 (<0.1%)	0	0		0	0	0	
Prothrombin time shortened	プロトロンビン時間短縮	0	1 (<0.1%)	0		0	0	0	
Pulmonary arterial pressure increased	肺動脈圧上昇	1 (<0.1%)	0	0		0	0	0	
Serum ferritin decreased	血清フェリチン減少	2 (<0.1%)	2 (<0.1%)	0		2 (<0.1%)	0	0	
Thyroid gland scan abnormal	甲状腺スキャン異常	0	0	0		1 (<0.1%)	0	0	
Transaminases increased	トランスアミナーゼ上昇	5 (0.2%)	1 (<0.1%)	0		7 (0.3%)	2 (<0.1%)	0	
Transferrin saturation decreased	トランスフェリン飽和度低下	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Troponin increased	トロポニン増加	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Ultrasound kidney abnormal	腎超音波検査異常	2 (<0.1%)	0	0		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Ultrasound liver abnormal	肝超音波検査異常	0	0	1 (<0.1%)		0	0	0	
Urinary sediment present	尿沈渣陽性	0	0	0		1 (<0.1%)	0	0	
Urine analysis abnormal	尿検査異常	0	0	0		1 (<0.1%)	0	0	
Urine output decreased	尿量減少	0	1 (<0.1%)	0		0	0	0	
Vitamin D decreased	ビタミンD減少	0	0	0		1 (<0.1%)	0	0	
Walking distance test abnormal	歩行距離テスト異常	1 (<0.1%)	0	0		0	0	0	
Weight decreased	体重減少	4 (0.2%)	1 (<0.1%)	1 (<0.1%)		4 (0.2%)	8 (0.3%)	0	
Weight increased	体重増加	11 (0.5%)	4 (0.2%)	0		4 (0.2%)	3 (0.1%)	0	
White blood cell count decreased	白血球数減少	1 (<0.1%)	0	0		0	0	0	
White blood cell count increased	白血球数増加	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
White blood cells urine positive	尿中白血球陽性	1 (<0.1%)	0	0		0	0	0	
Metabolism and nutrition disorders	代謝および栄養障害	139 (5.8%)	50 (2.1%)	7 (0.3%)		163 (6.8%)	47 (2.0%)	8 (0.3%)	
Acidosis	アシドーシス	0	1 (<0.1%)	0		0	0	0	
Appetite disorder	食欲障害	0	0	0		1 (<0.1%)	0	0	
Cachexia	悪液質	0	1 (<0.1%)	0		0	0	0	
Calcium deficiency	カルシウム欠乏	1 (<0.1%)	0	0		0	0	0	
Combined hyperlipidaemia	複合型高脂血症	0	0	0		0	1 (<0.1%)	0	
Decreased appetite	食欲減退	12 (0.5%)	2 (<0.1%)	1 (<0.1%)		14 (0.6%)	5 (0.2%)	0	
Dehydration	脱水	3 (0.1%)	4 (0.2%)	1 (<0.1%)		3 (0.1%)	3 (0.1%)	2 (<0.1%)	
Diabetes mellitus	糖尿病	12 (0.5%)	5 (0.2%)	0		4 (0.2%)	4 (0.2%)	0	
Diabetes mellitus inadequate control	コントロール不良の糖尿病	2 (<0.1%)	1 (<0.1%)	0		0	0	0	
Dyslipidaemia	脂質異常症	5 (0.2%)	0	0		7 (0.3%)	2 (<0.1%)	0	
Failure to thrive	成長障害	0	0	0		0	0	1 (<0.1%)	
Fluid overload	水分過負荷	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Fluid retention	体液貯留	1 (<0.1%)	2 (<0.1%)	0		2 (<0.1%)	0	0	
Folate deficiency	葉酸欠乏	3 (0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Food craving	食物渇望	0	0	0		1 (<0.1%)	0	0	
Food intolerance	食物不耐性	0	0	0		0	1 (<0.1%)	0	
Glucose tolerance impaired	耐糖能障害	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Gout	痛風	9 (0.4%)	7 (0.3%)	0		13 (0.5%)	10 (0.4%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Hypercalcaemia	高カルシウム血症	1 (<0.1%)	1 (<0.1%)	0		0	0	1 (<0.1%)	
Hypercholesterolaemia	高コレステロール血症	13 (0.5%)	5 (0.2%)	0		25 (1.0%)	4 (0.2%)	0	
Hyperglycaemia	高血糖	7 (0.3%)	1 (<0.1%)	0		4 (0.2%)	5 (0.2%)	0	
Hyperhomocysteinaemia	高ホモシステイン血症	7 (0.3%)	2 (<0.1%)	0		6 (0.2%)	0	0	
Hyperkalaemia	高カリウム血症	1 (<0.1%)	1 (<0.1%)	0		8 (0.3%)	1 (<0.1%)	0	
Hyperlipidaemia	高脂血症	8 (0.3%)	3 (0.1%)	0		11 (0.5%)	3 (0.1%)	0	
Hypertriglyceridaemia	高トリグリセリド血症	4 (0.2%)	0	0		3 (0.1%)	0	0	
Hyperuricaemia	高尿酸血症	5 (0.2%)	0	0		5 (0.2%)	0	0	
Hypoalbuminaemia	低アルブミン血症	0	0	0		1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Hypocalcaemia	低カルシウム血症	1 (<0.1%)	0	1 (<0.1%)		2 (<0.1%)	1 (<0.1%)	0	
Hypochloraemia	低クロール血症	0	0	0		1 (<0.1%)	0	0	
Hypoglycaemia	低血糖症	0	4 (0.2%)	1 (<0.1%)		1 (<0.1%)	0	0	
Hypokalaemia	低カリウム血症	28 (1.2%)	7 (0.3%)	3 (0.1%)		38 (1.6%)	8 (0.3%)	0	
Hypomagnesaemia	低マグネシウム血症	0	3 (0.1%)	0		0	0	0	
Hyponatraemia	低ナトリウム血症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)		4 (0.2%)	1 (<0.1%)	1 (<0.1%)	
Hypophosphataemia	低リン酸血症	0	0	0		5 (0.2%)	0	0	
Hypoproteinaemia	低蛋白血症	2 (<0.1%)	0	0		0	0	0	
Hypovolaemia	血液量減少症	0	1 (<0.1%)	0		0	1 (<0.1%)	1 (<0.1%)	
Increased appetite	食欲亢進	0	0	0		1 (<0.1%)	0	0	
Iron deficiency	鉄欠乏	10 (0.4%)	0	0		4 (0.2%)	1 (<0.1%)	0	
Ketoacidosis	ケトアシドーシス	0	0	0		0	1 (<0.1%)	0	
Lactic acidosis	乳酸アシドーシス	0	0	0		0	1 (<0.1%)	0	
Latent tetany	潜伏テタニー	1 (<0.1%)	0	0		0	0	0	
Lipid metabolism disorder	脂質代謝障害	0	0	0		1 (<0.1%)	0	0	
Magnesium deficiency	マグネシウム欠乏	1 (<0.1%)	0	0		0	0	0	
Malnutrition	栄養障害	0	0	0		0	0	1 (<0.1%)	
Metabolic acidosis	代謝性アシドーシス	0	0	0		0	1 (<0.1%)	0	
Metabolic disorder	代謝障害	0	0	0		0	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	10 (0.4%)	0	0		8 (0.3%)	0	0	
Obesity	肥満	0	0	0		1 (<0.1%)	1 (<0.1%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
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%)	0	0		3 (0.1%)	0	0	
Polydipsia	多飲症	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Shock hypoglycaemic	低血糖ショック	1 (<0.1%)	0	0		0	0	0	
Type 2 diabetes mellitus	２型糖尿病	7 (0.3%)	3 (0.1%)	1 (<0.1%)		2 (<0.1%)	1 (<0.1%)	0	
Vitamin B12 deficiency	ビタミンＢ１２欠乏	4 (0.2%)	1 (<0.1%)	0		3 (0.1%)	2 (<0.1%)	0	
Vitamin D deficiency	ビタミンＤ欠乏	5 (0.2%)	1 (<0.1%)	0		2 (<0.1%)	2 (<0.1%)	0	
Weight loss poor	体重減少不良	1 (<0.1%)	0	0		0	0	0	
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	360 (14.9%)	145 (6.0%)	25 (1.0%)		381 (15.8%)	140 (5.8%)	26 (1.1%)	
Ankylosing spondylitis	強直性脊椎炎	0	0	0		1 (<0.1%)	0	0	
Arthralgia	関節痛	60 (2.5%)	23 (1.0%)	2 (<0.1%)		56 (2.3%)	19 (0.8%)	2 (<0.1%)	
Arthritis	関節炎	7 (0.3%)	3 (0.1%)	0		7 (0.3%)	2 (<0.1%)	0	
Articular calcification	関節石灰化	0	1 (<0.1%)	0		0	0	0	
Back pain	背部痛	60 (2.5%)	22 (0.9%)	6 (0.2%)		85 (3.5%)	43 (1.8%)	3 (0.1%)	
Bone cyst	骨嚢腫	0	0	0		1 (<0.1%)	0	0	
Bone pain	骨痛	5 (0.2%)	4 (0.2%)	0		5 (0.2%)	1 (<0.1%)	0	
Bunion	バニオン	0	1 (<0.1%)	0		0	0	0	
Bursa disorder	滑液包障害	0	0	0		1 (<0.1%)	0	0	
Bursitis	滑液包炎	1 (<0.1%)	3 (0.1%)	0		2 (<0.1%)	2 (<0.1%)	0	
Cervical spinal stenosis	頚部脊柱管狭窄症	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Coccydynia	尾骨痛	0	0	0		1 (<0.1%)	0	0	
Costochondritis	肋軟骨炎	1 (<0.1%)	1 (<0.1%)	0		3 (0.1%)	0	0	
Exostosis	外骨腫	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Flank pain	側腹部痛	4 (0.2%)	1 (<0.1%)	0		9 (0.4%)	5 (0.2%)	0	
Foot deformity	足変形	2 (<0.1%)	0	0		0	0	0	
Gouty arthritis	痛風性関節炎	0	1 (<0.1%)	1 (<0.1%)		0	1 (<0.1%)	0	
Groin pain	鼠径部痛	2 (<0.1%)	3 (0.1%)	0		4 (0.2%)	1 (<0.1%)	0	
Haemarthrosis	出血性関節症	2 (<0.1%)	2 (<0.1%)	0		2 (<0.1%)	1 (<0.1%)	0	
Intervertebral disc compression	椎間板圧迫	0	0	0		1 (<0.1%)	0	0	
Intervertebral disc degeneration	椎間板変性症	0	1 (<0.1%)	0		0	1 (<0.1%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Intervertebral disc disorder	椎間板障害	0	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Intervertebral disc protrusion	椎間板突出	1 (<0.1%)	2 (<0.1%)	2 (<0.1%)		2 (<0.1%)	2 (<0.1%)	0	
Jaw cyst	顎骨嚢胞	0	0	0		0	1 (<0.1%)	0	
Joint contracture	関節拘縮	0	1 (<0.1%)	0		0	0	0	
Joint effusion	関節滲出液	7 (0.3%)	1 (<0.1%)	0		0	2 (<0.1%)	0	
Joint stiffness	関節硬直	3 (0.1%)	0	0		2 (<0.1%)	1 (<0.1%)	0	
Joint swelling	関節腫脹	14 (0.6%)	0	1 (<0.1%)		11 (0.5%)	2 (<0.1%)	0	
Kyphosis	脊柱後弯症	0	1 (<0.1%)	0		0	0	0	
Ligament calcification	靭帯石灰化	0	0	0		1 (<0.1%)	0	0	
Limb discomfort	四肢不快感	4 (0.2%)	0	0		4 (0.2%)	1 (<0.1%)	0	
Lordosis	脊柱前弯症	1 (<0.1%)	0	0		0	0	0	
Lower extremity mass	下肢腫瘤	1 (<0.1%)	1 (<0.1%)	0		4 (0.2%)	0	0	
Mobility decreased	運動性低下	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Monarthritis	単関節炎	0	0	0		2 (<0.1%)	0	0	
Muscle contracture	筋拘縮	3 (0.1%)	0	0		0	1 (<0.1%)	0	
Muscle fatigue	筋肉疲労	3 (0.1%)	0	0		1 (<0.1%)	0	0	
Muscle haemorrhage	筋肉内出血	1 (<0.1%)	0	1 (<0.1%)		2 (<0.1%)	4 (0.2%)	5 (0.2%)	
Muscle rigidity	筋固縮	1 (<0.1%)	0	0		0	0	0	
Muscle spasms	筋痙縮	38 (1.6%)	11 (0.5%)	0		46 (1.9%)	8 (0.3%)	0	
Muscle tightness	筋緊張	2 (<0.1%)	0	0		2 (<0.1%)	0	0	
Muscle twitching	筋攣縮	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Muscular weakness	筋力低下	4 (0.2%)	5 (0.2%)	1 (<0.1%)		4 (0.2%)	2 (<0.1%)	1 (<0.1%)	
Musculoskeletal chest pain	筋骨格系胸痛	21 (0.9%)	7 (0.3%)	1 (<0.1%)		16 (0.7%)	7 (0.3%)	0	
Musculoskeletal discomfort	筋骨格不快感	1 (<0.1%)	0	0		3 (0.1%)	0	0	
Musculoskeletal pain	筋骨格痛	22 (0.9%)	17 (0.7%)	1 (<0.1%)		31 (1.3%)	5 (0.2%)	3 (0.1%)	
Musculoskeletal stiffness	筋骨格硬直	3 (0.1%)	3 (0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Myalgia	筋肉痛	23 (1.0%)	12 (0.5%)	2 (<0.1%)		27 (1.1%)	5 (0.2%)	0	
Myalgia intercostal	肋間筋肉痛	0	0	0		0	1 (<0.1%)	0	
Myofascial pain syndrome	筋膜疼痛症候群	0	0	0		1 (<0.1%)	0	0	
Neck mass	頚部腫瘤	1 (<0.1%)	0	0		0	0	0	
Neck pain	頚部痛	11 (0.5%)	3 (0.1%)	1 (<0.1%)		18 (0.7%)	4 (0.2%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Osteitis	骨炎	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Osteitis deformans	変形性骨炎	0	1 (<0.1%)	0		0	0	0	
Osteoarthritis	変形性関節症	12 (0.5%)	12 (0.5%)	3 (0.1%)		8 (0.3%)	12 (0.5%)	0	
Osteochondritis	骨軟骨炎	1 (<0.1%)	0	0		0	0	0	
Osteolysis	骨溶解	1 (<0.1%)	0	1 (<0.1%)		0	0	0	
Osteonecrosis	骨壊死	0	1 (<0.1%)	1 (<0.1%)		0	1 (<0.1%)	0	
Osteopenia	骨減少症	1 (<0.1%)	0	0		0	0	0	
Osteoporosis	骨粗鬆症	4 (0.2%)	1 (<0.1%)	0		2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Osteorrhagia	骨出血	0	0	0		1 (<0.1%)	0	0	
Pain in extremity	四肢痛	129 (5.3%)	23 (1.0%)	2 (<0.1%)		122 (5.1%)	29 (1.2%)	3 (0.1%)	
Pain in jaw	顎痛	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Pathological fracture	病的骨折	0	1 (<0.1%)	0		0	0	0	
Periarthritis	関節周囲炎	1 (<0.1%)	3 (0.1%)	0		2 (<0.1%)	0	1 (<0.1%)	
Plantar fasciitis	足底筋膜炎	1 (<0.1%)	0	0		0	0	0	
Polyarthritis	多発性関節炎	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Pseudarthrosis	偽関節	0	0	0		0	0	1 (<0.1%)	
Pubic pain	恥骨痛	1 (<0.1%)	0	0		0	0	0	
Rhabdomyolysis	横紋筋融解症	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Rheumatoid arthritis	関節リウマチ	1 (<0.1%)	0	1 (<0.1%)		3 (0.1%)	1 (<0.1%)	0	
Rotator cuff syndrome	肩回旋筋腱板症候群	3 (0.1%)	2 (<0.1%)	0		2 (<0.1%)	1 (<0.1%)	0	
Sacroiliitis	仙腸骨炎	1 (<0.1%)	0	0		0	0	0	
Scleroderma	強皮症	0	0	0		0	1 (<0.1%)	0	
Scoliosis	側弯症	1 (<0.1%)	1 (<0.1%)	0		0	0	1 (<0.1%)	
Sensation of heaviness	重感	2 (<0.1%)	1 (<0.1%)	0		6 (0.2%)	1 (<0.1%)	0	
Soft tissue haemorrhage	軟部組織出血	0	0	0		1 (<0.1%)	0	0	
Soft tissue mass	軟部組織腫瘤	1 (<0.1%)	0	0		0	0	0	
Spinal column stenosis	脊柱管狭窄症	0	0	0		1 (<0.1%)	0	1 (<0.1%)	
Spinal disorder	脊椎障害	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Spinal osteoarthritis	変形性脊椎症	7 (0.3%)	2 (<0.1%)	0		7 (0.3%)	0	2 (<0.1%)	
Spondylitis	脊椎炎	0	0	0		1 (<0.1%)	1 (<0.1%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Sympathetic posterior cervical syndrome	交感神経性後頚部症候群	1 (<0.1%)	0	0		0	0	0	
Synovial cyst	滑液嚢腫	2 (<0.1%)	1 (<0.1%)	0		7 (0.3%)	0	0	
Synovial disorder	滑膜障害	1 (<0.1%)	0	0		0	0	0	
Systemic lupus erythematosus	全身性エリテマトーデス	1 (<0.1%)	0	0		0	0	3 (0.1%)	
Temporomandibular joint syndrome	顎関節症候群	0	0	0		1 (<0.1%)	0	0	
Tendon disorder	腱障害	2 (<0.1%)	1 (<0.1%)	0		2 (<0.1%)	0	0	
Tendon pain	腱痛	0	0	0		2 (<0.1%)	0	0	
Tendonitis	腱炎	10 (0.4%)	3 (0.1%)	0		4 (0.2%)	0	0	
Tenosynovitis	腱鞘炎	2 (<0.1%)	0	0		2 (<0.1%)	0	0	
Torticollis	斜頚	0	2 (<0.1%)	0		0	0	0	
Vertebral column mass	脊柱腫瘤	1 (<0.1%)	0	0		0	0	0	
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）	42 (1.7%)	27 (1.1%)	44 (1.8%)		38 (1.6%)	29 (1.2%)	37 (1.5%)	
Acute lymphocytic leukaemia	急性リンパ性白血病	0	0	0		0	0	1 (<0.1%)	
Acute promyelocytic leukaemia	急性前骨髄球性白血病	1 (<0.1%)	0	0		0	0	0	
Adenocarcinoma	腺癌	0	0	1 (<0.1%)		0	0	0	
Adrenal adenoma	副腎腺腫	1 (<0.1%)	0	1 (<0.1%)		1 (<0.1%)	0	0	
Adrenal neoplasm	副腎新生物	0	0	0		0	1 (<0.1%)	0	
Angiolipoma	血管脂肪腫	1 (<0.1%)	0	0		0	0	0	
Angiomyolipoma	血管筋脂肪腫	0	0	0		1 (<0.1%)	0	0	
Anogenital warts	肛門性器疣贅	0	0	0		1 (<0.1%)	0	0	
B-cell lymphoma	Ｂ細胞性リンパ腫	0	0	1 (<0.1%)		0	0	0	
Basal cell carcinoma	基底細胞癌	6 (0.2%)	1 (<0.1%)	0		5 (0.2%)	2 (<0.1%)	0	
Benign breast neoplasm	乳房の良性新生物	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Benign hepatic neoplasm	肝の良性新生物	2 (<0.1%)	0	0		0	0	0	
Benign neoplasm	良性新生物	0	0	0		1 (<0.1%)	0	0	
Benign oesophageal neoplasm	食道の良性新生物	0	1 (<0.1%)	0		0	0	0	
Benign ovarian tumour	卵巣良性腫瘍	1 (<0.1%)	0	0		0	0	0	
Benign renal neoplasm	腎臓の良性新生物	1 (<0.1%)	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Bile duct cancer non-resectable	切除不能な胆管癌	0	0	0		0	0	1 (<0.1%)	
Bladder cancer	膀胱癌	0	0	0		0	1 (<0.1%)	1 (<0.1%)	
Bladder neoplasm	膀胱新生物	0	0	0		0	2 (<0.1%)	0	
Bowen's disease	ボーエン病	1 (<0.1%)	0	0		0	0	0	
Brain neoplasm	脳新生物	0	0	2 (<0.1%)		0	0	0	
Breast cancer	乳癌	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Breast cancer metastatic	転移性乳癌	0	0	1 (<0.1%)		0	0	0	
Breast cancer recurrent	再発乳癌	0	1 (<0.1%)	0		0	0	1 (<0.1%)	
Breast neoplasm	乳房新生物	0	1 (<0.1%)	0		0	0	0	
Bronchial carcinoma	気管支癌	0	0	0		0	0	1 (<0.1%)	
Cerebellar tumour	小脳腫瘍	1 (<0.1%)	0	0		0	0	0	
Chronic myeloid leukaemia	慢性骨髄性白血病	0	0	0		1 (<0.1%)	0	0	
Colon adenoma	大腸腺腫	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Colon cancer	結腸癌	0	3 (0.1%)	2 (<0.1%)		0	0	0	
Colon cancer metastatic	転移性結腸癌	0	0	0		0	0	1 (<0.1%)	
Colon cancer recurrent	再発結腸癌	0	0	0		0	1 (<0.1%)	0	
Colon neoplasm	結腸新生物	0	0	1 (<0.1%)		0	0	0	
Colorectal cancer	結腸直腸癌	0	0	2 (<0.1%)		0	0	0	
Essential thrombocythaemia	本態性血小板血症	1 (<0.1%)	0	0		0	0	0	
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	0		0	0	0	
Fibroadenoma of breast	乳腺線維腺腫	0	1 (<0.1%)	0		0	0	0	
Fibroma	線維腫	1 (<0.1%)	0	0		0	0	0	
Focal nodular hyperplasia	限局性結節性過形成	1 (<0.1%)	0	0		0	0	0	
Gallbladder cancer	胆嚢癌	0	0	1 (<0.1%)		0	0	0	
Gastric cancer	胃癌	0	1 (<0.1%)	3 (0.1%)		0	0	0	
Gastric neoplasm	胃新生物	0	0	0		0	0	1 (<0.1%)	
Gastrointestinal stromal tumour	消化管間質性腫瘍	0	0	0		0	0	1 (<0.1%)	
Gastrointestinal tract adenoma	胃腸管腺腫	0	0	0		1 (<0.1%)	0	0	
Haemangioma of liver	肝臓血管腫	3 (0.1%)	0	0		7 (0.3%)	0	0	
Haemangioma of skin	皮膚血管腫	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Haemangioma of spleen	脾血管腫	0	0	0		1 (<0.1%)	0	0	
Hepatic neoplasm	肝新生物	0	0	1 (<0.1%)		0	0	0	
Histiocytosis haematophagic	貪食細胞性組織球症	0	0	1 (<0.1%)		0	0	0	
Inflammatory pseudotumour	炎症性偽腫瘍	1 (<0.1%)	0	0		0	0	0	
Lipoma	脂肪腫	3 (0.1%)	0	0		0	0	0	
Liposarcoma	脂肪肉腫	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Lung adenocarcinoma	肺腺癌	0	0	3 (0.1%)		0	3 (0.1%)	1 (<0.1%)	
Lung cancer metastatic	転移性肺癌	0	0	1 (<0.1%)		0	0	2 (<0.1%)	
Lung carcinoma cell type unspecified recurrent	再発肺癌、細胞タイプ不明	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Lung neoplasm	肺新生物	3 (0.1%)	1 (<0.1%)	0		5 (0.2%)	0	0	
Lung neoplasm malignant	肺の悪性新生物	0	0	5 (0.2%)		0	1 (<0.1%)	3 (0.1%)	
Lung squamous cell carcinoma stage unspecified	肺扁平上皮癌、病期不明	0	1 (<0.1%)	0		0	0	1 (<0.1%)	
Lymphoma	リンパ腫	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Malignant ascites	悪性腹水	0	0	1 (<0.1%)		0	0	1 (<0.1%)	
Malignant melanoma	悪性黒色腫	0	0	1 (<0.1%)		0	0	0	
Malignant pleural effusion	悪性胸水	0	0	0		0	1 (<0.1%)	0	
Melanocytic naevus	メラノサイト性母斑	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Meningioma	髄膜腫	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Mesothelioma malignant	悪性中皮腫	0	0	0		0	1 (<0.1%)	0	
Mesothelioma malignant advanced	進行した悪性中皮腫	0	0	0		0	1 (<0.1%)	0	
Metastases to bone	骨転移	0	0	0		0	0	1 (<0.1%)	
Metastases to central nervous system	中枢神経系転移	0	0	0		0	0	2 (<0.1%)	
Metastases to liver	肝転移	0	0	2 (<0.1%)		0	1 (<0.1%)	3 (0.1%)	
Metastases to lung	肺転移	0	0	0		0	0	3 (0.1%)	
Metastases to lymph nodes	リンパ節転移	0	0	0		0	0	1 (<0.1%)	
Metastases to peritoneum	腹膜転移	0	0	1 (<0.1%)		0	0	0	
Metastases to pleura	胸膜転移	0	0	0		0	1 (<0.1%)	1 (<0.1%)	
Metastases to spine	脊椎転移	0	0	1 (<0.1%)		0	0	0	
Metastasis	転移	0	0	0		0	0	1 (<0.1%)	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Metastatic gastric cancer	転移性胃癌	0	0	0		0	0	1 (<0.1%)	
Metastatic neoplasm	転移性新生物	0	0	1 (<0.1%)		0	0	2 (<0.1%)	
Morton's neuroma	モートン神経腫	1 (<0.1%)	0	0		0	0	0	
Multiple myeloma	多発性骨髄腫	0	0	2 (<0.1%)		1 (<0.1%)	0	0	
Myelodysplastic syndrome	骨髄異形成症候群	0	0	0		0	0	1 (<0.1%)	
Neoplasm	新生物	1 (<0.1%)	0	0		0	0	0	
Neoplasm malignant	悪性新生物	0	0	0		0	0	2 (<0.1%)	
Neoplasm prostate	前立腺新生物	0	0	1 (<0.1%)		0	0	0	
Non-small cell lung cancer	非小細胞肺癌	0	1 (<0.1%)	1 (<0.1%)		0	0	0	
Ovarian cancer	卵巣癌	0	0	1 (<0.1%)		0	0	0	
Ovarian epithelial cancer	卵巣上皮癌	0	0	2 (<0.1%)		0	0	0	
Ovarian germ cell teratoma benign	卵巣胚細胞良性奇形腫	1 (<0.1%)	0	0		0	0	0	
Pancreatic carcinoma	膵癌	0	0	1 (<0.1%)		0	0	0	
Papilloma	乳頭腫	1 (<0.1%)	0	0		0	0	0	
Parathyroid tumour benign	良性副甲状腺腫瘍	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Pelvic neoplasm	骨盤新生物	0	0	0		0	0	1 (<0.1%)	
Pituitary tumour	下垂体腫瘍	0	1 (<0.1%)	0		0	0	0	
Polycythaemia vera	真性多血症	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Prostate cancer	前立腺癌	1 (<0.1%)	2 (<0.1%)	0		3 (0.1%)	2 (<0.1%)	4 (0.2%)	
Prostate cancer recurrent	再発前立腺癌	0	0	0		0	0	1 (<0.1%)	
Prostatic adenoma	前立腺腺腫	0	3 (0.1%)	0		0	1 (<0.1%)	1 (<0.1%)	
Rectal cancer	直腸癌	0	0	2 (<0.1%)		0	0	0	
Rectal cancer metastatic	転移性直腸癌	0	0	0		0	0	1 (<0.1%)	
Rectal neoplasm	直腸新生物	0	1 (<0.1%)	0		0	0	0	
Renal cancer	腎癌	0	0	1 (<0.1%)		0	0	0	
Renal cell carcinoma	腎細胞癌	0	1 (<0.1%)	0		0	0	0	
Renal neoplasm	腎新生物	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Sarcoma	肉腫	0	0	1 (<0.1%)		0	0	0	
Seborrhoeic keratosis	脂漏性角化症	3 (0.1%)	0	0		0	0	0	
Skin cancer	皮膚癌	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Skin papilloma	皮膚乳頭腫	1 (<0.1%)	0	0		0	0	0	
Squamous cell carcinoma	扁平上皮癌	0	0	0		1 (<0.1%)	0	0	
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0	0	0		1 (<0.1%)	2 (<0.1%)	0	
T-cell lymphoma	Ｔ細胞性リンパ腫	0	0	1 (<0.1%)		0	0	0	
Thyroid cancer	甲状腺癌	0	0	0		1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Thyroid neoplasm	甲状腺新生物	5 (0.2%)	2 (<0.1%)	0		4 (0.2%)	0	0	
Tumour haemorrhage	腫瘍出血	2 (<0.1%)	0	0		1 (<0.1%)	0	1 (<0.1%)	
Tumour pain	腫瘍疼痛	1 (<0.1%)	0	0		0	0	0	
Uterine leiomyoma	子宮平滑筋腫	4 (0.2%)	3 (0.1%)	0		2 (<0.1%)	2 (<0.1%)	0	
Nervous system disorders	神経系障害	282 (11.7%)	99 (4.1%)	29 (1.2%)		280 (11.6%)	94 (3.9%)	15 (0.6%)	
Ageusia	味覚消失	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Altered state of consciousness	意識変容状態	0	0	1 (<0.1%)		0	0	0	
Amnesia	健忘	3 (0.1%)	0	0		0	1 (<0.1%)	0	
Anosmia	無嗅覚	1 (<0.1%)	0	0		0	0	0	
Ataxia	運動失調	2 (<0.1%)	0	0		0	1 (<0.1%)	0	
Autonomic nervous system imbalance	自律神経失調	0	0	0		1 (<0.1%)	0	0	
Axonal neuropathy	軸索型ニューロパチー	0	1 (<0.1%)	0		0	0	0	
Balance disorder	平衡障害	4 (0.2%)	0	0		2 (<0.1%)	1 (<0.1%)	0	
Burning sensation	灼熱感	7 (0.3%)	0	0		3 (0.1%)	0	0	
Carotid arteriosclerosis	頚動脈硬化症	0	0	0		4 (0.2%)	1 (<0.1%)	0	
Carotid artery stenosis	頚動脈狭窄	0	0	0		1 (<0.1%)	0	0	
Carpal tunnel syndrome	手根管症候群	0	0	1 (<0.1%)		2 (<0.1%)	2 (<0.1%)	0	
Cauda equina syndrome	馬尾症候群	0	0	1 (<0.1%)		0	0	0	
Central nervous system lesion	中枢神経系病変	0	1 (<0.1%)	0		0	0	0	
Cerebellar haemorrhage	小脳出血	0	0	1 (<0.1%)		0	0	0	
Cerebral arteriosclerosis	脳動脈硬化症	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Cerebral artery stenosis	大脳動脈狭窄	0	1 (<0.1%)	0		0	0	0	
Cerebral atrophy	大脳萎縮	0	0	0		1 (<0.1%)	0	0	
Cerebral haemorrhage	脳出血	0	0	0		0	1 (<0.1%)	3 (0.1%)	
Cerebral infarction	脳梗塞	0	0	0		2 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Cerebral ischaemia	脳虚血	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Cerebrovascular accident	脳血管発作	0	0	1 (<0.1%)		0	0	0	
Cervical root pain	頚髄神経根痛	0	1 (<0.1%)	0		0	0	0	
Cervicobrachial syndrome	頚腕症候群	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Clumsiness	不器用	0	1 (<0.1%)	0		0	0	0	
Cognitive disorder	認知障害	1 (<0.1%)	0	0		0	0	0	
Complex regional pain syndrome	複合性局所疼痛症候群	0	0	0		0	3 (0.1%)	0	
Convulsion	痙攣	1 (<0.1%)	0	2 (<0.1%)		0	1 (<0.1%)	1 (<0.1%)	
Decreased vibratory sense	振動覚低下	0	1 (<0.1%)	0		0	0	0	
Dementia	認知症	1 (<0.1%)	0	0		0	0	0	
Dementia Alzheimer's type	アルツハイマー型認知症	2 (<0.1%)	0	0		0	0	1 (<0.1%)	
Depressed level of consciousness	意識レベルの低下	0	0	1 (<0.1%)		0	0	0	
Diabetic neuropathy	糖尿病性ニューロパチー	0	0	1 (<0.1%)		0	0	0	
Disturbance in attention	注意力障害	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Dizziness	浮動性めまい	55 (2.3%)	9 (0.4%)	0		68 (2.8%)	18 (0.7%)	0	
Dizziness exertional	労作性めまい	0	0	0		1 (<0.1%)	0	0	
Dizziness postural	体位性めまい	2 (<0.1%)	0	0		4 (0.2%)	0	0	
Dysaesthesia	異常感覚	2 (<0.1%)	0	0		2 (<0.1%)	0	0	
Dysarthria	構語障害	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Dysgeusia	味覚異常	5 (0.2%)	0	0		3 (0.1%)	0	0	
Dystonia	ジストニー	0	0	0		1 (<0.1%)	0	0	
Encephalomalacia	脳軟化	1 (<0.1%)	0	0		0	0	0	
Encephalopathy	脳症	0	0	0		0	1 (<0.1%)	0	
Epilepsy	てんかん	1 (<0.1%)	1 (<0.1%)	0		0	2 (<0.1%)	0	
Essential tremor	本態性振戦	1 (<0.1%)	0	0		0	0	0	
Facial neuralgia	顔面部神経痛	0	0	0		0	1 (<0.1%)	0	
Guillain-Barre syndrome	ギラン・バレー症候群	0	0	1 (<0.1%)		0	0	0	
Haemorrhage intracranial	頭蓋内出血	1 (<0.1%)	0	0		1 (<0.1%)	0	1 (<0.1%)	
Haemorrhagic transformation stroke	卒中の出血性変化	0	0	1 (<0.1%)		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Headache	頭痛	148 (6.1%)	43 (1.8%)	2 (<0.1%)		136 (5.7%)	32 (1.3%)	6 (0.2%)	
Hemiparesis	不全片麻痺	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Hepatic encephalopathy	肝性脳症	0	0	1 (<0.1%)		0	0	0	
Hyperaesthesia	知覚過敏	1 (<0.1%)	0	0		0	0	0	
Hypersomnia	過眠症	0	0	0		1 (<0.1%)	0	0	
Hypoaesthesia	感覚鈍麻	10 (0.4%)	2 (<0.1%)	0		16 (0.7%)	2 (<0.1%)	0	
Intercostal neuralgia	肋間神経痛	1 (<0.1%)	0	0		0	0	0	
Ischaemic stroke	虚血性脳卒中	0	6 (0.2%)	5 (0.2%)		2 (<0.1%)	3 (0.1%)	1 (<0.1%)	
Lacunar infarction	ラクナ梗塞	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Lethargy	嗜眠	9 (0.4%)	1 (<0.1%)	1 (<0.1%)		4 (0.2%)	2 (<0.1%)	0	
Leukoencephalopathy	白質脳症	0	1 (<0.1%)	0		0	0	0	
Loss of consciousness	意識消失	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Memory impairment	記憶障害	4 (0.2%)	0	0		2 (<0.1%)	1 (<0.1%)	0	
Migraine	片頭痛	5 (0.2%)	3 (0.1%)	2 (<0.1%)		4 (0.2%)	3 (0.1%)	0	
Migraine with aura	前兆を伴う片頭痛	1 (<0.1%)	0	0		0	0	0	
Muscle contractions involuntary	不随意性筋収縮	0	0	0		1 (<0.1%)	0	0	
Nerve compression	神経圧迫	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Nervous system disorder	神経系障害	0	1 (<0.1%)	0		0	0	0	
Neuralgia	神経痛	3 (0.1%)	0	0		3 (0.1%)	2 (<0.1%)	0	
Neuropathy peripheral	末梢性ニューロパチー	3 (0.1%)	3 (0.1%)	0		3 (0.1%)	0	0	
Orthostatic intolerance	起立不耐性	0	0	0		1 (<0.1%)	0	0	
Paraesthesia	錯感覚	23 (1.0%)	6 (0.2%)	0		23 (1.0%)	2 (<0.1%)	0	
Paraparesis	不全対麻痺	0	0	1 (<0.1%)		0	0	0	
Parkinson's disease	パーキンソン病	0	1 (<0.1%)	0		0	2 (<0.1%)	0	
Parkinsonism	パーキンソニズム	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Partial seizures	部分発作	0	0	0		1 (<0.1%)	0	0	
Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1 (<0.1%)	0	0		0	0	0	
Peroneal nerve palsy	腓骨神経麻痺	0	1 (<0.1%)	0		0	0	0	
Polyneuropathy	多発ニューロパチー	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Poor quality sleep	睡眠の質低下	0	0	0		2 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Post herpetic neuralgia	ヘルペス後神経痛	0	0	0		0	1 (<0.1%)	0	
Presyncope	失神寸前の状態	8 (0.3%)	2 (<0.1%)	1 (<0.1%)		5 (0.2%)	3 (0.1%)	1 (<0.1%)	
Pseudoradicular syndrome	偽性根症候群	0	0	0		1 (<0.1%)	0	0	
Radicular pain	神経根痛	0	1 (<0.1%)	0		0	0	0	
Radiculitis	神経根炎	0	0	0		1 (<0.1%)	0	0	
Restless legs syndrome	下肢静止不能症候群	1 (<0.1%)	3 (0.1%)	0		3 (0.1%)	1 (<0.1%)	0	
Sciatica	坐骨神経痛	11 (0.5%)	5 (0.2%)	1 (<0.1%)		12 (0.5%)	4 (0.2%)	1 (<0.1%)	
Sensory disturbance	感覚障害	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Sinus headache	副鼻腔炎に伴う頭痛	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Somnolence	傾眠	3 (0.1%)	0	0		6 (0.2%)	0	0	
Spinal cord compression	脊髄圧迫	0	0	0		0	0	1 (<0.1%)	
Subacute combined cord degeneration	亜急性脊髄連合変性症	0	1 (<0.1%)	0		0	0	0	
Subarachnoid haemorrhage	くも膜下出血	0	0	0		0	1 (<0.1%)	0	
Syncope	失神	9 (0.4%)	8 (0.3%)	4 (0.2%)		7 (0.3%)	11 (0.5%)	0	
Tension headache	緊張性頭痛	1 (<0.1%)	0	0		3 (0.1%)	1 (<0.1%)	0	
Thermohyperaesthesia	温度覚過敏	0	0	0		1 (<0.1%)	0	0	
Transient ischaemic attack	一過性脳虚血発作	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)		2 (<0.1%)	2 (<0.1%)	0	
Tremor	振戦	8 (0.3%)	6 (0.2%)	0		9 (0.4%)	1 (<0.1%)	0	
Trigeminal neuralgia	三叉神経痛	0	0	0		1 (<0.1%)	0	0	
VIIth nerve paralysis	第７脳神経麻痺	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Vascular headache	血管性頭痛	0	0	0		1 (<0.1%)	0	0	
Pregnancy, puerperium and perinatal conditions	妊娠、産褥および周産期の状態	2 (<0.1%)	1 (<0.1%)	0		4 (0.2%)	2 (<0.1%)	1 (<0.1%)	
Perineal haematoma	会陰血腫	0	0	0		1 (<0.1%)	0	0	
Post abortion haemorrhage	流産後の出血	0	0	0		0	1 (<0.1%)	0	
Pregnancy	妊娠	2 (<0.1%)	1 (<0.1%)	0		3 (0.1%)	2 (<0.1%)	1 (<0.1%)	
Psychiatric disorders	精神障害	158 (6.6%)	57 (2.4%)	2 (<0.1%)		164 (6.8%)	49 (2.0%)	3 (0.1%)	
Acute stress disorder	急性ストレス反応	0	0	0		1 (<0.1%)	0	0	
Affective disorder	感情障害	0	2 (<0.1%)	0		0	0	0	
Agitation	激越	2 (<0.1%)	2 (<0.1%)	0		0	1 (<0.1%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Agoraphobia	広場恐怖症	0	0	0		1 (<0.1%)	0	0	
Alcohol abuse	アルコール乱用	0	1 (<0.1%)	0		2 (<0.1%)	0	0	
Alcohol withdrawal syndrome	アルコール離脱症候群	0	0	0		1 (<0.1%)	0	0	
Alcoholic hangover	アルコールによる宿酔	0	0	0		0	1 (<0.1%)	0	
Alcoholism	アルコール症	0	0	0		1 (<0.1%)	0	0	
Anxiety	不安	64 (2.7%)	16 (0.7%)	0		61 (2.5%)	15 (0.6%)	0	
Anxiety disorder	不安障害	0	0	0		1 (<0.1%)	0	0	
Apathy	無感情	1 (<0.1%)	0	0		0	0	0	
Attention deficit/hyperactivity disorder	注意欠陥多動性障害	0	1 (<0.1%)	0		0	0	0	
Bipolar I disorder	双極Ⅰ型障害	1 (<0.1%)	1 (<0.1%)	0		0	0	1 (<0.1%)	
Confusional state	錯乱状態	5 (0.2%)	3 (0.1%)	0		6 (0.2%)	1 (<0.1%)	0	
Delirium	譫妄	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Delusion	妄想	0	1 (<0.1%)	0		0	0	0	
Depressed mood	抑うつ気分	2 (<0.1%)	0	0		0	1 (<0.1%)	0	
Depression	うつ病	20 (0.8%)	17 (0.7%)	2 (<0.1%)		26 (1.1%)	15 (0.6%)	1 (<0.1%)	
Depressive symptom	抑うつ症状	0	1 (<0.1%)	0		0	0	0	
Disorientation	失見当識	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Emotional distress	感情的苦悩	1 (<0.1%)	0	0		0	0	0	
Initial insomnia	初期不眠症	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Insomnia	不眠症	59 (2.4%)	8 (0.3%)	0		68 (2.8%)	8 (0.3%)	0	
Libido increased	リビド一亢進	1 (<0.1%)	0	0		0	0	0	
Loss of libido	リビド消失	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Mania	躁病	0	1 (<0.1%)	0		0	0	0	
Mental disorder	精神障害	0	0	0		1 (<0.1%)	0	0	
Mental disorder due to a general medical condition	身体疾患による精神障害	0	0	0		0	0	1 (<0.1%)	
Mental status changes	精神状態変化	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Mood swings	気分動揺	1 (<0.1%)	0	0		0	0	0	
Nervousness	神経過敏	5 (0.2%)	2 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Neurosis	神経症	0	3 (0.1%)	0		0	1 (<0.1%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Nightmare	悪夢	1 (<0.1%)	0	0		0	0	0	
Orgasm abnormal	オルガズム異常	0	0	0		0	1 (<0.1%)	0	
Panic attack	パニック発作	6 (0.2%)	0	0		1 (<0.1%)	2 (<0.1%)	0	
Panic disorder	パニック障害	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Panic reaction	パニック反応	0	0	0		0	1 (<0.1%)	0	
Persecutory delusion	被害妄想	1 (<0.1%)	0	0		0	0	0	
Post-traumatic stress disorder	外傷後ストレス障害	0	0	0		0	1 (<0.1%)	0	
Psychotic disorder	精神病性障害	1 (<0.1%)	0	0		0	0	0	
Restlessness	落ち着きのなさ	2 (<0.1%)	0	0		0	0	0	
Sleep disorder	睡眠障害	5 (0.2%)	0	0		9 (0.4%)	1 (<0.1%)	0	
Somatoform disorder	身体表現性障害	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Stress	ストレス	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Suicide attempt	自殺企図	0	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Renal and urinary disorders	腎および尿路障害	100 (4.1%)	42 (1.7%)	7 (0.3%)		121 (5.0%)	35 (1.5%)	13 (0.5%)	0
Acute prerenal failure	急性腎前性腎不全	0	0	1 (<0.1%)		0	0	0	
Anuria	無尿	0	0	0		0	1 (<0.1%)	0	
Bilirubinuria	ビリルビン尿	0	0	0		0	1 (<0.1%)	0	
Bladder dilatation	膀胱拡大	0	0	0		0	0	1 (<0.1%)	
Bladder mass	膀胱腫瘤	0	1 (<0.1%)	0		0	0	0	
Bladder pain	膀胱痛	0	0	0		0	1 (<0.1%)	0	
Bladder prolapse	膀胱脱	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Bladder spasm	膀胱痙縮	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Calculus bladder	膀胱結石	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Calculus ureteric	尿管結石	0	0	0		0	1 (<0.1%)	0	
Calculus urinary	尿路結石	0	0	0		1 (<0.1%)	0	0	
Cystitis haemorrhagic	出血性膀胱炎	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Dysuria	排尿困難	9 (0.4%)	4 (0.2%)	0		9 (0.4%)	0	0	
Enuresis	遺尿	0	0	0		1 (<0.1%)	0	0	
Glomerulonephritis membranous	膜性糸球体腎炎	0	0	1 (<0.1%)		0	0	0	
Haematuria	血尿	52 (2.2%)	18 (0.7%)	2 (<0.1%)		52 (2.2%)	16 (0.7%)	3 (0.1%)	1 (<0.1%)
Hydronephrosis	水腎症	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Incontinence	失禁	1 (<0.1%)	0	0		0	0	0	
Kidney enlargement	腎腫大	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Microalbuminuria	ミクロアルブミン尿	0	0	0		2 (<0.1%)	0	0	
Micturition disorder	排尿異常	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Nephritis	腎炎	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Nephroangiosclerosis	腎血管硬化症	0	0	0		1 (<0.1%)	0	0	
Nephrocalcinosis	腎石灰沈着症	0	0	0		1 (<0.1%)	0	0	
Nephrolithiasis	腎結石症	8 (0.3%)	1 (<0.1%)	0		7 (0.3%)	3 (0.1%)	3 (0.1%)	
Nephropathy toxic	中毒性ネフロパシー	0	0	0		0	1 (<0.1%)	0	
Nephrosclerosis	腎硬化症	1 (<0.1%)	0	0		0	0	0	
Nephrotic syndrome	ネフローゼ症候群	0	0	1 (<0.1%)		0	0	0	
Neurogenic bladder	神経因性膀胱	0	0	0		1 (<0.1%)	0	0	
Nocturia	夜間頻尿	1 (<0.1%)	0	0		0	0	0	
Oliguria	乏尿	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Pollakiuria	頻尿	4 (0.2%)	1 (<0.1%)	0		7 (0.3%)	1 (<0.1%)	1 (<0.1%)	
Polyuria	多尿	3 (0.1%)	0	0		2 (<0.1%)	0	0	
Proteinuria	蛋白尿	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Pyelocaliectasis	腎盂腎杯拡張症	0	0	0		1 (<0.1%)	0	0	
Pyuria	膿尿	0	0	0		1 (<0.1%)	0	0	
Renal atrophy	腎萎縮	0	0	0		2 (<0.1%)	0	0	
Renal colic	腎仙痛	0	1 (<0.1%)	0		2 (<0.1%)	4 (0.2%)	0	
Renal cyst	腎嚢胞	17 (0.7%)	1 (<0.1%)	0		24 (1.0%)	1 (<0.1%)	1 (<0.1%)	
Renal failure	腎不全	0	1 (<0.1%)	1 (<0.1%)		1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Renal failure acute	急性腎不全	2 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	3 (0.1%)	2 (<0.1%)	
Renal haemorrhage	腎出血	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Renal impairment	腎機能障害	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)		1 (<0.1%)	2 (<0.1%)	0	
Renal mass	腎腫瘤	1 (<0.1%)	1 (<0.1%)	0		2 (<0.1%)	0	0	
Renal pain	腎臓痛	1 (<0.1%)	1 (<0.1%)	0		3 (0.1%)	0	0	
Renal tubular necrosis	腎尿細管壊死	0	0	0		0	0	1 (<0.1%)	
Stress urinary incontinence	腹圧性尿失禁	0	0	0		1 (<0.1%)	0	0	
Ureteric perforation	尿管穿孔	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Urethral disorder	尿道障害	0	0	0		0	1 (<0.1%)	0	
Urethral stenosis	尿道狭窄	0	0	0		3 (0.1%)	0	0	
Urge incontinence	切迫性尿失禁	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Urinary bladder polyp	膀胱ポリープ	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Urinary incontinence	尿失禁	3 (0.1%)	1 (<0.1%)	0		3 (0.1%)	1 (<0.1%)	0	
Urinary retention	尿閉	2 (<0.1%)	6 (0.2%)	1 (<0.1%)		1 (<0.1%)	4 (0.2%)	0	
Urinary tract disorder	尿路障害	0	1 (<0.1%)	0		0	0	0	
Urinary tract obstruction	尿路閉塞	2 (<0.1%)	0	0		0	0	0	
Reproductive system and breast disorders	生殖系および乳房障害	109 (4.5%)	61 (2.5%)	8 (0.3%)		101 (4.2%)	29 (1.2%)	6 (0.2%)	
Amenorrhoea	無月経	1 (<0.1%)	1 (<0.1%)	0		3 (0.1%)	1 (<0.1%)	0	
Atrophic vulvovaginitis	萎縮性外陰腟炎	3 (0.1%)	0	1 (<0.1%)		0	0	0	
Balanitis	亀頭炎	1 (<0.1%)	0	0		0	0	0	
Balanoposthitis	亀頭包皮炎	1 (<0.1%)	0	0		0	0	0	
Bartholin's cyst	バルトリン嚢腫	0	1 (<0.1%)	0		0	0	0	
Benign prostatic hyperplasia	良性前立腺肥大症	8 (0.3%)	4 (0.2%)	0		5 (0.2%)	1 (<0.1%)	0	
Breast calcifications	乳房石灰化	0	0	0		1 (<0.1%)	0	0	
Breast discharge	乳房分泌	0	0	0		1 (<0.1%)	0	0	
Breast disorder	乳房障害	1 (<0.1%)	0	0		0	0	0	
Breast haematoma	乳房血腫	1 (<0.1%)	0	0		0	0	0	
Breast induration	乳房硬結	1 (<0.1%)	0	0		0	0	0	
Breast mass	乳房腫瘤	2 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Breast necrosis	乳房壊死	0	0	0		1 (<0.1%)	0	0	
Breast pain	乳房痛	1 (<0.1%)	0	0		3 (0.1%)	1 (<0.1%)	0	
Breast swelling	乳房腫脹	1 (<0.1%)	0	0		0	0	0	
Breast tenderness	乳房圧痛	1 (<0.1%)	0	0		0	0	0	
Cervical cyst	子宮頚部嚢胞	1 (<0.1%)	0	0		0	0	0	
Cervical dysplasia	子宮頚部上皮異形成	0	0	0		0	1 (<0.1%)	0	
Cervical polyp	子宮頚管ポリープ	0	1 (<0.1%)	0		3 (0.1%)	0	0	
Cervix disorder	子宮頚部障害	0	1 (<0.1%)	0		0	0	0	
Coital bleeding	性交出血	3 (0.1%)	0	0		2 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Cystocele	膀胱瘤	1 (<0.1%)	0	0		0	0	0	
Dysfunctional uterine bleeding	機能障害性子宮出血	0	1 (<0.1%)	0		0	0	0	
Dysmenorrhoea	月経困難症	5 (0.2%)	3 (0.1%)	0		7 (0.3%)	2 (<0.1%)	0	
Dyspareunia	性交困難	1 (<0.1%)	0	0		0	0	0	
Endometrial hyperplasia	子宮内膜増殖症	0	0	0		1 (<0.1%)	0	0	
Endometrial hypertrophy	子宮内膜肥厚	0	0	0		0	1 (<0.1%)	0	
Epididymitis	精巣上体炎	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Erectile dysfunction	勃起不全	2 (<0.1%)	1 (<0.1%)	0		0	0	0	
Fibrocystic breast disease	線維嚢胞性乳腺疾患	0	0	0		1 (<0.1%)	0	0	
Genital discomfort	性器不快感	0	0	0		1 (<0.1%)	0	0	
Genital erythema	性器紅斑	1 (<0.1%)	0	0		0	0	0	
Genital haemorrhage	性器出血	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Genital lesion	生殖器病変	0	1 (<0.1%)	0		0	0	0	
Genital pain	生殖器痛	0	0	0		1 (<0.1%)	0	0	
Genital ulceration	性器潰瘍形成	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Gynaecomastia	女性化乳房	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Haematospermia	血精液症	0	0	0		3 (0.1%)	0	0	
Haemorrhagic ovarian cyst	出血性卵巣嚢胞	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Hypomenorrhoea	過少月経	0	0	0		1 (<0.1%)	0	0	
Menometrorrhagia	機能性子宮出血	0	0	0		2 (<0.1%)	1 (<0.1%)	0	
Menopausal symptoms	閉経期症状	0	0	0		2 (<0.1%)	0	0	
Menorrhagia	月経過多	39 (1.6%)	29 (1.2%)	5 (0.2%)		33 (1.4%)	10 (0.4%)	2 (<0.1%)	
Menstruation delayed	月経遅延	1 (<0.1%)	0	0		0	0	0	
Menstruation irregular	不規則月経	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Metrorrhagia	不正子宮出血	9 (0.4%)	3 (0.1%)	1 (<0.1%)		10 (0.4%)	5 (0.2%)	1 (<0.1%)	
Nipple exudate bloody	血性乳頭滲出液	1 (<0.1%)	0	0		0	0	0	
Nipple pain	乳頭痛	0	0	0		1 (<0.1%)	0	0	
Ovarian cyst	卵巣嚢胞	7 (0.3%)	0	0		3 (0.1%)	1 (<0.1%)	1 (<0.1%)	
Ovarian enlargement	卵巣腫大	0	0	0		1 (<0.1%)	0	0	
Pelvic pain	骨盤痛	3 (0.1%)	1 (<0.1%)	0		3 (0.1%)	0	0	
Penile haematoma	陰茎血腫	0	0	0		0	1 (<0.1%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Penile oedema	陰茎浮腫	0	0	0		0	1 (<0.1%)	0	
Polycystic ovaries	多嚢胞性卵巣	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Priapism	持続勃起症	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Prostatic calcification	前立腺石灰化	0	0	0		2 (<0.1%)	0	0	
Prostatic dysplasia	前立腺異形成	1 (<0.1%)	0	0		0	0	0	
Prostatic mass	前立腺腫瘤	0	0	0		0	1 (<0.1%)	0	
Prostatism	前立腺症	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Prostatitis	前立腺炎	2 (<0.1%)	2 (<0.1%)	0		4 (0.2%)	1 (<0.1%)	1 (<0.1%)	
Prostatomegaly	前立腺腫大	0	1 (<0.1%)	0		3 (0.1%)	1 (<0.1%)	0	
Scrotal haematocoele	陰嚢血瘤	1 (<0.1%)	0	0		0	0	0	
Scrotal swelling	陰嚢腫脹	0	0	0		1 (<0.1%)	0	0	
Testicular cyst	精巣嚢胞	0	0	0		1 (<0.1%)	0	0	
Uterine atrophy	子宮萎縮	2 (<0.1%)	0	0		0	0	0	
Uterine cervical erosion	子宮頚部びらん	0	0	0		1 (<0.1%)	0	0	
Uterine cervix atrophy	子宮頚部萎縮	2 (<0.1%)	0	0		0	0	0	
Uterine cyst	子宮嚢胞	0	0	0		1 (<0.1%)	0	0	
Uterine enlargement	子宮肥大	1 (<0.1%)	0	0		0	0	0	
Uterine polyp	子宮ポリープ	0	2 (<0.1%)	0		2 (<0.1%)	0	0	
Uterine prolapse	子宮脱	0	0	1 (<0.1%)		0	0	0	
Uterine spasm	子宮痙攣	0	1 (<0.1%)	0		0	0	0	
Vaginal discharge	膣分泌物	0	0	0		1 (<0.1%)	0	0	
Vaginal haemorrhage	膣出血	19 (0.8%)	7 (0.3%)	0		10 (0.4%)	1 (<0.1%)	1 (<0.1%)	
Vaginal inflammation	膣の炎症	0	0	0		1 (<0.1%)	0	0	
Vulval disorder	外陰部障害	0	1 (<0.1%)	0		0	0	0	
Vulvovaginal discomfort	外陰膣不快感	1 (<0.1%)	0	0		0	0	0	
Vulvovaginal dryness	外陰膣乾燥	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Vulvovaginal pruritus	外陰膣そう痒症	2 (<0.1%)	0	0		0	0	0	
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	475 (19.7%)	139 (5.8%)	39 (1.6%)	2 (<0.1%)	470 (19.5%)	146 (6.1%)	30 (1.2%)	0
Acute pulmonary oedema	急性肺水腫	0	0	1 (<0.1%)		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Acute respiratory distress syndrome	急性呼吸窮迫症候群	0	0	1 (<0.1%)		0	0	1 (<0.1%)	
Acute respiratory failure	急性呼吸不全	0	0	1 (<0.1%)		0	0	0	
Allergic cough	アレルギー性咳嗽	0	0	0		3 (0.1%)	0	0	
Alveolar proteinosis	肺胞蛋白症	1 (<0.1%)	0	0		0	0	0	
Alveolitis	胞隔炎	0	1 (<0.1%)	0		0	0	0	
Alveolitis allergic	アレルギー性胞隔炎	0	0	0		0	1 (<0.1%)	0	
Asthma	喘息	6 (0.2%)	8 (0.3%)	1 (<0.1%)		10 (0.4%)	5 (0.2%)	1 (<0.1%)	
Asthma exercise induced	運動誘発喘息	0	0	0		1 (<0.1%)	0	0	
Atelectasis	無気肺	3 (0.1%)	2 (<0.1%)	0		0	0	0	
Bronchial disorder	気管支障害	1 (<0.1%)	0	0		0	0	0	
Bronchial haemorrhage	気管支出血	0	1 (<0.1%)	0		0	0	0	
Bronchial hyperreactivity	気管支反応性亢進	2 (<0.1%)	0	0		0	0	0	
Bronchial irritation	気管支刺激	1 (<0.1%)	0	0		0	0	0	
Bronchial obstruction	気管支閉塞	0	0	0		0	1 (<0.1%)	0	
Bronchiectasis	気管支拡張症	0	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Bronchitis chronic	慢性気管支炎	2 (<0.1%)	0	0		3 (0.1%)	1 (<0.1%)	0	
Bronchopneumopathy	気管支肺症	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Bronchospasm	気管支痙攣	4 (0.2%)	0	0		4 (0.2%)	0	1 (<0.1%)	
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	5 (0.2%)	9 (0.4%)	3 (0.1%)		6 (0.2%)	4 (0.2%)	2 (<0.1%)	
Cough	咳嗽	136 (5.6%)	17 (0.7%)	1 (<0.1%)	1 (<0.1%)	149 (6.2%)	19 (0.8%)	1 (<0.1%)	0
Diaphragmalgia	横隔膜痛	0	0	0		1 (<0.1%)	0	0	
Diaphragmatic disorder	横隔膜障害	0	0	0		1 (<0.1%)	0	0	
Diaphragmatic hernia	横隔膜ヘルニア	0	0	0		1 (<0.1%)	0	0	
Dry throat	咽喉乾燥	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Dysphonia	発声障害	4 (0.2%)	0	0		6 (0.2%)	0	0	
Dyspnoea	呼吸困難	105 (4.4%)	50 (2.1%)	5 (0.2%)	1 (<0.1%)	91 (3.8%)	41 (1.7%)	4 (0.2%)	
Dyspnoea at rest	安静時呼吸困難	0	0	0		1 (<0.1%)	0	0	
Dyspnoea exertional	労作性呼吸困難	17 (0.7%)	1 (<0.1%)	1 (<0.1%)		20 (0.8%)	1 (<0.1%)	0	
Dyspnoea paroxysmal nocturnal	発作性夜間呼吸困難	1 (<0.1%)	0	0		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Emphysema	肺気腫	1 (<0.1%)	1 (<0.1%)	0		2 (<0.1%)	0	0	
Epistaxis	鼻出血	195 (8.1%)	22 (0.9%)	1 (<0.1%)		176 (7.3%)	18 (0.7%)	3 (0.1%)	
Haemoptysis	喀血	76 (3.2%)	5 (0.2%)	0		71 (3.0%)	8 (0.3%)	2 (<0.1%)	
Haemothorax	血胸	1 (<0.1%)	0	1 (<0.1%)		0	0	2 (<0.1%)	
Hiccups	しゃっくり	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Hypercapnia	高炭酸ガス血症	0	0	0		0	0	1 (<0.1%)	
Hyperventilation	過換気	2 (<0.1%)	2 (<0.1%)	0		0	2 (<0.1%)	0	
Hypoxia	低酸素症	0	2 (<0.1%)	0		1 (<0.1%)	0	0	
Increased upper airway secretion	上気道分泌増加	0	0	0		1 (<0.1%)	0	0	
Interstitial lung disease	間質性肺疾患	0	0	1 (<0.1%)		0	0	0	
Laryngeal haemorrhage	喉頭出血	0	0	0		1 (<0.1%)	0	0	
Laryngeal hypertrophy	喉頭肥大	0	0	0		1 (<0.1%)	0	0	
Laryngeal inflammation	喉頭の炎症	1 (<0.1%)	0	0		0	0	0	
Laryngeal oedema	喉頭浮腫	1 (<0.1%)	0	0		0	0	0	
Lower respiratory tract inflammation	下気道の炎症	1 (<0.1%)	0	0		0	0	0	
Lung cyst	肺嚢胞	0	0	0		1 (<0.1%)	0	0	
Lung disorder	肺障害	2 (<0.1%)	3 (0.1%)	0		4 (0.2%)	1 (<0.1%)	0	
Lung infiltration	肺浸潤	1 (<0.1%)	0	0		0	0	1 (<0.1%)	
Mediastinal haemorrhage	縦隔出血	0	0	0		1 (<0.1%)	0	0	
Nasal congestion	鼻閉	5 (0.2%)	1 (<0.1%)	0		5 (0.2%)	0	0	
Nasal dryness	鼻乾燥	3 (0.1%)	0	0		0	0	0	
Nasal obstruction	鼻閉塞	0	0	0		3 (0.1%)	0	0	
Nasal polyps	鼻茸	1 (<0.1%)	0	0		0	0	0	
Nasal septum deviation	鼻中隔弯曲	2 (<0.1%)	0	0		0	0	0	
Nocturnal dyspnoea	夜間呼吸困難	0	0	0		2 (<0.1%)	0	0	
Obstructive airways disorder	閉塞性気道障害	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Oropharyngeal blistering	口腔咽頭水疱形成	0	0	0		1 (<0.1%)	0	0	
Oropharyngeal discomfort	口腔咽頭不快感	1 (<0.1%)	0	0		0	0	0	
Oropharyngeal pain	口腔咽頭痛	24 (1.0%)	3 (0.1%)	0		24 (1.0%)	4 (0.2%)	0	
Orthopnoea	起坐呼吸	3 (0.1%)	0	0		2 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Paranasal cyst	副鼻腔嚢胞	0	0	0		1 (<0.1%)	0	0	
Paranasal sinus haematoma	副鼻腔血腫	0	0	0		0	1 (<0.1%)	0	
Paranasal sinus hypersecretion	副鼻腔分泌過多	0	0	0		1 (<0.1%)	0	0	
Paranasal sinus mucosal hypertrophy	副鼻腔粘膜肥厚	0	0	0		1 (<0.1%)	0	0	
Pharyngeal cyst	咽頭嚢腫	0	0	0		0	1 (<0.1%)	0	
Pharyngeal haemorrhage	咽頭出血	1 (<0.1%)	0	0		0	0	0	
Pharyngeal hypertrophy	咽頭肥大	0	0	0		1 (<0.1%)	0	0	
Pharyngeal inflammation	咽頭の炎症	1 (<0.1%)	0	0		0	0	0	
Pleural adhesion	胸膜癒着	3 (0.1%)	0	0		3 (0.1%)	1 (<0.1%)	0	
Pleural effusion	胸水	7 (0.3%)	7 (0.3%)	5 (0.2%)	1 (<0.1%)	6 (0.2%)	18 (0.7%)	4 (0.2%)	
Pleural fibrosis	胸膜線維症	2 (<0.1%)	1 (<0.1%)	0		0	0	0	
Pleural haemorrhage	胸腔内出血	0	0	1 (<0.1%)		0	0	0	
Pleurisy	胸膜炎	2 (<0.1%)	3 (0.1%)	1 (<0.1%)		5 (0.2%)	6 (0.2%)	0	
Pleuritic pain	胸膜痛	10 (0.4%)	9 (0.4%)	3 (0.1%)		8 (0.3%)	11 (0.5%)	0	
Pneumonia aspiration	誤嚥性肺炎	1 (<0.1%)	0	0		0	0	0	
Pneumothorax	気胸	0	1 (<0.1%)	0		0	4 (0.2%)	0	
Productive cough	湿性咳嗽	9 (0.4%)	0	0		7 (0.3%)	2 (<0.1%)	0	
Pulmonary arterial hypertension	肺動脈高血圧症	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Pulmonary congestion	肺うっ血	2 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Pulmonary embolism	肺塞栓症	0	0	4 (0.2%)		0	0	1 (<0.1%)	
Pulmonary fibrosis	肺線維症	1 (<0.1%)	0	0		2 (<0.1%)	1 (<0.1%)	0	
Pulmonary haemorrhage	肺出血	0	0	2 (<0.1%)		0	0	0	
Pulmonary hypertension	肺高血圧症	5 (0.2%)	1 (<0.1%)	3 (0.1%)		5 (0.2%)	6 (0.2%)	1 (<0.1%)	
Pulmonary infarction	肺梗塞	1 (<0.1%)	2 (<0.1%)	2 (<0.1%)		0	2 (<0.1%)	1 (<0.1%)	
Pulmonary oedema	肺水腫	0	1 (<0.1%)	0		1 (<0.1%)	2 (<0.1%)	0	
Pulmonary sarcoidosis	肺サルコイドーシス	1 (<0.1%)	0	0		0	0	0	
Pulmonary venous thrombosis	肺静脈血栓症	0	0	1 (<0.1%)		0	0	0	
Rales	ラ音	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Reflux laryngitis	逆流性喉頭炎	1 (<0.1%)	0	0		0	0	0	
Respiratory arrest	呼吸停止	0	0	1 (<0.1%)		0	0	1 (<0.1%)	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Respiratory distress	呼吸窮迫	0	1 (<0.1%)	0		0	0	1 (<0.1%)	
Respiratory failure	呼吸不全	1 (<0.1%)	3 (0.1%)	2 (<0.1%)		0	0	3 (0.1%)	
Respiratory tract congestion	気道うっ血	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Respiratory tract haemorrhage	気道出血	0	0	0		1 (<0.1%)	0	0	
Respiratory tract inflammation	気道の炎症	0	0	0		0	1 (<0.1%)	0	
Rhinitis allergic	アレルギー性鼻炎	8 (0.3%)	0	0		6 (0.2%)	0	0	
Rhinitis seasonal	季節性鼻炎	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Rhinorrhoea	鼻漏	5 (0.2%)	0	1 (<0.1%)		7 (0.3%)	0	0	
Sinus congestion	副鼻腔うっ血	4 (0.2%)	1 (<0.1%)	1 (<0.1%)		3 (0.1%)	2 (<0.1%)	0	
Sinus polyp	副鼻腔ポリープ	1 (<0.1%)	0	0		0	0	0	
Sleep apnoea syndrome	睡眠時無呼吸症候群	3 (0.1%)	0	1 (<0.1%)		5 (0.2%)	1 (<0.1%)	2 (<0.1%)	
Sneezing	くしゃみ	0	0	0		1 (<0.1%)	0	0	
Snoring	いびき	0	0	0		1 (<0.1%)	0	0	
Sputum discoloured	変色痰	0	0	0		2 (<0.1%)	0	0	
Tachypnoea	頻呼吸	9 (0.4%)	2 (<0.1%)	0		5 (0.2%)	2 (<0.1%)	0	
Throat irritation	咽喉刺激感	1 (<0.1%)	0	0		4 (0.2%)	0	0	
Throat tightness	咽喉絞扼感	1 (<0.1%)	0	0		0	0	0	
Tracheal inflammation	気管の炎症	1 (<0.1%)	0	0		0	0	0	
Upper-airway cough syndrome	上気道咳症候群	1 (<0.1%)	1 (<0.1%)	0		2 (<0.1%)	0	0	
Wheezing	喘鳴	1 (<0.1%)	1 (<0.1%)	0		3 (0.1%)	0	0	
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	243 (10.1%)	64 (2.7%)	5 (0.2%)		226 (9.4%)	35 (1.5%)	3 (0.1%)	
Acne	ざ瘡	7 (0.3%)	1 (<0.1%)	0		6 (0.2%)	0	0	
Actinic keratosis	日光性角化症	0	1 (<0.1%)	0		2 (<0.1%)	0	0	
Alopecia	脱毛症	19 (0.8%)	4 (0.2%)	0		26 (1.1%)	2 (<0.1%)	1 (<0.1%)	
Alopecia areata	円形脱毛症	0	0	0		1 (<0.1%)	0	0	
Angioedema	血管浮腫	1 (<0.1%)	2 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Blister	水疱	2 (<0.1%)	0	0		4 (0.2%)	0	0	
Blood blister	血性水疱	2 (<0.1%)	0	0		2 (<0.1%)	0	0	
Chloasma	肝斑	0	0	0		1 (<0.1%)	0	0	
Cold sweat	冷汗	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Cutaneous lupus erythematosus	皮膚エリテマトーデス	1 (<0.1%)	0	0		0	0	0	
Cutaneous vasculitis	皮膚血管炎	1 (<0.1%)	0	0		0	0	0	
Decubitus ulcer	褥瘡性潰瘍	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Dermal cyst	皮膚嚢腫	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Dermatitis	皮膚炎	2 (<0.1%)	4 (0.2%)	0		3 (0.1%)	1 (<0.1%)	0	
Dermatitis acneiform	ざ瘡様皮膚炎	1 (<0.1%)	0	0		0	0	0	
Dermatitis allergic	アレルギー性皮膚炎	7 (0.3%)	3 (0.1%)	0		5 (0.2%)	2 (<0.1%)	0	
Dermatitis atopic	アトピー性皮膚炎	2 (<0.1%)	0	0		0	0	0	
Dermatitis contact	接触性皮膚炎	3 (0.1%)	2 (<0.1%)	0		4 (0.2%)	0	0	
Dermatitis exfoliative	剥脱性皮膚炎	0	1 (<0.1%)	0		0	0	0	
Dermatomyositis	皮膚筋炎	0	0	1 (<0.1%)		0	0	0	
Diabetic ulcer	糖尿病性潰瘍	0	0	0		1 (<0.1%)	0	0	
Drug eruption	薬疹	3 (0.1%)	1 (<0.1%)	0		2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Dry skin	皮膚乾燥	5 (0.2%)	1 (<0.1%)	0		4 (0.2%)	0	0	
Dyshidrosis	発汗障害	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Ecchymosis	斑状出血	16 (0.7%)	1 (<0.1%)	0		18 (0.7%)	2 (<0.1%)	0	
Eczema	湿疹	11 (0.5%)	1 (<0.1%)	0		8 (0.3%)	1 (<0.1%)	0	
Erythema	紅斑	11 (0.5%)	1 (<0.1%)	0		8 (0.3%)	1 (<0.1%)	0	
Erythema nodosum	結節性紅斑	0	0	0		1 (<0.1%)	0	0	
Haemorrhage subcutaneous	皮下出血	1 (<0.1%)	0	0		2 (<0.1%)	2 (<0.1%)	0	
Hair texture abnormal	毛質異常	2 (<0.1%)	0	0		0	0	0	
Heat rash	紅色汗疹	0	0	0		2 (<0.1%)	0	0	
Hirsutism	男性型多毛症	0	0	0		1 (<0.1%)	0	0	
Hyperhidrosis	多汗症	12 (0.5%)	1 (<0.1%)	0		6 (0.2%)	1 (<0.1%)	0	
Hyperkeratosis	過角化	3 (0.1%)	0	0		0	0	0	
Increased tendency to bruise	内出血発生の増加傾向	4 (0.2%)	0	0		1 (<0.1%)	0	0	
Ingrowing nail	嵌入爪	0	0	0		0	2 (<0.1%)	0	
Intertrigo	間擦疹	3 (0.1%)	0	0		0	0	0	
Itching scar	瘢痕そう痒感	0	0	0		1 (<0.1%)	0	0	
Keratosis pilaris	毛孔性角化症	1 (<0.1%)	0	0		0	0	0	
Koilonychia	さじ状爪	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Lentigo	黒子	1 (<0.1%)	0	0		0	0	0	
Lichen planus	扁平苔癬	1 (<0.1%)	0	0		0	0	0	
Lichenoid keratosis	苔癬様角化症	0	0	0		1 (<0.1%)	0	0	
Macule	斑	1 (<0.1%)	0	0		0	0	0	
Nail bed bleeding	爪床出血	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Nail bed inflammation	爪床の炎症	0	0	0		0	1 (<0.1%)	0	
Nail disorder	爪の障害	0	0	0		1 (<0.1%)	0	0	
Nail pigmentation	爪色素沈着	1 (<0.1%)	0	0		0	0	0	
Night sweats	寝汗	5 (0.2%)	0	0		7 (0.3%)	1 (<0.1%)	0	
Onychalgia	爪痛	0	0	0		1 (<0.1%)	0	0	
Onychoclasis	爪破損	1 (<0.1%)	0	0		0	0	0	
Onychomadesis	爪甲脱落症	0	0	0		1 (<0.1%)	0	0	
Onychomalacia	爪軟化症	1 (<0.1%)	0	0		0	0	0	
Pain of skin	皮膚疼痛	1 (<0.1%)	0	0		0	0	0	
Palmar-plantar erythrodysaesthesia syndrome	手掌・足底発赤知覚不全症候群	0	1 (<0.1%)	0		0	0	0	
Petechiae	点状出血	3 (0.1%)	0	0		5 (0.2%)	0	0	
Photosensitivity allergic reaction	アレルギー性光線過敏性反応	1 (<0.1%)	0	0		0	0	0	
Pityriasis	粃糠疹	0	0	0		1 (<0.1%)	0	0	
Pityriasis rosea	ばら色粃糠疹	0	0	0		1 (<0.1%)	0	0	
Precancerous skin lesion	前癌性皮膚病変	0	1 (<0.1%)	0		0	0	0	
Prurigo	痒疹	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Pruritus	そう痒症	43 (1.8%)	8 (0.3%)	3 (0.1%)		25 (1.0%)	2 (<0.1%)	0	
Pruritus generalised	全身性そう痒症	4 (0.2%)	0	0		2 (<0.1%)	1 (<0.1%)	0	
Psoriasis	乾癬	2 (<0.1%)	2 (<0.1%)	0		2 (<0.1%)	1 (<0.1%)	0	
Purpura	紫斑	4 (0.2%)	1 (<0.1%)	1 (<0.1%)		1 (<0.1%)	0	0	
Rash	発疹	51 (2.1%)	20 (0.8%)	0		55 (2.3%)	6 (0.2%)	0	
Rash erythematous	紅斑性皮疹	2 (<0.1%)	0	0		3 (0.1%)	1 (<0.1%)	0	
Rash generalised	全身性皮疹	2 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Rash macular	斑状皮疹	2 (<0.1%)	1 (<0.1%)	0		3 (0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Rash maculo-papular	斑状丘疹状皮疹	0	0	0		1 (<0.1%)	0	0	
Rash morbilliform	麻疹様発疹	0	1 (<0.1%)	0		0	0	0	
Rash papular	丘疹性皮疹	2 (<0.1%)	0	0		1 (<0.1%)	0	1 (<0.1%)	
Rash pruritic	そう痒性皮疹	2 (<0.1%)	0	0		2 (<0.1%)	0	0	
Rash vesicular	小水疱性皮疹	0	1 (<0.1%)	0		0	0	0	
Rosacea	酒さ	2 (<0.1%)	0	0		0	0	0	
Scar	瘢痕	1 (<0.1%)	0	0		0	0	0	
Scar pain	瘢痕痛	0	0	0		1 (<0.1%)	0	0	
Seborrhoeic dermatitis	脂漏性皮膚炎	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Skin discolouration	皮膚変色	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Skin disorder	皮膚障害	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Skin exfoliation	皮膚剥脱	2 (<0.1%)	0	0		0	0	0	
Skin fissures	皮膚亀裂	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Skin haemorrhage	皮膚出血	11 (0.5%)	1 (<0.1%)	0		5 (0.2%)	3 (0.1%)	0	
Skin irritation	皮膚刺激	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Skin lesion	皮膚病変	7 (0.3%)	1 (<0.1%)	0		4 (0.2%)	0	0	
Skin mass	皮膚腫瘤	0	0	0		1 (<0.1%)	0	0	
Skin necrosis	皮膚壊死	0	0	0		1 (<0.1%)	0	0	
Skin ulcer	皮膚潰瘍	4 (0.2%)	2 (<0.1%)	0		2 (<0.1%)	3 (0.1%)	0	
Skin ulcer haemorrhage	出血性皮膚潰瘍	0	0	0		1 (<0.1%)	0	0	
Skin warm	皮膚熱感	1 (<0.1%)	0	0		0	0	0	
Stasis dermatitis	うっ滞性皮膚炎	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Swelling face	顔面腫脹	0	0	0		1 (<0.1%)	0	0	
Telangiectasia	毛細血管拡張症	0	0	0		3 (0.1%)	0	0	
Transient acantholytic dermatosis	一過性棘融解性皮膚症	1 (<0.1%)	0	0		0	0	0	
Urticaria	蕁麻疹	5 (0.2%)	5 (0.2%)	0		4 (0.2%)	2 (<0.1%)	0	
Xanthoma	黄色腫	0	0	0		1 (<0.1%)	0	0	
Xeroderma	乾皮症	0	0	0		1 (<0.1%)	0	0	
Social circumstances	社会環境	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)		2 (<0.1%)	1 (<0.1%)	0	
Alcohol use	アルコール摂取	0	1 (<0.1%)	0		0	1 (<0.1%)	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Exposure to communicable disease	伝染病曝露	1 (<0.1%)	0	0		0	0	0	
Menopause	閉経	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Miscarriage of partner	パートナーの自然流産	0	0	1 (<0.1%)		0	0	0	
Stress at work	職場でのストレス	0	0	0		1 (<0.1%)	0	0	
Surgical and medical procedures	外科および内科処置	2 (<0.1%)	4 (0.2%)	0		2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Abortion induced	人工流産	0	2 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Medical device removal	医療機器除去	0	1 (<0.1%)	0		0	0	0	
Radical neck dissection	根治的頚部郭清術	1 (<0.1%)	0	0		0	0	0	
Spinal laminectomy	脊椎椎弓切除	0	1 (<0.1%)	0		0	0	0	
Tooth extraction	抜歯	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Vascular disorders	血管障害	185 (7.7%)	55 (2.3%)	14 (0.6%)		223 (9.3%)	58 (2.4%)	12 (0.5%)	
Aortic aneurysm	大動脈瘤	1 (<0.1%)	0	1 (<0.1%)		2 (<0.1%)	2 (<0.1%)	2 (<0.1%)	
Aortic aneurysm rupture	大動脈瘤破裂	0	0	0		0	0	1 (<0.1%)	
Aortic arteriosclerosis	大動脈硬化症	2 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Aortic calcification	大動脈石灰化	1 (<0.1%)	0	0		3 (0.1%)	0	0	
Aortic dilatation	大動脈拡張	2 (<0.1%)	0	0		4 (0.2%)	0	0	
Aortic dissection	大動脈解離	0	0	1 (<0.1%)		0	0	0	
Aortic thrombosis	大動脈血栓症	1 (<0.1%)	0	0		0	0	1 (<0.1%)	
Arterial disorder	動脈障害	1 (<0.1%)	0	0		0	0	0	
Arterial haemorrhage	動脈出血	0	0	1 (<0.1%)		0	0	0	
Arterial stenosis	動脈狭窄	1 (<0.1%)	0	0		0	0	0	
Arteriosclerosis	動脈硬化症	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Circulatory collapse	循環虚脱	0	0	1 (<0.1%)		1 (<0.1%)	1 (<0.1%)	0	
Collateral circulation	側副血行	5 (0.2%)	0	0		5 (0.2%)	1 (<0.1%)	0	
Deep vein thrombosis	深部静脈血栓症	1 (<0.1%)	0	0		0	0	0	
Distributive shock	血液分布異常性ショック	0	0	0		0	0	1 (<0.1%)	
Embolism arterial	動脈塞栓症	0	0	0		0	1 (<0.1%)	0	
Extremity necrosis	四肢壊死	0	0	0		0	1 (<0.1%)	0	
Flushing	潮紅	0	0	0		4 (0.2%)	0	0	
Haematoma	血腫	43 (1.8%)	12 (0.5%)	2 (<0.1%)		78 (3.2%)	11 (0.5%)	3 (0.1%)	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Hot flush	ほてり	5 (0.2%)	3 (0.1%)	0		10 (0.4%)	0	1 (<0.1%)	
Hypertension	高血圧	86 (3.6%)	23 (1.0%)	2 (<0.1%)		64 (2.7%)	23 (1.0%)	1 (<0.1%)	
Hypertensive crisis	高血圧クリーゼ	1 (<0.1%)	2 (<0.1%)	0		1 (<0.1%)	2 (<0.1%)	0	
Hypotension	低血圧	15 (0.6%)	10 (0.4%)	1 (<0.1%)		12 (0.5%)	7 (0.3%)	0	
Iliac artery occlusion	腸骨動脈閉塞	0	0	0		1 (<0.1%)	0	0	
Iliac artery thrombosis	腸骨動脈血栓症	0	0	0		0	0	1 (<0.1%)	
Intra-abdominal haematoma	腹腔内血腫	0	0	0		1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Intra-abdominal haemorrhage	腹腔内出血	0	0	1 (<0.1%)		0	0	2 (<0.1%)	
Labile blood pressure	不安定血圧	0	0	0		0	1 (<0.1%)	0	
Labile hypertension	不安定高血圧	0	1 (<0.1%)	0		0	0	0	
Lymphocele	リンパ嚢腫	0	1 (<0.1%)	0		0	0	0	
Lymphoedema	リンパ浮腫	1 (<0.1%)	0	0		0	0	0	
Orthostatic hypotension	起立性低血圧	3 (0.1%)	0	1 (<0.1%)		6 (0.2%)	1 (<0.1%)	0	
Pallor	蒼白	0	1 (<0.1%)	0		0	0	0	
Paradoxical embolism	奇異性塞栓症	0	0	1 (<0.1%)		0	0	0	
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	0	0	1 (<0.1%)		1 (<0.1%)	0	0	
Peripheral coldness	末梢冷感	2 (<0.1%)	0	0		2 (<0.1%)	0	0	
Peripheral ischaemia	末梢性虚血	0	0	1 (<0.1%)		0	0	0	
Periphlebitis	静脈周囲炎	1 (<0.1%)	0	0		0	0	0	
Phlebitis	静脈炎	2 (<0.1%)	0	0		6 (0.2%)	1 (<0.1%)	0	
Phlebitis superficial	表在性静脈炎	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Poor peripheral circulation	末梢循環不良	0	0	0		1 (<0.1%)	0	0	
Post thrombotic syndrome	血栓後症候群	2 (<0.1%)	2 (<0.1%)	0		2 (<0.1%)	0	0	
Raynaud's phenomenon	レイノー現象	0	0	0		1 (<0.1%)	0	0	
Subclavian steal syndrome	鎖骨下動脈スチール症候群	0	0	0		1 (<0.1%)	0	0	
Superficial vein prominence	表在静脈隆起	0	0	0		1 (<0.1%)	0	0	
Superior vena cava syndrome	上大静脈症候群	0	0	0		0	1 (<0.1%)	0	
Systolic hypertension	収縮期高血圧	0	0	0		1 (<0.1%)	0	0	
Temporal arteritis	側頭動脈炎	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-5 重症度別の TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing N=2412 (100%)	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing N=2405 (100%)
Thrombophlebitis	血栓性静脈炎	4 (0.2%)	0	0		4 (0.2%)	1 (<0.1%)	0	
Thrombophlebitis superficial	表在性血栓性静脈炎	2 (<0.1%)	0	1 (<0.1%)		1 (<0.1%)	0	0	
Thrombosis	血栓症	0	0	0		0	1 (<0.1%)	0	
Varicose ulceration	静脈瘤性潰瘍	0	0	0		1 (<0.1%)	0	0	
Varicose vein	静脈瘤	3 (0.1%)	0	0		12 (0.5%)	1 (<0.1%)	0	
Vasoconstriction	血管収縮	1 (<0.1%)	0	0		0	0	0	
Vasodilatation	血管拡張	1 (<0.1%)	0	0		3 (0.1%)	0	0	
Vein pain	静脈痛	3 (0.1%)	0	0		4 (0.2%)	1 (<0.1%)	0	
Vena cava thrombosis	大静脈血栓症	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Venous haemorrhage	静脈出血	0	1 (<0.1%)	0		0	0	0	
Venous insufficiency	静脈不全	8 (0.3%)	1 (<0.1%)	0		10 (0.4%)	2 (<0.1%)	0	
Venous thrombosis	静脈血栓症	0	0	0		1 (<0.1%)	0	0	

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Only the most severe intensity is counted for multiple occurrences of the same AE in each subject.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-3-4.sas erjli 21MAR2013 10:11
End of table

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Number of subjects (%) with at least one adverse event		196 (33.2%)	107 (18.1%)	22 (3.7%)		201 (33.6%)	105 (17.6%)	29 (4.8%)	
Blood and lymphatic system disorders	血液およびリンパ系障害	0	2 (0.3%)	0		3 (0.5%)	2 (0.3%)	0	
Anaemia	貧血	0	2 (0.3%)	0		2 (0.3%)	2 (0.3%)	0	
Iron deficiency anaemia	鉄欠乏性貧血	0	0	0		1 (0.2%)	0	0	
Cardiac disorders	心臓障害	4 (0.7%)	5 (0.8%)	2 (0.3%)		7 (1.2%)	7 (1.2%)	7 (1.2%)	
Acute myocardial infarction	急性心筋梗塞	0	0	1 (0.2%)		0	0	0	
Angina pectoris	狭心症	0	0	0		1 (0.2%)	1 (0.2%)	0	
Angina unstable	不安定狭心症	0	0	0		0	1 (0.2%)	2 (0.3%)	
Arrhythmia	不整脈	0	0	0		0	1 (0.2%)	1 (0.2%)	
Atrial fibrillation	心房細動	1 (0.2%)	3 (0.5%)	0		2 (0.3%)	2 (0.3%)	1 (0.2%)	
Bradycardia	徐脈	1 (0.2%)	0	1 (0.2%)		0	0	1 (0.2%)	
Cardiac arrest	心停止	0	0	0		0	0	1 (0.2%)	
Cardiac failure congestive	うっ血性心不全	0	0	0		0	1 (0.2%)	0	
Cardiomyopathy	心筋症	0	1 (0.2%)	0		0	0	0	
Extrasystoles	期外収縮	0	0	0		1 (0.2%)	0	0	
Myocardial ischaemia	心筋虚血	0	0	0		0	1 (0.2%)	0	
Palpitations	動悸	3 (0.5%)	0	0		1 (0.2%)	1 (0.2%)	1 (0.2%)	
Pericarditis	心膜炎	0	0	0		0	1 (0.2%)	0	
Sick sinus syndrome	洞不全症候群	0	1 (0.2%)	0		0	0	0	
Sinus bradycardia	洞性徐脈	0	0	0		1 (0.2%)	0	0	
Supraventricular tachycardia	上室性頻脈	1 (0.2%)	1 (0.2%)	0		0	0	0	
Tachycardia	頻脈	0	0	0		2 (0.3%)	0	0	
Tachycardia paroxysmal	発作性頻脈	1 (0.2%)	0	0		0	0	0	
Congenital, familial and genetic disorders	先天性、家族性および遺伝性障害	1 (0.2%)	1 (0.2%)	0		1 (0.2%)	0	0	
Basal cell naevus syndrome	基底細胞母斑症候群	0	1 (0.2%)	0		0	0	0	
Factor V Leiden mutation	第Ⅴ因子ライデン変異	1 (0.2%)	0	0		0	0	0	
Hydrocele	陰嚢水瘤	0	0	0		1 (0.2%)	0	0	
Ear and labyrinth disorders	耳および迷路障害	5 (0.8%)	1 (0.2%)	0		3 (0.5%)	3 (0.5%)	0	
Deafness unilateral	片耳難聴	0	0	0		0	1 (0.2%)	0	
Ear haemorrhage	耳出血	1 (0.2%)	0	0		0	1 (0.2%)	0	
Ear pain	耳痛	1 (0.2%)	0	0		0	0	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Motion sickness	乗物酔い	1 (0.2%)	0	0		0	0	0	
Tinnitus	耳鳴	0	0	0		1 (0.2%)	0	0	
Vertigo	回転性めまい	2 (0.3%)	1 (0.2%)	0		2 (0.3%)	1 (0.2%)	0	
Endocrine disorders	内分泌障害	1 (0.2%)	0	0		1 (0.2%)	0	0	
Goitre	甲状腺腫	1 (0.2%)	0	0		0	0	0	
Hyperthyroidism	甲状腺機能亢進症	0	0	0		1 (0.2%)	0	0	
Hypothyroidism	甲状腺機能低下症	1 (0.2%)	0	0		0	0	0	
Eye disorders	眼障害	5 (0.8%)	1 (0.2%)	0		11 (1.8%)	4 (0.7%)	0	
Cataract	白内障	0	0	0		2 (0.3%)	0	0	
Conjunctival haemorrhage	結膜出血	0	0	0		4 (0.7%)	2 (0.3%)	0	
Conjunctivitis	結膜炎	0	0	0		1 (0.2%)	0	0	
Dry eye	眼乾燥	1 (0.2%)	0	0		1 (0.2%)	0	0	
Eye pain	眼痛	1 (0.2%)	0	0		0	0	0	
Eye pruritus	眼そう痒症	0	0	0		1 (0.2%)	0	0	
Ocular hyperaemia	眼充血	0	0	0		1 (0.2%)	0	0	
Photopsia	光視症	0	1 (0.2%)	0		0	0	0	
Scleral haemorrhage	強膜出血	0	0	0		0	1 (0.2%)	0	
Vision blurred	霧視	1 (0.2%)	0	0		2 (0.3%)	0	0	
Visual impairment	視力障害	2 (0.3%)	0	0		0	0	0	
Vitreous detachment	硝子体剥離	0	0	0		0	1 (0.2%)	0	
Gastrointestinal disorders	胃腸障害	32 (5.4%)	13 (2.2%)	3 (0.5%)		66 (11.0%)	18 (3.0%)	4 (0.7%)	
Abdominal discomfort	腹部不快感	1 (0.2%)	0	0		4 (0.7%)	1 (0.2%)	0	
Abdominal distension	腹部膨満	0	0	0		0	1 (0.2%)	0	
Abdominal hernia	腹部ヘルニア	1 (0.2%)	0	0		0	0	0	
Abdominal hernia obstructive	閉塞を伴う腹部ヘルニア	0	0	1 (0.2%)		0	0	0	
Abdominal pain	腹痛	3 (0.5%)	3 (0.5%)	1 (0.2%)		0	2 (0.3%)	0	
Abdominal pain lower	下腹部痛	2 (0.3%)	0	0		0	0	0	
Abdominal pain upper	上腹部痛	0	1 (0.2%)	0		7 (1.2%)	3 (0.5%)	0	
Colitis ischaemic	虚血性大腸炎	0	1 (0.2%)	0		0	0	0	
Constipation	便秘	3 (0.5%)	1 (0.2%)	1 (0.2%)		6 (1.0%)	0	0	
Diarrhoea	下痢	6 (1.0%)	2 (0.3%)	0		6 (1.0%)	1 (0.2%)	0	
Diverticulum	憩室	1 (0.2%)	1 (0.2%)	0		1 (0.2%)	0	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Dry mouth	口内乾燥	1 (0.2%)	0	0		2 (0.3%)	0	0	
Dyspepsia	消化不良	4 (0.7%)	0	0		8 (1.3%)	0	0	
Dysphagia	嚥下障害	0	0	0		0	0	1 (0.2%)	
Epigastric discomfort	心窩部不快感	0	0	0		0	1 (0.2%)	0	
Flatulence	鼓腸	2 (0.3%)	0	0		0	0	0	
Food poisoning	食中毒	0	0	0		1 (0.2%)	0	0	
Gastric disorder	胃障害	1 (0.2%)	0	0		0	0	0	
Gastric ulcer	胃潰瘍	0	1 (0.2%)	0		0	1 (0.2%)	0	
Gastritis	胃炎	3 (0.5%)	1 (0.2%)	0		2 (0.3%)	1 (0.2%)	0	
Gastritis haemorrhagic	出血性胃炎	0	0	0		1 (0.2%)	0	0	
Gastrointestinal haemorrhage	胃腸出血	0	0	0		0	1 (0.2%)	1 (0.2%)	
Gastrooesophageal reflux disease	胃食道逆流性疾患	0	0	0		3 (0.5%)	0	0	
Gingival bleeding	歯肉出血	2 (0.3%)	0	0		11 (1.8%)	0	0	
Gingivitis	歯肉炎	0	0	0		1 (0.2%)	0	0	
Haematochezia	血便排泄	1 (0.2%)	0	0		0	0	0	
Haemorrhoidal haemorrhage	痔出血	1 (0.2%)	0	0		1 (0.2%)	2 (0.3%)	0	
Haemorrhoids	痔核	1 (0.2%)	1 (0.2%)	0		1 (0.2%)	1 (0.2%)	0	
Hiatus hernia	裂孔ヘルニア	0	0	0		0	0	1 (0.2%)	
Inguinal hernia	鼠径ヘルニア	1 (0.2%)	1 (0.2%)	0		0	1 (0.2%)	0	
Intestinal obstruction	腸閉塞	0	0	0		0	0	1 (0.2%)	
Intra-abdominal haematoma	腹腔内血腫	1 (0.2%)	0	0		0	0	0	
Lip haematoma	口唇血腫	0	0	0		1 (0.2%)	0	0	
Lip pain	口唇痛	1 (0.2%)	0	0		0	0	0	
Melaena	メレナ	0	0	0		1 (0.2%)	0	0	
Mouth haemorrhage	口腔内出血	0	0	0		1 (0.2%)	0	0	
Mouth ulceration	口腔内潰瘍形成	1 (0.2%)	0	0		0	0	0	
Nausea	悪心	6 (1.0%)	0	0		6 (1.0%)	1 (0.2%)	0	
Oral pain	口腔内痛	0	0	0		1 (0.2%)	0	0	
Rectal haemorrhage	直腸出血	2 (0.3%)	2 (0.3%)	0		3 (0.5%)	1 (0.2%)	0	
Retching	レッチング	0	0	0		1 (0.2%)	0	0	
Sigmoiditis	S状結腸炎	0	0	0		1 (0.2%)	0	0	
Tongue blistering	舌水疱形成	0	0	0		1 (0.2%)	0	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Toothache	歯痛	0	0	0		5 (0.8%)	1 (0.2%)	0	
Vomiting	嘔吐	5 (0.8%)	1 (0.2%)	0		2 (0.3%)	1 (0.2%)	0	
General disorders and administration site conditions	一般・全身障害および投与部位の状態	34 (5.8%)	17 (2.9%)	0		45 (7.5%)	13 (2.2%)	1 (0.2%)	
Asthenia	無力症	5 (0.8%)	1 (0.2%)	0		2 (0.3%)	2 (0.3%)	0	
Chest discomfort	胸部不快感	2 (0.3%)	1 (0.2%)	0		0	0	0	
Chest pain	胸痛	8 (1.4%)	7 (1.2%)	0		13 (2.2%)	3 (0.5%)	0	
Cyst	嚢胞	1 (0.2%)	0	0		0	0	0	
Drug intolerance	薬物不耐性	0	0	0		0	1 (0.2%)	0	
Exercise tolerance decreased	運動耐性低下	0	0	0		1 (0.2%)	0	0	
Fatigue	疲労	2 (0.3%)	1 (0.2%)	0		6 (1.0%)	0	0	
Feeling cold	冷感	0	0	0		1 (0.2%)	0	0	
General physical health deterioration	全身健康状態低下	0	0	0		0	1 (0.2%)	0	
Hunger	空腹	1 (0.2%)	0	0		0	0	0	
Inflammation	炎症	1 (0.2%)	0	0		0	1 (0.2%)	0	
Influenza like illness	インフルエンザ様疾患	1 (0.2%)	0	0		4 (0.7%)	0	0	
Malaise	倦怠感	1 (0.2%)	0	0		2 (0.3%)	0	0	
Non-cardiac chest pain	非心臓性胸痛	0	1 (0.2%)	0		0	0	0	
Oedema	浮腫	0	0	0		1 (0.2%)	1 (0.2%)	0	
Oedema peripheral	末梢性浮腫	12 (2.0%)	5 (0.8%)	0		11 (1.8%)	2 (0.3%)	0	
Pain	疼痛	0	0	0		0	1 (0.2%)	1 (0.2%)	
Pitting oedema	圧痕浮腫	2 (0.3%)	1 (0.2%)	0		2 (0.3%)	0	0	
Pyrexia	発熱	5 (0.8%)	2 (0.3%)	0		4 (0.7%)	1 (0.2%)	0	
Thirst	口渇	1 (0.2%)	0	0		0	0	0	
Hepatobiliary disorders	肝胆道系障害	2 (0.3%)	0	2 (0.3%)		1 (0.2%)	3 (0.5%)	0	
Biliary colic	胆道仙痛	1 (0.2%)	0	1 (0.2%)		0	0	0	
Cholecystitis	胆嚢炎	0	0	1 (0.2%)		0	1 (0.2%)	0	
Cholelithiasis	胆石症	0	0	0		0	3 (0.5%)	0	
Cholestasis	胆汁うっ滞	1 (0.2%)	0	0		0	0	0	
Hepatic steatosis	脂肪肝	0	0	0		1 (0.2%)	0	0	
Immune system disorders	免疫系障害	2 (0.3%)	1 (0.2%)	0		5 (0.8%)	3 (0.5%)	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Antiphospholipid syndrome	抗リン脂質抗体症候群	0	0	0		0	1 (0.2%)	0	
Drug hypersensitivity	薬物過敏症	0	0	0		1 (0.2%)	0	0	
Hypersensitivity	過敏症	1 (0.2%)	1 (0.2%)	0		1 (0.2%)	1 (0.2%)	0	
Seasonal allergy	季節性アレルギー	1 (0.2%)	0	0		3 (0.5%)	1 (0.2%)	0	
Infections and infestations	感染症および寄生虫症	81 (13.7%)	29 (4.9%)	1 (0.2%)		79 (13.2%)	22 (3.7%)	5 (0.8%)	
Abdominal abscess	腹部膿瘍	0	0	0		0	1 (0.2%)	0	
Abdominal infection	腹部感染	0	0	0		0	1 (0.2%)	0	
Appendicitis	虫垂炎	0	0	0		0	0	1 (0.2%)	
Bronchiolitis	細気管支炎	0	0	0		1 (0.2%)	0	0	
Bronchitis	気管支炎	14 (2.4%)	3 (0.5%)	0		8 (1.3%)	3 (0.5%)	0	
Candidiasis	カンジダ症	1 (0.2%)	0	0		1 (0.2%)	0	0	
Cellulitis	蜂巣炎	2 (0.3%)	1 (0.2%)	0		1 (0.2%)	0	0	
Cystitis	膀胱炎	0	1 (0.2%)	0		1 (0.2%)	1 (0.2%)	0	
Diverticulitis	憩室炎	1 (0.2%)	0	0		0	0	0	
Ear infection	耳感染	0	1 (0.2%)	0		1 (0.2%)	0	0	
Enterocolitis infectious	感染性小腸結腸炎	1 (0.2%)	0	0		0	0	0	
Erysipelas	丹毒	0	2 (0.3%)	0		1 (0.2%)	0	0	
Folliculitis	毛包炎	1 (0.2%)	0	0		0	0	0	
Fungal skin infection	皮膚真菌感染	1 (0.2%)	0	0		2 (0.3%)	0	0	
Furuncle	せつ	1 (0.2%)	0	0		1 (0.2%)	0	0	
Gastroenteritis	胃腸炎	8 (1.4%)	2 (0.3%)	0		3 (0.5%)	2 (0.3%)	0	
Gonorrhoea	淋疾	0	0	0		1 (0.2%)	0	0	
Helicobacter infection	ヘリコバクター感染	1 (0.2%)	0	0		0	0	0	
Herpes zoster	帯状疱疹	3 (0.5%)	0	0		2 (0.3%)	0	0	
Influenza	インフルエンザ	9 (1.5%)	3 (0.5%)	0		8 (1.3%)	3 (0.5%)	0	
Intestinal gangrene	腸壊疽	0	0	1 (0.2%)		0	0	0	
Labyrinthitis	迷路炎	1 (0.2%)	0	0		0	0	0	
Laryngitis	喉頭炎	0	0	0		2 (0.3%)	0	0	
Localised infection	限局性感染	0	2 (0.3%)	0		1 (0.2%)	0	1 (0.2%)	
Lower respiratory tract infection	下気道感染	2 (0.3%)	3 (0.5%)	0		1 (0.2%)	1 (0.2%)	0	
Lung abscess	肺膿瘍	0	0	0		0	1 (0.2%)	0	
Lung infection	肺感染	0	1 (0.2%)	0		0	0	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Nasopharyngitis	鼻咽頭炎	26 (4.4%)	4 (0.7%)	0		27 (4.5%)	4 (0.7%)	0	
Omphalitis	臍炎	0	0	0		0	1 (0.2%)	0	
Oral herpes	口腔ヘルペス	1 (0.2%)	0	0		0	0	0	
Otitis media	中耳炎	1 (0.2%)	0	0		0	0	0	
Pelvic infection	骨盤内感染	0	1 (0.2%)	0		0	0	0	
Pharyngitis	咽頭炎	5 (0.8%)	1 (0.2%)	0		2 (0.3%)	0	0	
Pneumonia	肺炎	1 (0.2%)	1 (0.2%)	0		1 (0.2%)	2 (0.3%)	1 (0.2%)	
Post procedural infection	処置後感染	0	2 (0.3%)	0		1 (0.2%)	0	0	
Postoperative abscess	術後膿瘍	0	0	0		0	1 (0.2%)	0	
Pulpitis dental	歯髄炎	1 (0.2%)	0	0		0	0	0	
Respiratory tract infection	気道感染	2 (0.3%)	1 (0.2%)	0		1 (0.2%)	0	1 (0.2%)	
Respiratory tract infection viral	ウイルス性気道感染	0	0	0		1 (0.2%)	0	0	
Rhinitis	鼻炎	2 (0.3%)	0	0		3 (0.5%)	0	0	
Sinusitis	副鼻腔炎	2 (0.3%)	1 (0.2%)	0		7 (1.2%)	0	0	
Skin infection	皮膚感染	0	0	0		1 (0.2%)	0	0	
Subcutaneous abscess	皮下組織膿瘍	1 (0.2%)	0	0		0	0	0	
Thrombophlebitis septic	化膿性血栓静脈炎	1 (0.2%)	0	0		0	0	0	
Tinea pedis	足部白癬	0	0	0		1 (0.2%)	0	0	
Tonsillitis	扁桃炎	0	0	0		1 (0.2%)	1 (0.2%)	0	
Tooth abscess	歯膿瘍	0	0	0		2 (0.3%)	0	0	
Tooth infection	歯感染	1 (0.2%)	1 (0.2%)	0		0	2 (0.3%)	0	
Upper respiratory tract infection	上気道感染	9 (1.5%)	2 (0.3%)	0		8 (1.3%)	0	0	
Urinary tract infection	尿路感染	2 (0.3%)	1 (0.2%)	0		5 (0.8%)	1 (0.2%)	1 (0.2%)	
Vaginal infection	膣感染	1 (0.2%)	1 (0.2%)	0		0	0	0	
Viral infection	ウイルス感染	2 (0.3%)	0	0		2 (0.3%)	1 (0.2%)	0	
Viral upper respiratory tract infection	ウイルス性上気道感染	1 (0.2%)	0	0		0	0	0	
Wound infection	創傷感染	0	0	0		1 (0.2%)	0	0	
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	39 (6.6%)	12 (2.0%)	3 (0.5%)		45 (7.5%)	9 (1.5%)	1 (0.2%)	
Accident	事故	0	0	0		1 (0.2%)	0	0	
Anaemia postoperative	術後貧血	0	0	0		1 (0.2%)	0	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Ankle fracture	足関節部骨折	0	0	0		0	1 (0.2%)	0	
Arthropod bite	節足動物咬傷	2 (0.3%)	1 (0.2%)	0		1 (0.2%)	0	0	
Arthropod sting	節足動物刺傷	0	1 (0.2%)	0		1 (0.2%)	0	0	
Back injury	背部損傷	0	1 (0.2%)	0		0	0	0	
Carbon monoxide poisoning	一酸化炭素中毒	0	0	0		1 (0.2%)	0	0	
Chest injury	胸部損傷	0	0	1 (0.2%)		0	0	0	
Contusion	挫傷	12 (2.0%)	4 (0.7%)	0		19 (3.2%)	0	0	
Drug exposure during pregnancy	妊娠時の薬物曝露	0	0	1 (0.2%)		0	0	0	
Excoriation	擦過傷	2 (0.3%)	0	0		4 (0.7%)	0	0	
Eye injury	眼外傷	1 (0.2%)	0	0		0	0	0	
Face injury	顔面損傷	0	0	0		1 (0.2%)	0	0	
Fall	転倒・転落	5 (0.8%)	2 (0.3%)	0		4 (0.7%)	0	0	
Hand fracture	手骨折	1 (0.2%)	1 (0.2%)	0		1 (0.2%)	0	0	
Joint dislocation	関節脱臼	0	0	0		1 (0.2%)	1 (0.2%)	0	
Joint injury	関節損傷	0	0	0		1 (0.2%)	2 (0.3%)	0	
Joint sprain	関節捻挫	5 (0.8%)	0	0		4 (0.7%)	0	0	
Ligament rupture	靭帯断裂	0	0	0		1 (0.2%)	0	0	
Limb injury	四肢損傷	1 (0.2%)	1 (0.2%)	0		2 (0.3%)	0	0	
Muscle strain	筋挫傷	3 (0.5%)	0	0		2 (0.3%)	1 (0.2%)	0	
Open wound	開放創	0	0	0		1 (0.2%)	0	0	
Periorbital haematoma	眼窩周囲血腫	1 (0.2%)	0	0		0	0	0	
Post procedural haematoma	処置後血腫	1 (0.2%)	0	0		0	0	0	
Post procedural haemorrhage	処置後出血	1 (0.2%)	1 (0.2%)	0		2 (0.3%)	2 (0.3%)	0	
Procedural nausea	処置による悪心	1 (0.2%)	0	0		0	0	0	
Procedural pain	処置による疼痛	0	1 (0.2%)	0		0	0	0	
Radius fracture	橈骨骨折	1 (0.2%)	1 (0.2%)	0		0	0	0	
Rib fracture	肋骨骨折	0	0	0		0	1 (0.2%)	0	
Skin injury	皮膚損傷	1 (0.2%)	0	0		0	0	0	
Skin laceration	皮膚裂傷	0	0	0		1 (0.2%)	1 (0.2%)	0	
Skull fracture	頭蓋骨骨折	0	0	0		0	1 (0.2%)	0	
Subcutaneous haematoma	皮下血腫	2 (0.3%)	0	0		0	0	0	
Synovial rupture	滑膜断裂	0	0	0		1 (0.2%)	0	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Tendon rupture	腱断裂	0	0	0		1 (0.2%)	0	1 (0.2%)	
Tooth avulsion	歯の完全脱臼	1 (0.2%)	0	0		0	0	0	
Tooth fracture	歯牙破折	0	0	0		1 (0.2%)	0	0	
Traumatic fracture	外傷性骨折	0	0	1 (0.2%)		0	0	0	
Traumatic haematoma	外傷性血腫	1 (0.2%)	1 (0.2%)	0		0	0	0	
Traumatic haemorrhage	外傷性出血	0	1 (0.2%)	0		2 (0.3%)	0	0	
Ulna fracture	尺骨骨折	0	0	0		0	1 (0.2%)	0	
Wound	創傷	1 (0.2%)	0	0		2 (0.3%)	0	0	
Wound secretion	創部分泌	1 (0.2%)	0	0		1 (0.2%)	0	0	
Investigations	臨床検査	19 (3.2%)	4 (0.7%)	0		22 (3.7%)	6 (1.0%)	2 (0.3%)	
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	3 (0.5%)	1 (0.2%)	0		2 (0.3%)	0	0	
Antiphospholipid antibodies positive	抗リン脂質抗体陽性	0	0	0		1 (0.2%)	0	0	
Arthroscopy	関節鏡検査	0	0	0		1 (0.2%)	0	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	2 (0.3%)	1 (0.2%)	0		4 (0.7%)	0	0	
Bilirubin conjugated increased	抱合ビリルビン増加	2 (0.3%)	0	0		1 (0.2%)	0	0	
Biopsy prostate	前立腺生検	1 (0.2%)	0	0		1 (0.2%)	0	0	
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0	0	0		0	1 (0.2%)	0	
Blood amylase increased	血中アミラーゼ増加	0	0	0		1 (0.2%)	0	0	
Blood bilirubin increased	血中ビリルビン増加	2 (0.3%)	0	0		2 (0.3%)	0	0	
Blood cholesterol increased	血中コレステロール増加	1 (0.2%)	0	0		1 (0.2%)	0	0	
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	2 (0.3%)	0	0		0	0	0	
Blood creatinine increased	血中クレアチニン増加	1 (0.2%)	0	0		0	0	0	
Blood culture positive	血液培養陽性	0	0	0		0	1 (0.2%)	0	
Blood glucose increased	血中ブドウ糖増加	0	0	0		1 (0.2%)	0	0	
Blood pressure increased	血圧上昇	0	0	0		1 (0.2%)	0	0	
Blood testosterone decreased	血中テストステロン減少	0	0	0		1 (0.2%)	0	0	
Blood urine present	尿中血陽性	0	0	0		1 (0.2%)	0	0	
Cardiac murmur	心雑音	0	0	0		1 (0.2%)	0	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Catheterisation cardiac	心カテーテル	0	1 (0.2%)	0		0	0	0	
Colonoscopy	結腸内視鏡検査	3 (0.5%)	0	0		2 (0.3%)	0	0	
Creatinine renal clearance decreased	腎クレアチニン・クリアランス減少	0	0	0		1 (0.2%)	0	0	
Endoscopy upper gastrointestinal tract	上部消化管内視鏡検査	1 (0.2%)	0	0		0	1 (0.2%)	0	
Fibrin D dimer increased	フィブリンDダイマー増加	1 (0.2%)	0	0		0	0	0	
Haemoglobin decreased	ヘモグロビン減少	0	0	0		0	1 (0.2%)	0	
Hepatic enzyme increased	肝酵素上昇	0	0	0		2 (0.3%)	0	1 (0.2%)	
Hysteroscopy	ヒステロスコピー	0	0	0		1 (0.2%)	0	0	
Liver function test abnormal	肝機能検査異常	2 (0.3%)	1 (0.2%)	0		1 (0.2%)	2 (0.3%)	1 (0.2%)	
Protein S decreased	プロテインＳ減少	0	0	0		1 (0.2%)	0	0	
Prothrombin time prolonged	プロトロンビン時間延長	0	0	0		1 (0.2%)	0	0	
Sigmoidoscopy	Ｓ状結腸鏡検査	1 (0.2%)	0	0		0	0	0	
Vitamin B12 decreased	ビタミンＢ１２減少	1 (0.2%)	0	0		0	0	0	
Vitamin D decreased	ビタミンD減少	1 (0.2%)	0	0		0	0	0	
Weight decreased	体重減少	1 (0.2%)	1 (0.2%)	0		1 (0.2%)	0	0	
Metabolism and nutrition disorders	代謝および栄養障害	7 (1.2%)	2 (0.3%)	1 (0.2%)		9 (1.5%)	3 (0.5%)	0	
Diabetes mellitus	糖尿病	1 (0.2%)	0	0		2 (0.3%)	0	0	
Diabetic ketoacidosis	糖尿病性ケトアシドーシス	0	0	1 (0.2%)		0	0	0	
Glucose tolerance impaired	耐糖能障害	0	0	0		0	1 (0.2%)	0	
Gout	痛風	1 (0.2%)	0	0		2 (0.3%)	1 (0.2%)	0	
Hypercholesterolaemia	高コレステロール血症	0	0	0		1 (0.2%)	0	0	
Hyperglycaemia	高血糖	0	0	0		1 (0.2%)	0	0	
Hyperkalaemia	高カリウム血症	1 (0.2%)	0	0		1 (0.2%)	0	0	
Hyperlipidaemia	高脂血症	1 (0.2%)	1 (0.2%)	0		0	1 (0.2%)	0	
Hyperuricaemia	高尿酸血症	0	0	0		1 (0.2%)	0	0	
Hypokalaemia	低カリウム血症	2 (0.3%)	0	0		1 (0.2%)	0	0	
Hyponatraemia	低ナトリウム血症	1 (0.2%)	0	0		0	0	0	
Iron deficiency	鉄欠乏	1 (0.2%)	1 (0.2%)	0		0	0	0	
Metabolic syndrome	代謝症候群	0	0	0		1 (0.2%)	0	0	
Vitamin D deficiency	ビタミンD欠乏	0	0	0		1 (0.2%)	0	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	64 (10.8%)	27 (4.6%)	1 (0.2%)		75 (12.5%)	33 (5.5%)	2 (0.3%)	
Arthralgia	関節痛	14 (2.4%)	7 (1.2%)	0		17 (2.8%)	3 (0.5%)	0	
Arthritis	関節炎	1 (0.2%)	1 (0.2%)	0		1 (0.2%)	2 (0.3%)	1 (0.2%)	
Back pain	背部痛	5 (0.8%)	2 (0.3%)	0		14 (2.3%)	7 (1.2%)	1 (0.2%)	
Bone cyst	骨嚢腫	1 (0.2%)	0	0		0	0	0	
Bone pain	骨痛	0	0	0		1 (0.2%)	0	0	
Bursitis	滑液包炎	1 (0.2%)	1 (0.2%)	0		1 (0.2%)	1 (0.2%)	0	
Coccydynia	尾骨痛	1 (0.2%)	0	0		1 (0.2%)	0	0	
Costochondritis	肋軟骨炎	1 (0.2%)	0	0		1 (0.2%)	0	0	
Exostosis	外骨腫	0	1 (0.2%)	0		0	1 (0.2%)	0	
Fibromyalgia	線維筋痛	0	1 (0.2%)	0		0	0	0	
Gouty arthritis	痛風性関節炎	0	0	0		1 (0.2%)	0	0	
Intervertebral disc protrusion	椎間板突出	0	0	0		1 (0.2%)	1 (0.2%)	0	
Joint stiffness	関節硬直	1 (0.2%)	0	0		0	0	0	
Joint swelling	関節腫脹	3 (0.5%)	0	0		4 (0.7%)	0	0	
Limb discomfort	四肢不快感	0	0	0		2 (0.3%)	0	0	
Muscle fatigue	筋肉疲労	1 (0.2%)	0	0		0	0	0	
Muscle spasms	筋痙縮	7 (1.2%)	0	0		8 (1.3%)	1 (0.2%)	0	
Muscle tightness	筋緊張	1 (0.2%)	0	0		0	0	0	
Muscular weakness	筋力低下	0	0	0		1 (0.2%)	0	0	
Musculoskeletal chest pain	筋骨格系胸痛	1 (0.2%)	1 (0.2%)	0		5 (0.8%)	0	0	
Musculoskeletal discomfort	筋骨格不快感	1 (0.2%)	0	0		0	0	0	
Musculoskeletal pain	筋骨格痛	3 (0.5%)	0	0		1 (0.2%)	3 (0.5%)	0	
Musculoskeletal stiffness	筋骨格硬直	0	1 (0.2%)	0		0	0	0	
Myalgia	筋肉痛	6 (1.0%)	2 (0.3%)	0		4 (0.7%)	0	0	
Neck pain	頚部痛	2 (0.3%)	1 (0.2%)	0		0	0	0	
Osteoarthritis	骨関節炎	3 (0.5%)	2 (0.3%)	0		6 (1.0%)	4 (0.7%)	0	
Osteopenia	骨減少症	0	0	0		1 (0.2%)	0	0	
Osteoporosis	骨粗鬆症	1 (0.2%)	0	0		0	0	0	
Pain in extremity	四肢痛	26 (4.4%)	8 (1.4%)	1 (0.2%)		22 (3.7%)	7 (1.2%)	0	
Plantar fasciitis	足底筋膜炎	0	0	0		0	1 (0.2%)	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Polymyalgia rheumatica	リウマチ性多発筋痛	0	0	0		1 (0.2%)	0	0	
Rheumatoid arthritis	関節リウマチ	0	1 (0.2%)	0		0	1 (0.2%)	0	
Rotator cuff syndrome	肩回旋筋腱板症候群	1 (0.2%)	0	0		1 (0.2%)	0	0	
Spinal column stenosis	脊柱管狭窄症	0	1 (0.2%)	0		0	0	0	
Spinal osteoarthritis	変形性脊椎炎	0	1 (0.2%)	0		0	1 (0.2%)	0	
Spondylolysis	脊椎分離	0	0	0		1 (0.2%)	0	0	
Synovial cyst	滑液嚢腫	2 (0.3%)	0	0		1 (0.2%)	0	0	
Temporomandibular joint syndrome	顎関節症候群	0	0	0		1 (0.2%)	0	0	
Tendonitis	腱炎	1 (0.2%)	0	0		0	0	0	
Torticollis	斜頚	1 (0.2%)	0	0		0	1 (0.2%)	0	
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）	3 (0.5%)	4 (0.7%)	3 (0.5%)		1 (0.2%)	2 (0.3%)	1 (0.2%)	
Basal cell carcinoma	基底細胞癌	1 (0.2%)	0	0		0	1 (0.2%)	0	
Benign vascular neoplasm	血管の良性新生物	1 (0.2%)	0	0		0	0	0	
Colon cancer	結腸癌	0	0	1 (0.2%)		0	0	0	
Colorectal cancer	結腸直腸癌	0	0	1 (0.2%)		0	0	0	
Endometrial cancer	子宮内膜癌	0	1 (0.2%)	0		0	0	0	
Haemangioma of liver	肝臓血管腫	0	0	0		1 (0.2%)	0	0	
Kaposi's sarcoma	カポジ肉腫	0	1 (0.2%)	0		0	0	0	
Malignant melanoma in situ	表皮内悪性黒色腫	1 (0.2%)	0	0		0	0	0	
Naevus haemorrhage	母斑出血	1 (0.2%)	0	0		0	0	0	
Oesophageal neoplasm	食道新生物	0	0	0		0	1 (0.2%)	0	
Prostate cancer recurrent	再発前立腺癌	0	1 (0.2%)	0		0	0	0	
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0	0	0		0	0	1 (0.2%)	
Uterine leiomyoma	子宮平滑筋腫	0	0	1 (0.2%)		0	0	0	
Vaginal neoplasm	膣新生物	0	1 (0.2%)	0		0	0	0	
Nervous system disorders	神経系障害	29 (4.9%)	12 (2.0%)	2 (0.3%)		30 (5.0%)	13 (2.2%)	0	
Aphonia	失声症	1 (0.2%)	0	0		0	0	0	
Burning sensation	灼熱感	1 (0.2%)	1 (0.2%)	0		0	0	0	
Carotid arteriosclerosis	頚動脈硬化症	0	0	0		0	1 (0.2%)	0	
Carpal tunnel syndrome	手根管症候群	0	0	0		2 (0.3%)	0	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Convulsion	痙攣	0	0	0		1 (0.2%)	0	0	
Dizziness	浮動性めまい	8 (1.4%)	0	0		4 (0.7%)	2 (0.3%)	0	
Dizziness postural	体位性めまい	1 (0.2%)	0	0		1 (0.2%)	0	0	
Dysarthria	構語障害	0	1 (0.2%)	0		0	0	0	
Dysgeusia	味覚異常	2 (0.3%)	0	0		0	0	0	
Dysphasia	不全失語症	0	1 (0.2%)	0		0	0	0	
Epilepsy	てんかん	1 (0.2%)	1 (0.2%)	0		0	1 (0.2%)	0	
Haemorrhage intracranial	頭蓋内出血	0	0	1 (0.2%)		0	0	0	
Headache	頭痛	9 (1.5%)	6 (1.0%)	0		13 (2.2%)	5 (0.8%)	0	
Hydrocephalus	水頭症	0	0	0		0	1 (0.2%)	0	
Hypoaesthesia	感覚鈍麻	0	0	0		2 (0.3%)	0	0	
Ischaemic stroke	虚血性脳卒中	0	0	1 (0.2%)		0	0	0	
Lethargy	嗜眠	0	0	0		1 (0.2%)	0	0	
Mental impairment	精神的機能障害	0	0	0		1 (0.2%)	0	0	
Migraine	片頭痛	2 (0.3%)	1 (0.2%)	0		1 (0.2%)	0	0	
Paraesthesia	錯感覚	1 (0.2%)	0	0		2 (0.3%)	0	0	
Phantom pain	幻痛	0	0	0		1 (0.2%)	0	0	
Polyneuropathy	多発ニューロパチー	1 (0.2%)	0	0		0	0	0	
Presyncope	失神寸前の状態	0	0	0		1 (0.2%)	0	0	
Sciatica	坐骨神経痛	1 (0.2%)	1 (0.2%)	0		1 (0.2%)	2 (0.3%)	0	
Sensory disturbance	感覚障害	1 (0.2%)	0	0		0	0	0	
Somnolence	傾眠	0	0	0		1 (0.2%)	0	0	
Syncope	失神	2 (0.3%)	2 (0.3%)	0		2 (0.3%)	1 (0.2%)	0	
Transient ischaemic attack	一過性脳虚血発作	1 (0.2%)	0	0		0	1 (0.2%)	0	
Tremor	振戦	1 (0.2%)	0	0		0	0	0	
Vascular dementia	血管性認知症	0	1 (0.2%)	0		0	0	0	
Pregnancy, puerperium and perinatal conditions	妊娠、産褥および周産期の状態	0	0	0		1 (0.2%)	0	0	
Pregnancy	妊娠	0	0	0		1 (0.2%)	0	0	
Psychiatric disorders	精神障害	6 (1.0%)	4 (0.7%)	0		12 (2.0%)	2 (0.3%)	1 (0.2%)	
Anxiety	不安	2 (0.3%)	1 (0.2%)	0		2 (0.3%)	1 (0.2%)	0	
Depressed mood	抑うつ気分	0	1 (0.2%)	0		1 (0.2%)	0	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Depression	うつ病	0	0	0		4 (0.7%)	0	1 (0.2%)	
Insomnia	不眠症	2 (0.3%)	2 (0.3%)	0		4 (0.7%)	0	0	
Mood altered	気分変化	0	0	0		1 (0.2%)	0	0	
Nervousness	神経過敏	1 (0.2%)	0	0		0	0	0	
Panic attack	パニック発作	0	0	0		0	1 (0.2%)	0	
Schizophrenia	統合失調症	1 (0.2%)	0	0		0	0	0	
Stress	ストレス	1 (0.2%)	0	0		0	0	0	
Renal and urinary disorders	腎および尿路障害	6 (1.0%)	1 (0.2%)	1 (0.2%)		10 (1.7%)	4 (0.7%)	2 (0.3%)	
Cystitis haemorrhagic	出血性膀胱炎	0	0	0		0	1 (0.2%)	0	
Dysuria	排尿困難	0	0	0		1 (0.2%)	1 (0.2%)	0	
Haematuria	血尿	2 (0.3%)	0	0		9 (1.5%)	2 (0.3%)	2 (0.3%)	
Hydronephrosis	水腎症	0	0	1 (0.2%)		0	0	0	
Nephritis	腎炎	1 (0.2%)	0	0		0	0	0	
Nocturia	夜間頻尿	1 (0.2%)	0	0		0	0	0	
Pollakiuria	頻尿	1 (0.2%)	0	0		1 (0.2%)	0	0	
Proteinuria	蛋白尿	0	0	0		1 (0.2%)	0	0	
Renal cyst	腎嚢胞	1 (0.2%)	0	0		0	0	0	
Renal failure	腎不全	0	1 (0.2%)	0		0	0	0	
Renal failure acute	急性腎不全	0	0	0		1 (0.2%)	0	0	
Urinary incontinence	尿失禁	0	0	0		0	1 (0.2%)	0	
Reproductive system and breast disorders	生殖系および乳房障害	12 (2.0%)	2 (0.3%)	1 (0.2%)		10 (1.7%)	4 (0.7%)	1 (0.2%)	
Bartholin's cyst	バルトリン嚢腫	1 (0.2%)	0	0		0	0	0	
Benign prostatic hyperplasia	良性前立腺肥大症	0	0	0		2 (0.3%)	0	0	
Dysmenorrhoea	月経困難症	1 (0.2%)	0	0		0	0	0	
Epididymitis	精巣上体炎	0	0	0		1 (0.2%)	0	0	
Erectile dysfunction	勃起不全	1 (0.2%)	0	0		0	0	0	
Gynaecomastia	女性化乳房	1 (0.2%)	0	0		0	0	0	
Menometrorrhagia	機能性子宮出血	0	0	0		0	0	1 (0.2%)	
Menorrhagia	月経過多	2 (0.3%)	0	0		1 (0.2%)	4 (0.7%)	0	
Menstruation irregular	不規則月経	0	1 (0.2%)	0		0	0	0	
Metrorrhagia	不正子宮出血	0	0	0		1 (0.2%)	1 (0.2%)	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Peyronie's disease	ペイロニー病	0	0	0		1 (0.2%)	0	0	
Postmenopausal haemorrhage	閉経後出血	1 (0.2%)	0	0		0	0	0	
Prostatitis	前立腺炎	2 (0.3%)	0	0		0	0	0	
Prostatomegaly	前立腺腫大	0	0	0		2 (0.3%)	0	0	
Scrotal cyst	陰嚢嚢胞	0	0	0		1 (0.2%)	0	0	
Testicular swelling	精巣腫脹	0	1 (0.2%)	0		0	0	0	
Uterine polyp	子宮ポリープ	0	0	0		1 (0.2%)	0	0	
Vaginal haemorrhage	腟出血	5 (0.8%)	0	0		0	1 (0.2%)	0	
Vaginal prolapse	腟脱	0	0	1 (0.2%)		0	0	0	
Vulvovaginal discomfort	外陰腟不快感	1 (0.2%)	0	0		0	0	0	
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	37 (6.3%)	16 (2.7%)	1 (0.2%)		46 (7.7%)	9 (1.5%)	2 (0.3%)	
Acute pulmonary oedema	急性肺水腫	0	0	0		1 (0.2%)	0	1 (0.2%)	
Apnoeic attack	無呼吸発作	0	0	0		1 (0.2%)	0	0	
Asthma	喘息	1 (0.2%)	0	0		0	1 (0.2%)	0	
Atelectasis	無気肺	1 (0.2%)	0	0		0	0	0	
Bronchitis chronic	慢性気管支炎	0	0	0		1 (0.2%)	0	0	
Bronchospasm	気管支痙攣	0	0	0		0	1 (0.2%)	0	
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	0	0	0		0	2 (0.3%)	1 (0.2%)	
Cough	咳嗽	17 (2.9%)	4 (0.7%)	0		15 (2.5%)	1 (0.2%)	0	
Dry throat	咽喉乾燥	0	0	0		1 (0.2%)	0	0	
Dyspnoea	呼吸困難	5 (0.8%)	6 (1.0%)	0		4 (0.7%)	3 (0.5%)	0	
Dyspnoea exertional	労作性呼吸困難	2 (0.3%)	1 (0.2%)	0		4 (0.7%)	0	0	
Epistaxis	鼻出血	11 (1.9%)	0	0		21 (3.5%)	3 (0.5%)	0	
Haemoptysis	喀血	1 (0.2%)	0	0		1 (0.2%)	0	0	
Lung disorder	肺障害	0	0	0		1 (0.2%)	0	0	
Nasal cavity mass	鼻腔腫瘤	1 (0.2%)	0	0		0	0	0	
Nasal congestion	鼻閉	1 (0.2%)	0	0		0	0	0	
Oropharyngeal pain	口腔咽頭痛	1 (0.2%)	1 (0.2%)	0		6 (1.0%)	0	0	
Pleuritic pain	胸膜痛	0	1 (0.2%)	0		0	0	0	
Productive cough	湿性咳嗽	0	0	0		2 (0.3%)	0	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Pulmonary arterial hypertension	肺動脈高血圧症	0	1 (0.2%)	0		0	0	0	
Pulmonary embolism	肺塞栓症	0	0	1 (0.2%)		0	0	0	
Pulmonary hypertension	肺高血圧症	0	0	0		1 (0.2%)	0	0	
Rales	ラ音	0	1 (0.2%)	0		0	0	0	
Respiratory failure	呼吸不全	0	1 (0.2%)	0		0	0	0	
Rhinitis allergic	アレルギー性鼻炎	1 (0.2%)	0	0		1 (0.2%)	0	0	
Rhinorrhoea	鼻漏	1 (0.2%)	0	0		1 (0.2%)	0	0	
Sleep apnoea syndrome	睡眠時無呼吸症候群	1 (0.2%)	1 (0.2%)	0		0	0	0	
Sneezing	くしゃみ	0	0	0		1 (0.2%)	0	0	
Tachypnoea	頻呼吸	0	0	0		1 (0.2%)	0	0	
Throat irritation	咽喉刺激感	0	0	0		1 (0.2%)	0	0	
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	31 (5.3%)	4 (0.7%)	1 (0.2%)		31 (5.2%)	4 (0.7%)	1 (0.2%)	
Acne	ざ瘡	0	0	0		3 (0.5%)	0	1 (0.2%)	
Actinic keratosis	日光性角化症	1 (0.2%)	0	0		1 (0.2%)	0	0	
Alopecia	脱毛症	1 (0.2%)	0	0		1 (0.2%)	0	0	
Dermatitis	皮膚炎	0	1 (0.2%)	0		2 (0.3%)	1 (0.2%)	0	
Dermatitis allergic	アレルギー性皮膚炎	1 (0.2%)	1 (0.2%)	0		1 (0.2%)	0	0	
Dermatitis contact	接触性皮膚炎	0	0	0		1 (0.2%)	0	0	
Dry skin	皮膚乾燥	0	0	0		1 (0.2%)	0	0	
Ecchymosis	斑状出血	1 (0.2%)	0	0		1 (0.2%)	0	0	
Eczema	湿疹	7 (1.2%)	0	0		1 (0.2%)	0	0	
Ephelides	雀卵斑	0	0	0		1 (0.2%)	0	0	
Erythema	紅斑	1 (0.2%)	0	0		0	0	0	
Hyperhidrosis	多汗症	1 (0.2%)	0	0		3 (0.5%)	0	0	
Onychoclasis	爪破損	2 (0.3%)	0	0		0	0	0	
Panniculitis	脂肪織炎	0	0	0		1 (0.2%)	0	0	
Petechiae	点状出血	0	0	0		1 (0.2%)	0	0	
Plantar erythema	足底紅斑	1 (0.2%)	0	0		0	0	0	
Pruritus	そう痒症	2 (0.3%)	0	0		2 (0.3%)	0	0	
Pruritus generalised	全身性そう痒症	0	0	0		1 (0.2%)	0	0	
Psoriasis	乾癬	0	1 (0.2%)	0		0	0	0	
Purpura senile	老人性紫斑	0	0	0		1 (0.2%)	0	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Rash	発疹	7 (1.2%)	0	0		5 (0.8%)	0	0	
Rash generalised	全身性皮疹	0	1 (0.2%)	0		0	0	0	
Rash macular	斑状皮疹	0	0	0		1 (0.2%)	0	0	
Seborrhoeic dermatitis	脂漏性皮膚炎	1 (0.2%)	0	0		0	0	0	
Skin discolouration	皮膚変色	1 (0.2%)	0	0		1 (0.2%)	0	0	
Skin exfoliation	皮膚剥脱	1 (0.2%)	0	0		0	0	0	
Skin haemorrhage	皮膚出血	1 (0.2%)	0	0		3 (0.5%)	0	0	
Skin hyperpigmentation	皮膚色素過剰	0	0	0		1 (0.2%)	0	0	
Skin induration	皮膚硬結	1 (0.2%)	0	0		0	0	0	
Skin irritation	皮膚刺激	0	0	0		1 (0.2%)	0	0	
Skin lesion	皮膚病変	1 (0.2%)	0	0		1 (0.2%)	0	0	
Skin ulcer	皮膚潰瘍	2 (0.3%)	1 (0.2%)	0		0	2 (0.3%)	0	
Stasis dermatitis	うっ滞性皮膚炎	0	0	0		2 (0.3%)	0	0	
Stevens-Johnson syndrome	スティーブンス・ジョンソン症候群	0	0	1 (0.2%)		0	0	0	
Urticaria	蕁麻疹	0	0	0		0	1 (0.2%)	0	
Social circumstances	社会環境	0	0	0		1 (0.2%)	0	0	
Activities of daily living impaired	日常生活動作障害者	0	0	0		1 (0.2%)	0	0	
Surgical and medical procedures	外科および内科処置	8 (1.4%)	2 (0.3%)	0		13 (2.2%)	5 (0.8%)	0	
Anal fistula excision	痔瘻切除	1 (0.2%)	0	0		0	0	0	
Appendicectomy	虫垂切除	0	0	0		0	1 (0.2%)	0	
Bladder calculus removal	膀胱結石除去	0	0	0		0	1 (0.2%)	0	
Bunion operation	バニオン手術	0	0	0		1 (0.2%)	0	0	
Cataract operation	白内障手術	0	0	0		2 (0.3%)	0	0	
Dental implantation	歯科インプラント埋込み	0	0	0		1 (0.2%)	0	0	
Dental operation	歯科手術	2 (0.3%)	1 (0.2%)	0		0	0	0	
Elective surgery	待期的手術	0	0	0		1 (0.2%)	0	0	
Haemorrhoid operation	痔核手術	0	0	0		1 (0.2%)	0	0	
Knee arthroplasty	膝関節形成	1 (0.2%)	0	0		0	0	0	
Knee operation	膝手術	0	1 (0.2%)	0		0	0	0	
Medical device removal	医療機器除去	0	0	0		1 (0.2%)	0	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Mole excision	色素性母斑切除	1 (0.2%)	0	0		0	0	0	
Oesophagogastric fundoplasty	食道－胃底部形成術	0	1 (0.2%)	0		0	0	0	
Polypectomy	ポリープ切除	1 (0.2%)	0	0		0	0	0	
Skin neoplasm excision	皮膚新生物切除	0	0	0		1 (0.2%)	0	0	
Tooth extraction	抜歯	1 (0.2%)	0	0		3 (0.5%)	2 (0.3%)	0	
Transurethral prostatectomy	経尿道的前立腺摘除	1 (0.2%)	0	0		0	0	0	
Umbilical hernia repair	臍帯ヘルニア修復	0	0	0		0	1 (0.2%)	0	
Uterine dilation and curettage	子宮頚管拡張および子宮内掻爬	0	0	0		1 (0.2%)	0	0	
Wart excision	疣贅切除	0	0	0		1 (0.2%)	0	0	
Vascular disorders	血管障害	39 (6.6%)	7 (1.2%)	2 (0.3%)		29 (4.8%)	6 (1.0%)	3 (0.5%)	
Bleeding varicose vein	出血性静脈瘤	0	0	0		1 (0.2%)	0	0	
Circulatory collapse	循環虚脱	0	0	0		0	0	1 (0.2%)	
Diabetic microangiopathy	糖尿病性微小血管症	0	0	0		1 (0.2%)	0	0	
Erythromelalgia	紅痛症	1 (0.2%)	0	0		0	0	0	
Flushing	潮紅	1 (0.2%)	0	0		0	0	0	
Haematoma	血腫	7 (1.2%)	1 (0.2%)	0		6 (1.0%)	1 (0.2%)	0	
Hot flush	ほてり	1 (0.2%)	0	0		1 (0.2%)	0	0	
Hypertension	高血圧	8 (1.4%)	0	1 (0.2%)		3 (0.5%)	2 (0.3%)	1 (0.2%)	
Hypotension	低血圧	1 (0.2%)	1 (0.2%)	0		0	1 (0.2%)	0	
Orthostatic hypotension	起立性低血圧	1 (0.2%)	0	0		0	0	0	
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	0	0	1 (0.2%)		0	0	0	
Phlebitis	静脈炎	2 (0.3%)	0	0		2 (0.3%)	0	0	
Phlebitis superficial	表在性静脈炎	2 (0.3%)	0	0		0	0	0	
Post thrombotic syndrome	血栓後症候群	1 (0.2%)	0	0		1 (0.2%)	1 (0.2%)	0	
Thrombophlebitis	血栓性静脈炎	7 (1.2%)	2 (0.3%)	0		0	0	1 (0.2%)	
Thrombophlebitis superficial	表在性血栓性静脈炎	3 (0.5%)	1 (0.2%)	0		1 (0.2%)	0	0	
Varicophlebitis	静脈瘤性静脈炎	1 (0.2%)	0	0		0	0	0	
Varicose vein	静脈瘤	2 (0.3%)	1 (0.2%)	0		0	0	0	
Vascular rupture	血管破裂	0	0	0		1 (0.2%)	0	0	
Vein disorder	静脈障害	0	0	0		1 (0.2%)	0	0	

表 2.7.4.7-6 重症度別の TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Venous insufficiency	静脈不全	0	0	0		1 (0.2%)	1 (0.2%)	0	
Wound haemorrhage	創傷出血	6 (1.0%)	1 (0.2%)	0		10 (1.7%)	1 (0.2%)	0	

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Only the most severe intensity is counted for multiple occurrences of the same AE in each subject.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-3-4.sas erjli 21MAR2013 10:13
End of table

表 2.7.4.7-7 重症度別の治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Number of subjects (%) with at least one adverse event		282 (16.4%)	95 (5.5%)	24 (1.4%)		274 (16.0%)	99 (5.8%)	21 (1.2%)	
Blood and lymphatic system disorders	血液およびリンパ系障害	4 (0.2%)	6 (0.3%)	9 (0.5%)		4 (0.2%)	5 (0.3%)	1 (<0.1%)	
Anaemia	貧血	1 (<0.1%)	5 (0.3%)	6 (0.3%)		1 (<0.1%)	4 (0.2%)	1 (<0.1%)	
Haemorrhagic diathesis	出血性素因	1 (<0.1%)	0	0		2 (0.1%)	0	0	
Iron deficiency anaemia	鉄欠乏性貧血	0	2 (0.1%)	0		1 (<0.1%)	0	0	
Microcytic anaemia	小球性貧血	0	0	1 (<0.1%)		0	0	0	
Polycythaemia	赤血球増加症	1 (<0.1%)	0	0		0	0	0	
Spontaneous haematoma	特発性血腫	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Thrombocytopenia	血小板減少症	1 (<0.1%)	0	1 (<0.1%)		0	1 (<0.1%)	0	
Cardiac disorders	心臓障害	7 (0.4%)	0	0		1 (<0.1%)	0	0	
Cyanosis	チアノーゼ	1 (<0.1%)	0	0		0	0	0	
Diastolic dysfunction	拡張機能障害	1 (<0.1%)	0	0		0	0	0	
Palpitations	動悸	2 (0.1%)	0	0		1 (<0.1%)	0	0	
Tachycardia	頻脈	3 (0.2%)	0	0		0	0	0	
Ear and labyrinth disorders	耳および迷路障害	4 (0.2%)	2 (0.1%)	0		1 (<0.1%)	0	1 (<0.1%)	
Deafness neurosensory	感音性難聴	1 (<0.1%)	0	0		0	0	0	
Ear haemorrhage	耳出血	1 (<0.1%)	0	0		1 (<0.1%)	0	1 (<0.1%)	
Ear pain	耳痛	0	1 (<0.1%)	0		0	0	0	
Hearing impaired	聴覚障害	0	1 (<0.1%)	0		0	0	0	
Vertigo	回転性めまい	2 (0.1%)	1 (<0.1%)	0		0	0	0	
Eye disorders	眼障害	8 (0.5%)	6 (0.3%)	0		18 (1.1%)	1 (<0.1%)	0	
Conjunctival haemorrhage	結膜出血	8 (0.5%)	1 (<0.1%)	0		14 (0.8%)	0	0	
Eye haemorrhage	眼出血	0	2 (0.1%)	0		2 (0.1%)	1 (<0.1%)	0	
Hyphaema	前房出血	0	1 (<0.1%)	0		0	0	0	
Ocular hyperaemia	眼充血	0	0	0		2 (0.1%)	0	0	
Retinal exudates	網膜滲出物	0	1 (<0.1%)	0		0	0	0	
Vision blurred	霧視	0	1 (<0.1%)	0		0	0	0	
Vitreous detachment	硝子体剥離	0	1 (<0.1%)	0		0	0	0	
Gastrointestinal disorders	胃腸障害	103 (6.0%)	11 (0.6%)	4 (0.2%)		59 (3.4%)	23 (1.3%)	5 (0.3%)	
Abdominal discomfort	腹部不快感	3 (0.2%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Abdominal distension	腹部膨満	2 (0.1%)	0	0		0	0	0	

表 2.7.4.7-7 重症度別の治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Abdominal pain	腹痛	2 (0.1%)	0	0		0	0	0	
Abdominal pain lower	下腹部痛	1 (<0.1%)	0	0		0	0	0	
Abdominal pain upper	上腹部痛	2 (0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Anal haemorrhage	肛門出血	0	0	0		1 (<0.1%)	0	0	
Constipation	便秘	1 (<0.1%)	0	0		3 (0.2%)	0	0	
Diarrhoea	下痢	7 (0.4%)	1 (<0.1%)	0		2 (0.1%)	0	0	
Dry mouth	口内乾燥	2 (0.1%)	0	0		0	0	0	
Duodenal ulcer	十二指腸潰瘍	1 (<0.1%)	0	0		0	0	0	
Dyspepsia	消化不良	4 (0.2%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Flatulence	鼓腸	2 (0.1%)	0	0		0	0	0	
Gastric haemorrhage	胃出血	0	0	0		0	1 (<0.1%)	0	
Gastritis	胃炎	1 (<0.1%)	0	0		0	0	0	
Gastrointestinal haemorrhage	胃腸出血	0	1 (<0.1%)	2 (0.1%)		0	0	0	
Gastrooesophageal reflux disease	胃食道逆流性疾患	2 (0.1%)	1 (<0.1%)	0		0	0	0	
Gingival bleeding	歯肉出血	31 (1.8%)	0	0		18 (1.1%)	6 (0.4%)	0	
Gingival recession	歯肉退縮	0	0	0		1 (<0.1%)	0	0	
Gingival swelling	歯肉腫脹	0	0	0		0	1 (<0.1%)	0	
Haematemesis	吐血	0	1 (<0.1%)	1 (<0.1%)		3 (0.2%)	2 (0.1%)	1 (<0.1%)	
Haematochezia	血便排泄	4 (0.2%)	0	0		3 (0.2%)	2 (0.1%)	1 (<0.1%)	
Haemorrhoidal haemorrhage	痔出血	8 (0.5%)	0	0		3 (0.2%)	1 (<0.1%)	0	
Haemorrhoids	痔核	1 (<0.1%)	0	0		0	0	0	
Intestinal haemorrhage	腸出血	0	0	0		0	2 (0.1%)	0	
Intra-abdominal haematoma	腹腔内血腫	0	0	0		8 (0.5%)	3 (0.2%)	0	
Intra-abdominal haemorrhage	腹腔内出血	0	0	0		1 (<0.1%)	0	0	
Lower gastrointestinal haemorrhage	下部消化管出血	1 (<0.1%)	0	0		0	0	0	
Melaena	メレナ	5 (0.3%)	3 (0.2%)	0		0	2 (0.1%)	1 (<0.1%)	
Mouth haemorrhage	口腔内出血	5 (0.3%)	0	0		2 (0.1%)	0	0	
Nausea	悪心	9 (0.5%)	1 (<0.1%)	0		8 (0.5%)	2 (0.1%)	0	
Paraesthesia oral	口の錯感覚	1 (<0.1%)	0	0		0	0	0	
Rectal haemorrhage	直腸出血	24 (1.4%)	2 (0.1%)	1 (<0.1%)		8 (0.5%)	1 (<0.1%)	2 (0.1%)	
Upper gastrointestinal haemorrhage	上部消化管出血	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-7 重症度別の治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Vomiting	嘔吐	3 (0.2%)	1 (<0.1%)	0		2 (0.1%)	1 (<0.1%)	0	
General disorders and administration site conditions	一般・全身障害および投与部位の状態	17 (1.0%)	4 (0.2%)	0		23 (1.3%)	3 (0.2%)	0	
Chest pain	胸痛	0	0	0		1 (<0.1%)	0	0	
Chills	悪寒	1 (<0.1%)	0	0		0	0	0	
Drug resistance	薬剤耐性	0	0	0		0	1 (<0.1%)	0	
Fatigue	疲労	5 (0.3%)	0	0		2 (0.1%)	0	0	
Feeling hot	熱感	0	0	0		1 (<0.1%)	0	0	
Feeling of body temperature change	体温変動感	1 (<0.1%)	0	0		0	0	0	
Injection site extravasation	注射部位血管外漏出	0	0	0		2 (0.1%)	0	0	
Injection site haematoma	注射部位血腫	2 (0.1%)	0	0		11 (0.6%)	1 (<0.1%)	0	
Injection site haemorrhage	注射部位出血	0	0	0		1 (<0.1%)	0	0	
Injection site pain	注射部位疼痛	0	0	0		1 (<0.1%)	0	0	
Injection site swelling	注射部位腫脹	0	0	0		1 (<0.1%)	0	0	
Malaise	倦怠感	3 (0.2%)	0	0		0	0	0	
Oedema	浮腫	0	1 (<0.1%)	0		0	0	0	
Oedema peripheral	末梢性浮腫	3 (0.2%)	2 (0.1%)	0		0	1 (<0.1%)	0	
Pain	疼痛	0	0	0		1 (<0.1%)	0	0	
Puncture site haemorrhage	穿刺部位出血	0	0	0		2 (0.1%)	0	0	
Pyrexia	発熱	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Vessel puncture site haematoma	血管穿刺部位血腫	1 (<0.1%)	0	0		0	0	0	
Vessel puncture site haemorrhage	血管穿刺部位出血	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Hepatobiliary disorders	肝胆道系障害	0	1 (<0.1%)	1 (<0.1%)		0	1 (<0.1%)	0	
Hepatic function abnormal	肝機能異常	0	1 (<0.1%)	0		0	0	0	
Hepatitis acute	急性肝炎	0	0	1 (<0.1%)		0	0	0	
Hyperbilirubinaemia	高ビリルビン血症	0	0	0		0	1 (<0.1%)	0	
Immune system disorders	免疫系障害	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Drug hypersensitivity	薬物過敏症	0	0	0		1 (<0.1%)	0	0	
Hypersensitivity	過敏症	0	1 (<0.1%)	0		0	0	0	
Infections and infestations	感染症および寄生虫症	4 (0.2%)	4 (0.2%)	0		2 (0.1%)	0	0	
Bronchitis	気管支炎	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-7 重症度別の治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Localised infection	限局性感染	0	1 (<0.1%)	0		0	0	0	
Nasopharyngitis	鼻咽頭炎	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Oral fungal infection	口腔真菌感染	1 (<0.1%)	0	0		0	0	0	
Rash pustular	膿疱性皮疹	0	1 (<0.1%)	0		0	0	0	
Sinusitis	副鼻腔炎	1 (<0.1%)	0	0		0	0	0	
Skin infection	皮膚感染	0	1 (<0.1%)	0		0	0	0	
Tooth infection	歯感染	1 (<0.1%)	0	0		0	0	0	
Urinary tract infection	尿路感染	0	1 (<0.1%)	0		0	0	0	
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	44 (2.6%)	3 (0.2%)	2 (0.1%)		57 (3.3%)	12 (0.7%)	2 (0.1%)	
Accidental overdose	偶発的過量投与	0	0	0		0	1 (<0.1%)	0	
Contusion	挫傷	26 (1.5%)	2 (0.1%)	0		31 (1.8%)	7 (0.4%)	2 (0.1%)	
Drug toxicity	薬物毒性	0	0	1 (<0.1%)		0	0	0	
Excoriation	擦過傷	1 (<0.1%)	0	0		0	0	0	
Mouth injury	口腔内損傷	0	0	0		1 (<0.1%)	0	0	
Overdose	過量投与	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Post procedural haematuria	処置後血尿	2 (0.1%)	0	0		0	0	0	
Post procedural haemorrhage	処置後出血	3 (0.2%)	0	1 (<0.1%)		3 (0.2%)	0	0	
Skeletal injury	骨格損傷	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Subcutaneous haematoma	皮下血腫	8 (0.5%)	0	0		11 (0.6%)	1 (<0.1%)	0	
Therapeutic agent toxicity	治療薬毒性	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Traumatic haematoma	外傷性血腫	2 (0.1%)	0	0		3 (0.2%)	0	0	
Traumatic haemorrhage	外傷性出血	1 (<0.1%)	0	0		0	0	0	
Wound haemorrhage	創傷出血	4 (0.2%)	1 (<0.1%)	0		9 (0.5%)	0	0	
Investigations	臨床検査	18 (1.0%)	8 (0.5%)	1 (<0.1%)		55 (3.2%)	18 (1.1%)	3 (0.2%)	
Activated partial thromboplastin time prolonged	活性化部分トロンボプラスチン時間延長	1 (<0.1%)	0	0		0	0	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	0	0		0	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	8 (0.5%)	3 (0.2%)	0		16 (0.9%)	5 (0.3%)	0	

表 2.7.4.7-7　重症度別の治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	6 (　0.3%)	1 (<0.1%)	0		3 (　0.2%)	0	0	
Bilirubin conjugated increased	抱合ビリルビン増加	1 (<0.1%)	0	0		0	0	0	
Blood albumin increased	血中アルブミン増加	0	1 (<0.1%)	0		0	0	0	
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0	2 (　0.1%)	0		1 (<0.1%)	0	0	
Blood amylase increased	血中アミラーゼ増加	0	0	0		1 (<0.1%)	0	0	
Blood bilirubin increased	血中ビリルビン増加	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Blood thromboplastin decreased	血中トロンボプラスチン減少	1 (<0.1%)	0	0		0	0	0	
Blood urine present	尿中血陽性	0	1 (<0.1%)	0		0	0	0	
Coagulation factor VII level decreased	凝固第ＶＩＩ因子量減少	1 (<0.1%)	0	0		0	0	0	
Coagulation factor X level decreased	凝固第Ｘ因子量減少	1 (<0.1%)	0	0		0	0	0	
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2 (　0.1%)	1 (<0.1%)	0		0	0	0	
Haemoglobin decreased	ヘモグロビン減少	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Heart rate decreased	心拍数減少	0	0	0		1 (<0.1%)	0	0	
Hepatic enzyme increased	肝酵素上昇	0	0	0		4 (　0.2%)	2 (　0.1%)	1 (<0.1%)	
International normalised ratio abnormal	ＩＮＲ異常	0	0	0		0	1 (<0.1%)	1 (<0.1%)	
International normalised ratio decreased	ＩＮＲ減少	0	0	0		2 (　0.1%)	0	0	
International normalised ratio fluctuation	ＩＮＲ変動	0	0	0		2 (　0.1%)	0	0	
International normalised ratio increased	ＩＮＲ増加	0	0	0		22 (　1.3%)	6 (　0.4%)	1 (<0.1%)	
Liver function test abnormal	肝機能検査異常	2 (　0.1%)	1 (<0.1%)	1 (<0.1%)		4 (　0.2%)	0	0	
Occult blood	便潜血	0	0	0		1 (<0.1%)	0	0	
Platelet count decreased	血小板数減少	0	0	0		0	1 (<0.1%)	0	
Protein total increased	総蛋白増加	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-7 重症度別の治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Prothrombin time prolonged	プロトロンビン時間延長	0	0	0		0	1 (<0.1%)	0	
Transaminases increased	トランスアミナーゼ上昇	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Weight decreased	体重減少	2 (0.1%)	0	0		0	0	0	
White blood cell count decreased	白血球数減少	0	0	0		0	1 (<0.1%)	0	
Metabolism and nutrition disorders	代謝および栄養障害	6 (0.3%)	3 (0.2%)	0		1 (<0.1%)	1 (<0.1%)	0	
Decreased appetite	食欲減退	4 (0.2%)	1 (<0.1%)	0		0	0	0	
Diabetes mellitus	糖尿病	0	0	0		0	1 (<0.1%)	0	
Gout	痛風	0	0	0		1 (<0.1%)	0	0	
Hyperuricaemia	高尿酸血症	1 (<0.1%)	0	0		0	0	0	
Iron deficiency	鉄欠乏	0	1 (<0.1%)	0		0	0	0	
Tetany	テタニー	1 (<0.1%)	0	0		0	0	0	
Vitamin B12 deficiency	ビタミンＢ１２欠乏	0	1 (<0.1%)	0		0	0	0	
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	3 (0.2%)	2 (0.1%)	0		9 (0.5%)	4 (0.2%)	4 (0.2%)	
Haemarthrosis	出血性関節症	0	0	0		0	3 (0.2%)	1 (<0.1%)	
Limb discomfort	四肢不快感	0	0	0		1 (<0.1%)	0	0	
Muscle haemorrhage	筋肉内出血	0	0	0		1 (<0.1%)	0	3 (0.2%)	
Muscle spasms	筋痙縮	2 (0.1%)	0	0		1 (<0.1%)	0	0	
Musculoskeletal pain	筋骨格痛	0	0	0		1 (<0.1%)	0	0	
Neck pain	頚部痛	0	0	0		1 (<0.1%)	0	0	
Pain in extremity	四肢痛	1 (<0.1%)	2 (0.1%)	0		4 (0.2%)	1 (<0.1%)	0	
Nervous system disorders	神経系障害	26 (1.5%)	8 (0.5%)	2 (0.1%)		12 (0.7%)	1 (<0.1%)	3 (0.2%)	
Cerebral haemorrhage	脳出血	0	0	1 (<0.1%)		0	0	1 (<0.1%)	
Dizziness	浮動性めまい	5 (0.3%)	0	0		3 (0.2%)	0	0	
Dysaesthesia	異常感覚	1 (<0.1%)	0	0		0	0	0	
Haemorrhage intracranial	頭蓋内出血	0	0	1 (<0.1%)		0	0	1 (<0.1%)	
Headache	頭痛	17 (1.0%)	4 (0.2%)	0		8 (0.5%)	1 (<0.1%)	0	
Hyperaesthesia	知覚過敏	0	1 (<0.1%)	0		0	0	0	
Hypoaesthesia	感覚鈍麻	0	0	0		1 (<0.1%)	0	0	
Ischaemic stroke	虚血性脳卒中	0	0	0		0	0	1 (<0.1%)	
Lethargy	嗜眠	0	1 (<0.1%)	0		1 (<0.1%)	0	0	

表 2.7.4.7-7 重症度別の治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Migraine	片頭痛	0	1 (<0.1%)	0		0	0	0	
Neuralgia	神経痛	0	0	0		1 (<0.1%)	0	0	
Paraesthesia	錯感覚	4 (0.2%)	0	0		1 (<0.1%)	0	0	
Sciatica	坐骨神経痛	0	1 (<0.1%)	0		0	0	0	
Sensory disturbance	感覚障害	1 (<0.1%)	0	0		0	0	0	
Somnolence	傾眠	0	1 (<0.1%)	0		0	0	0	
Syncope	失神	1 (<0.1%)	0	0		0	0	0	
Psychiatric disorders	精神障害	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Insomnia	不眠症	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Sleep disorder	睡眠障害	0	0	0		0	1 (<0.1%)	0	
Renal and urinary disorders	腎および尿路障害	19 (1.1%)	8 (0.5%)	1 (<0.1%)		23 (1.3%)	11 (0.6%)	0	
Chromaturia	着色尿	0	0	0		2 (0.1%)	0	0	
Haematuria	血尿	18 (1.0%)	8 (0.5%)	1 (<0.1%)		22 (1.3%)	10 (0.6%)	0	
Pollakiuria	頻尿	1 (<0.1%)	0	0		0	0	0	
Urethral haemorrhage	尿道出血	0	0	0		1 (<0.1%)	0	0	
Urinary tract obstruction	尿路閉塞	0	0	0		0	1 (<0.1%)	0	
Urine odour abnormal	尿臭異常	0	0	0		1 (<0.1%)	0	0	
Reproductive system and breast disorders	生殖系および乳房障害	44 (2.6%)	28 (1.6%)	4 (0.2%)		20 (1.2%)	11 (0.6%)	1 (<0.1%)	
Dysfunctional uterine bleeding	機能障害性子宮出血	0	1 (<0.1%)	0		0	0	0	
Dysmenorrhoea	月経困難症	1 (<0.1%)	0	0		2 (0.1%)	0	0	
Erectile dysfunction	勃起不全	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Gynaecomastia	女性化乳房	1 (<0.1%)	0	0		0	0	0	
Menometrorrhagia	機能性子宮出血	0	1 (<0.1%)	0		0	0	0	
Menorrhagia	月経過多	21 (1.2%)	16 (0.9%)	3 (0.2%)		9 (0.5%)	6 (0.4%)	1 (<0.1%)	
Menstrual disorder	月経障害	2 (0.1%)	0	0		0	0	0	
Menstruation irregular	不規則月経	1 (<0.1%)	0	0		0	0	0	
Metrorrhagia	不正子宮出血	7 (0.4%)	1 (<0.1%)	0		2 (0.1%)	1 (<0.1%)	0	
Oligomenorrhoea	希発月経	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Penile haemorrhage	陰茎出血	0	0	0		1 (<0.1%)	0	0	
Uterine haemorrhage	子宮出血	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-7 重症度別の治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Vaginal haemorrhage	膣出血	14 (0.8%)	10 (0.6%)	1 (<0.1%)		4 (0.2%)	4 (0.2%)	0	
Vulvovaginal pain	外陰膣痛	0	0	0		1 (<0.1%)	0	0	
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	71 (4.1%)	12 (0.7%)	1 (<0.1%)		58 (3.4%)	7 (0.4%)	2 (0.1%)	
Cough	咳嗽	2 (0.1%)	0	0		0	1 (<0.1%)	0	
Dyspnoea	呼吸困難	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Dyspnoea exertional	労作性呼吸困難	2 (0.1%)	1 (<0.1%)	0		0	0	0	
Epistaxis	鼻出血	58 (3.4%)	8 (0.5%)	1 (<0.1%)		51 (3.0%)	4 (0.2%)	1 (<0.1%)	
Haemoptysis	喀血	10 (0.6%)	3 (0.2%)	0		8 (0.5%)	2 (0.1%)	0	
Haemothorax	血胸	0	0	0		0	0	1 (<0.1%)	
Productive cough	湿性咳嗽	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Throat irritation	咽喉刺激感	1 (<0.1%)	0	0		0	0	0	
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	45 (2.6%)	4 (0.2%)	1 (<0.1%)		37 (2.2%)	12 (0.7%)	1 (<0.1%)	
Acne	ざ瘡	1 (<0.1%)	0	0		0	0	0	
Alopecia	脱毛症	4 (0.2%)	1 (<0.1%)	0		7 (0.4%)	2 (0.1%)	0	
Dermatitis	皮膚炎	0	0	0		1 (<0.1%)	0	0	
Dermatitis allergic	アレルギー性皮膚炎	0	1 (<0.1%)	0		0	0	0	
Dermatitis exfoliative	剥脱性皮膚炎	0	0	0		0	1 (<0.1%)	0	
Drug eruption	薬疹	1 (<0.1%)	0	0		0	0	0	
Dry skin	皮膚乾燥	3 (0.2%)	0	0		1 (<0.1%)	0	0	
Ecchymosis	斑状出血	1 (<0.1%)	0	1 (<0.1%)		6 (0.4%)	0	1 (<0.1%)	
Eczema	湿疹	1 (<0.1%)	0	0		0	0	0	
Erythema	紅斑	2 (0.1%)	0	0		0	0	0	
Haemorrhage subcutaneous	皮下出血	1 (<0.1%)	0	0		0	0	0	
Hyperhidrosis	多汗症	1 (<0.1%)	0	0		0	0	0	
Increased tendency to bruise	挫傷発生の増加傾向	1 (<0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Leukocytoclastic vasculitis	白血球破砕性血管炎	0	0	0		0	1 (<0.1%)	0	
Nail bed bleeding	爪床出血	1 (<0.1%)	0	0		0	0	0	
Night sweats	寝汗	5 (0.3%)	0	0		3 (0.2%)	2 (0.1%)	0	
Petechiae	点状出血	2 (0.1%)	0	0		3 (0.2%)	0	0	
Pruritus	そう痒症	9 (0.5%)	0	0		5 (0.3%)	2 (0.1%)	0	

表 2.7.4.7-7 重症度別の治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing
Rash	発疹	8 (0.5%)	2 (0.1%)	0		1 (<0.1%)	2 (0.1%)	0	
Rash erythematous	紅斑性皮疹	0	0	0		1 (<0.1%)	0	0	
Rash generalised	全身性皮疹	0	0	0		0	1 (<0.1%)	0	
Rash pruritic	そう痒性皮疹	0	0	0		1 (<0.1%)	0	0	
Skin exfoliation	皮膚剥脱	1 (<0.1%)	0	0		0	0	0	
Skin haemorrhage	皮膚出血	6 (0.3%)	0	0		5 (0.3%)	0	0	
Skin lesion	皮膚病変	0	0	0		1 (<0.1%)	0	0	
Skin ulcer	皮膚潰瘍	0	0	0		0	2 (0.1%)	0	
Skin ulcer haemorrhage	出血性皮膚潰瘍	0	0	0		1 (<0.1%)	0	0	
Spider naevus	くも状母斑	1 (<0.1%)	0	0		0	0	0	
Stasis dermatitis	うっ滞性皮膚炎	0	0	0		1 (<0.1%)	0	0	
Urticaria	蕁麻疹	0	0	0		1 (<0.1%)	0	0	
Vascular disorders	血管障害	30 (1.7%)	5 (0.3%)	0		34 (2.0%)	9 (0.5%)	2 (0.1%)	
Arterial thrombosis limb	四肢動脈血栓症	0	0	0		0	1 (<0.1%)	0	
Blue toe syndrome	青趾症候群	0	0	0		1 (<0.1%)	0	0	
Circulatory collapse	循環虚脱	1 (<0.1%)	0	0		0	0	0	
Haematoma	血腫	21 (1.2%)	4 (0.2%)	0		30 (1.8%)	7 (0.4%)	1 (<0.1%)	
Hot flush	ほてり	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Hypertension	高血圧	0	0	0		1 (<0.1%)	0	0	
Hypotension	低血圧	1 (<0.1%)	0	0		0	0	0	
Peripheral coldness	末梢冷感	2 (0.1%)	1 (<0.1%)	0		0	0	0	
Phlebitis	静脈炎	0	0	0		0	1 (<0.1%)	0	
Post thrombotic syndrome	血栓後症候群	1 (<0.1%)	0	0		0	0	0	
Raynaud's phenomenon	レイノー現象	0	0	0		1 (<0.1%)	0	0	
Shock haemorrhagic	出血性ショック	0	0	0		0	0	1 (<0.1%)	
Varicose vein	静脈瘤	1 (<0.1%)	0	0		0	0	0	
Vasodilatation	血管拡張	1 (<0.1%)	0	0		0	0	0	
Venous thrombosis limb	四肢静脈血栓症	1 (<0.1%)	0	0		0	0	0	

表 2.7.4.7-7 重症度別の治験薬との因果関係が否定できない TEAE（試験 11702-DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0}	Rivaroxaban				Enoxaparin/VKA			
	MILD N=1718 (100%)	MODERATE N=1718 (100%)	SEVERE N=1718 (100%)	missing	MILD N=1711 (100%)	MODERATE N=1711 (100%)	SEVERE N=1711 (100%)	missing

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Only the most severe intensity is counted for multiple occurrences of the same AE in each subject.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-3-4.sas erjli 21MAR2013 10:10
End of table

表 2.7.4.7-8 重症度別の治験薬との因果関係が否定できない TEAE（試験 11702-PE、安全性解析対象集団）

Primary System Organ Class Preferred Term MedDRA version{14.1}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing
Number of subjects (%) with at least one adverse event		516 (21.4%)	200 (8.3%)	60 (2.5%)		561 (23.3%)	160 (6.7%)	63 (2.6%)	
Blood and lymphatic system disorders	血液およびリンパ系障害	9 (0.4%)	14 (0.6%)	4 (0.2%)		9 (0.4%)	7 (0.3%)	6 (0.2%)	
Anaemia	貧血	4 (0.2%)	10 (0.4%)	3 (0.1%)		4 (0.2%)	4 (0.2%)	2 (<0.1%)	
Anaemia of chronic disease	慢性疾患の貧血	0	1 (<0.1%)	0		0	0	0	
Coagulopathy	凝血異常	0	0	0		0	0	2 (<0.1%)	
Eosinophilia	好酸球増加症	0	0	0		0	1 (<0.1%)	0	
Haemorrhagic anaemia	出血性貧血	0	1 (<0.1%)	0		0	1 (<0.1%)	1 (<0.1%)	
Haemorrhagic diathesis	出血性素因	1 (<0.1%)	0	0		0	0	0	
Heparin-induced thrombocytopenia	ヘパリン起因性血小板減少症	0	1 (<0.1%)	0		0	0	0	
Hypercoagulation	凝固亢進	0	0	0		0	1 (<0.1%)	0	
Hypocoagulable state	凝固低下状態	0	0	0		0	0	1 (<0.1%)	
Iron deficiency anaemia	鉄欠乏性貧血	3 (0.1%)	0	0		2 (<0.1%)	0	0	
Leukocytosis	白血球増加症	0	0	0		0	1 (<0.1%)	0	
Leukopenia	白血球減少症	0	0	0		1 (<0.1%)	0	0	
Microcytic anaemia	小球性貧血	0	1 (<0.1%)	0		0	0	0	
Normochromic normocytic anaemia	正色素性正球性貧血	1 (<0.1%)	0	0		0	0	0	
Splenic haemorrhage	脾臓出血	0	0	0		0	0	1 (<0.1%)	
Spontaneous haematoma	特発性血腫	0	0	0		1 (<0.1%)	0	0	
Thrombocytopenia	血小板減少症	0	0	1 (<0.1%)		0	1 (<0.1%)	0	
Thrombocytosis	血小板増加症	0	0	0		1 (<0.1%)	0	0	
Cardiac disorders	心臓障害	7 (0.3%)	5 (0.2%)	2 (<0.1%)		1 (<0.1%)	0	2 (<0.1%)	
Angina unstable	不安定狭心症	0	2 (<0.1%)	0		0	0	0	
Cardiac failure acute	急性心不全	0	0	1 (<0.1%)		0	0	0	
Cardiac failure congestive	うっ血性心不全	0	0	1 (<0.1%)		0	0	0	
Congestive cardiomyopathy	うっ血性心筋症	0	0	1 (<0.1%)		0	0	0	
Coronary artery disease	冠動脈疾患	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Palpitations	動悸	5 (0.2%)	0	0		0	0	0	
Pericardial haemorrhage	心嚢内出血	0	0	0		0	0	2 (<0.1%)	
Right ventricular failure	右室不全	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-8 重症度別の治験薬との因果関係が否定できない TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing
Tachycardia	頻脈	3 (0.1%)	2 (<0.1%)	0		0	0	0	
Tricuspid valve incompetence	三尖弁閉鎖不全症	1 (<0.1%)	0	0		0	0	0	
Ear and labyrinth disorders	耳および迷路障害	3 (0.1%)	2 (<0.1%)	0		7 (0.3%)	3 (0.1%)	0	
Ear haemorrhage	耳出血	2 (<0.1%)	0	0		5 (0.2%)	2 (<0.1%)	0	
Hypoacusis	聴力低下	0	0	0		0	1 (<0.1%)	0	
Tinnitus	耳鳴	0	2 (<0.1%)	0		1 (<0.1%)	0	0	
Vertigo	回転性めまい	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Endocrine disorders	内分泌障害	0	1 (<0.1%)	1 (<0.1%)		0	0	1 (<0.1%)	
Addison's disease	アジソン病	0	0	1 (<0.1%)		0	0	0	
Adrenal haemorrhage	副腎出血	0	0	1 (<0.1%)		0	0	1 (<0.1%)	
Hyperthyroidism	甲状腺機能亢進症	0	1 (<0.1%)	0		0	0	0	
Eye disorders	眼障害	34 (1.4%)	1 (<0.1%)	0		27 (1.1%)	6 (0.2%)	2 (<0.1%)	
Conjunctival haemorrhage	結膜出血	19 (0.8%)	1 (<0.1%)	0		22 (0.9%)	3 (0.1%)	0	
Dry eye	眼乾燥	2 (<0.1%)	0	0		0	0	0	
Eye haemorrhage	眼出血	7 (0.3%)	0	0		4 (0.2%)	2 (<0.1%)	0	
Eye pruritus	眼そう痒症	0	0	0		1 (<0.1%)	0	0	
Eyelid oedema	眼瞼浮腫	1 (<0.1%)	0	0		0	0	0	
Eyelid skin dryness	眼瞼皮膚乾燥	1 (<0.1%)	0	0		0	0	0	
Ocular hyperaemia	眼充血	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Pupils unequal	瞳孔不同	0	0	0		0	0	1 (<0.1%)	
Retinal haemorrhage	網膜出血	0	0	0		0	0	1 (<0.1%)	
Scleral haemorrhage	強膜出血	1 (<0.1%)	0	0		0	0	0	
Scleral hyperaemia	強膜充血	2 (<0.1%)	0	0		0	0	0	
Scotoma	暗点	0	0	0		0	1 (<0.1%)	0	
Visual acuity reduced	視力低下	1 (<0.1%)	0	0		0	0	0	
Gastrointestinal disorders	胃腸障害	161 (6.7%)	41 (1.7%)	9 (0.4%)		138 (5.7%)	21 (0.9%)	17 (0.7%)	
Abdominal discomfort	腹部不快感	3 (0.1%)	2 (<0.1%)	0		1 (<0.1%)	0	0	
Abdominal mass	腹部腫瘤	0	0	0		1 (<0.1%)	0	0	
Abdominal pain	腹痛	3 (0.1%)	2 (<0.1%)	0		0	0	1 (<0.1%)	
Abdominal pain upper	上腹部痛	4 (0.2%)	0	0		1 (<0.1%)	0	0	
Abdominal wall haematoma	腹壁血腫	0	0	0		1 (<0.1%)	0	2 (<0.1%)	

表 2.7.4.7-8 重症度別の治験薬との因果関係が否定できない TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing
Anal haemorrhage	肛門出血	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Colitis ulcerative	潰瘍性大腸炎	0	1 (<0.1%)	0		0	0	0	
Constipation	便秘	4 (0.2%)	0	0		1 (<0.1%)	0	0	
Diarrhoea	下痢	8 (0.3%)	3 (0.1%)	1 (<0.1%)		4 (0.2%)	1 (<0.1%)	0	
Diarrhoea haemorrhagic	血性下痢	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Dry mouth	口内乾燥	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Dyspepsia	消化不良	9 (0.4%)	0	0		3 (0.1%)	0	0	
Faecaloma	糞塊	1 (<0.1%)	0	0		0	0	0	
Flatulence	鼓腸	0	0	0		1 (<0.1%)	0	0	
Gastric haemorrhage	胃出血	0	0	0		0	0	1 (<0.1%)	
Gastric ulcer haemorrhage	出血性胃潰瘍	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Gastritis	胃炎	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Gastritis haemorrhagic	出血性胃炎	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Gastrointestinal disorder	胃腸障害	2 (<0.1%)	0	0		0	0	0	
Gastrointestinal haemorrhage	胃腸出血	5 (0.2%)	2 (<0.1%)	2 (<0.1%)		1 (<0.1%)	1 (<0.1%)	3 (0.1%)	
Gastrointestinal pain	消化器痛	0	0	0		1 (<0.1%)	0	0	
Gastrointestinal ulcer	胃腸潰瘍	0	0	0		0	1 (<0.1%)	0	
Gastrooesophageal reflux disease	胃食道逆流性疾患	3 (0.1%)	0	0		0	1 (<0.1%)	0	
Gingival bleeding	歯肉出血	42 (1.7%)	4 (0.2%)	0		63 (2.6%)	1 (<0.1%)	0	
Gingivitis	歯肉炎	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Haematemesis	吐血	1 (<0.1%)	6 (0.2%)	1 (<0.1%)		1 (<0.1%)	2 (<0.1%)	0	
Haematochezia	血便排泄	7 (0.3%)	0	0		9 (0.4%)	0	0	
Haemorrhoidal haemorrhage	痔出血	10 (0.4%)	4 (0.2%)	0		8 (0.3%)	1 (<0.1%)	0	
Haemorrhoids	痔核	1 (<0.1%)	0	0		0	0	0	
Hypoaesthesia oral	口の感覚鈍麻	2 (<0.1%)	0	0		0	0	0	
Intestinal haemorrhage	腸出血	2 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	3 (0.1%)	
Irritable bowel syndrome	過敏性腸症候群	0	1 (<0.1%)	0		0	0	0	
Lip dry	口唇乾燥	1 (<0.1%)	0	0		0	0	0	
Lip haemorrhage	口唇出血	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Lower gastrointestinal haemorrhage	下部消化管出血	5 (0.2%)	0	0		8 (0.3%)	1 (<0.1%)	0	
Melaena	メレナ	1 (<0.1%)	3 (0.1%)	0		5 (0.2%)	6 (0.2%)	2 (<0.1%)	

表 2.7.4.7-8 重症度別の治験薬との因果関係が否定できない TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing
Mouth haemorrhage	口腔内出血	5 (0.2%)	0	0		1 (<0.1%)	0	0	
Mouth ulceration	口腔内潰瘍形成	0	0	0		1 (<0.1%)	0	0	
Nausea	悪心	15 (0.6%)	2 (<0.1%)	1 (<0.1%)		6 (0.2%)	1 (<0.1%)	0	
Oesophageal ulcer	食道潰瘍	0	0	1 (<0.1%)		0	0	0	
Oesophageal ulcer haemorrhage	食道潰瘍出血	0	0	0		0	0	1 (<0.1%)	
Oral pain	口腔内痛	1 (<0.1%)	0	0		0	0	0	
Paraesthesia oral	口の錯感覚	0	0	0		1 (<0.1%)	0	0	
Portal hypertensive gastropathy	門脈圧亢進性胃障害	1 (<0.1%)	0	0		0	0	0	
Post-tussive vomiting	咳嗽後嘔吐	0	0	0		0	1 (<0.1%)	0	
Rectal haemorrhage	直腸出血	33 (1.4%)	7 (0.3%)	1 (<0.1%)		23 (1.0%)	6 (0.2%)	3 (0.1%)	
Retroperitoneal haematoma	後腹膜血腫	0	0	0		1 (<0.1%)	0	1 (<0.1%)	
Submaxillary gland enlargement	顎下腺腫大	0	0	0		1 (<0.1%)	0	0	
Tongue disorder	舌障害	1 (<0.1%)	0	0		0	0	0	
Tongue haemorrhage	舌出血	2 (<0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	0	
Tooth discolouration	変色歯	1 (<0.1%)	0	0		0	0	0	
Toothache	歯痛	0	0	0		1 (<0.1%)	0	0	
Upper gastrointestinal haemorrhage	上部消化管出血	0	0	2 (<0.1%)		0	0	1 (<0.1%)	
Varices oesophageal	食道静脈瘤	1 (<0.1%)	0	0		0	0	0	
Vomiting	嘔吐	2 (<0.1%)	2 (<0.1%)	0		2 (<0.1%)	0	0	
General disorders and administration site conditions	一般・全身障害および投与部位の状態	25 (1.0%)	10 (0.4%)	7 (0.3%)		27 (1.1%)	8 (0.3%)	2 (<0.1%)	
Application site erythema	適用部位紅斑	0	0	0		1 (<0.1%)	0	0	
Asthenia	無力症	0	0	1 (<0.1%)		1 (<0.1%)	0	0	
Catheter site haemorrhage	カテーテル留置部位出血	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Chest discomfort	胸部不快感	0	0	0		1 (<0.1%)	0	0	
Chest pain	胸痛	4 (0.2%)	2 (<0.1%)	2 (<0.1%)		5 (0.2%)	1 (<0.1%)	0	
Chills	悪寒	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Death	死亡	0	0	1 (<0.1%)		0	0	2 (<0.1%)	
Drug intolerance	薬物不耐性	0	0	0		0	1 (<0.1%)	0	
Facial pain	顔面痛	1 (<0.1%)	0	0		0	0	0	

表 2.7.4.7-8 重症度別の治験薬との因果関係が否定できない TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing
Fatigue	疲労	9 (0.4%)	3 (0.1%)	1 (<0.1%)		3 (0.1%)	0	0	
Feeling cold	冷感	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Feeling hot	熱感	1 (<0.1%)	0	0		0	0	0	
Haemorrhagic cyst	出血性嚢胞	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Influenza like illness	インフルエンザ様疾患	1 (<0.1%)	0	0		0	0	0	
Injection site erythema	注射部位紅斑	0	0	0		1 (<0.1%)	0	0	
Injection site extravasation	注射部位血管外漏出	0	0	0		0	1 (<0.1%)	0	
Injection site haematoma	注射部位血腫	2 (<0.1%)	0	0		9 (0.4%)	1 (<0.1%)	0	
Injection site haemorrhage	注射部位出血	0	0	0		2 (<0.1%)	0	0	
Injection site pain	注射部位疼痛	0	0	0		1 (<0.1%)	0	0	
Injection site reaction	注射部位反応	0	0	0		1 (<0.1%)	0	0	
Malaise	倦怠感	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Oedema	浮腫	2 (<0.1%)	1 (<0.1%)	0		0	1 (<0.1%)	0	
Oedema peripheral	末梢性浮腫	2 (<0.1%)	1 (<0.1%)	0		3 (0.1%)	3 (0.1%)	0	
Sudden death	突然死	0	0	2 (<0.1%)		0	0	0	
Thirst	口渇	1 (<0.1%)	0	0		0	0	0	
Vessel puncture site haematoma	血管穿刺部位血腫	0	0	0		2 (<0.1%)	0	0	
Vessel puncture site haemorrhage	血管穿刺部位出血	3 (0.1%)	0	0		1 (<0.1%)	1 (<0.1%)	0	
Hepatobiliary disorders	肝胆道系障害	3 (0.1%)	5 (0.2%)	3 (0.1%)		8 (0.3%)	1 (<0.1%)	1 (<0.1%)	
Cholangitis sclerosing	硬化性胆管炎	0	0	1 (<0.1%)		0	0	0	
Cholecystitis	胆嚢炎	0	1 (<0.1%)	0		0	0	0	
Cholestasis	胆汁うっ滞	0	1 (<0.1%)	0		0	0	0	
Cytolytic hepatitis	肝細胞融解性肝炎	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Hepatic function abnormal	肝機能異常	2 (<0.1%)	2 (<0.1%)	0		7 (0.3%)	0	1 (<0.1%)	
Hepatitis	肝炎	0	0	0		0	1 (<0.1%)	0	
Hepatitis acute	急性肝炎	0	0	1 (<0.1%)		0	0	0	
Hepatitis chronic active	慢性活動性肝炎	0	0	1 (<0.1%)		0	0	0	
Hyperbilirubinaemia	高ビリルビン血症	0	0	0		1 (<0.1%)	0	0	
Immune system disorders	免疫系障害	0	0	0		1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Drug hypersensitivity	薬物過敏症	0	0	0		1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	
Infections and infestations	感染症および寄生虫症	10 (0.4%)	2 (<0.1%)	0		6 (0.2%)	1 (<0.1%)	0	

表 2.7.4.7-8 重症度別の治験薬との因果関係が否定できない TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing
Bronchitis	気管支炎	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	
Cellulitis	蜂巣炎	0	0	0		1 (<0.1%)	0	0	
Folliculitis	毛包炎	1 (<0.1%)	0	0		0	0	0	
Fungal skin infection	皮膚真菌感染	1 (<0.1%)	0	0		0	0	0	
Gastroenteritis	胃腸炎	1 (<0.1%)	0	0		0	0	0	
Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪	0	0	0		0	1 (<0.1%)	0	
Influenza	インフルエンザ	1 (<0.1%)	0	0		0	0	0	
Kidney infection	腎感染	1 (<0.1%)	0	0		0	0	0	
Nasopharyngitis	鼻咽頭炎	5 (0.2%)	0	0		1 (<0.1%)	0	0	
Pneumonia	肺炎	0	0	0		0	1 (<0.1%)	0	
Rhinitis	鼻炎	0	0	0		1 (<0.1%)	0	0	
Sinusitis	副鼻腔炎	0	1 (<0.1%)	0		1 (<0.1%)	0	0	
Skin infection	皮膚感染	0	0	0		1 (<0.1%)	0	0	
Upper respiratory tract infection	上気道感染	0	0	0		1 (<0.1%)	0	0	
Wound infection bacterial	細菌性創感染	1 (<0.1%)	0	0		0	0	0	
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	86 (3.6%)	21 (0.9%)	3 (0.1%)		126 (5.2%)	33 (1.4%)	8 (0.3%)	
Ankle fracture	足関節部骨折	0	0	0		1 (<0.1%)	0	0	
Cerebral haemorrhage traumatic	外傷性脳出血	0	0	1 (<0.1%)		0	0	0	
Contusion	挫傷	45 (1.9%)	8 (0.3%)	0		69 (2.9%)	15 (0.6%)	2 (<0.1%)	
Exposure during breast feeding	母乳保育時の曝露	1 (<0.1%)	0	0		0	0	0	
Graft haemorrhage	移植部位出血	1 (<0.1%)	0	0		0	0	0	
Haematuria traumatic	外傷性血尿	1 (<0.1%)	0	0		0	0	0	
Head injury	頭部損傷	1 (<0.1%)	0	0		0	0	0	
Incision site haemorrhage	切開部位出血	1 (<0.1%)	0	0		2 (<0.1%)	1 (<0.1%)	0	
Injury	損傷	0	0	0		1 (<0.1%)	0	0	
Kidney rupture	腎臓破裂	0	0	0		1 (<0.1%)	0	0	
Laceration	裂傷	1 (<0.1%)	0	0		0	0	0	
Operative haemorrhage	術中出血	0	1 (<0.1%)	0		0	1 (<0.1%)	0	
Overdose	過量投与	0	0	0		8 (0.3%)	4 (0.2%)	1 (<0.1%)	

表 2.7.4.7-8 重症度別の治験薬との因果関係が否定できない TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing
Periorbital haematoma	眼窩周囲血腫	1 (<0.1%)	0	0		2 (<0.1%)	0	0	
Perirenal haematoma	腎周囲血腫	0	0	0		0	1 (<0.1%)	0	
Post procedural haematoma	処置後血腫	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Post procedural haemorrhage	処置後出血	4 (0.2%)	2 (<0.1%)	1 (<0.1%)		4 (0.2%)	1 (<0.1%)	0	
Scratch	引っかき傷	0	0	0		1 (<0.1%)	0	0	
Skeletal injury	骨格損傷	0	1 (<0.1%)	0		0	0	0	
Splenic haematoma	脾血腫	0	0	0		0	0	1 (<0.1%)	
Subcutaneous haematoma	皮下血腫	16 (0.7%)	5 (0.2%)	0		25 (1.0%)	6 (0.2%)	1 (<0.1%)	
Subdural haematoma	硬膜下血腫	0	0	1 (<0.1%)		0	0	2 (<0.1%)	
Subdural haemorrhage	硬膜下出血	0	0	0		0	0	1 (<0.1%)	
Tooth fracture	歯牙破折	0	0	0		1 (<0.1%)	0	0	
Traumatic haematoma	外傷性血腫	4 (0.2%)	0	0		5 (0.2%)	3 (0.1%)	0	
Traumatic haemorrhage	外傷性出血	4 (0.2%)	2 (<0.1%)	0		1 (<0.1%)	0	0	
Vascular pseudoaneurysm	血管偽動脈瘤	0	0	0		1 (<0.1%)	0	0	
Wound haematoma	創傷血腫	0	0	0		0	1 (<0.1%)	0	
Wound haemorrhage	創傷出血	12 (0.5%)	4 (0.2%)	0		18 (0.7%)	0	0	
Investigations	臨床検査	46 (1.9%)	22 (0.9%)	8 (0.3%)		120 (5.0%)	34 (1.4%)	6 (0.2%)	
Activated partial thromboplastin time prolonged	活性化部分トロンボプラスチン時間延長	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)		0	0	0	
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	20 (0.8%)	5 (0.2%)	1 (<0.1%)		26 (1.1%)	5 (0.2%)	2 (<0.1%)	
Antiphospholipid antibodies positive	抗リン脂質抗体陽性	1 (<0.1%)	0	0		0	0	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	9 (0.4%)	1 (<0.1%)	0		8 (0.3%)	3 (0.1%)	0	
Bilirubin conjugated increased	抱合ビリルビン増加	2 (<0.1%)	1 (<0.1%)	0		0	0	0	
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3 (0.1%)	0	1 (<0.1%)		4 (0.2%)	0	0	
Blood amylase increased	血中アミラーゼ増加	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Blood bilirubin increased	血中ビリルビン増加	3 (0.1%)	2 (<0.1%)	0		0	0	0	
Blood creatinine increased	血中クレアチニン増加	0	0	0		1 (<0.1%)	0	0	
Blood potassium decreased	血中カリウム減少	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-8 重症度別の治験薬との因果関係が否定できない TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing
Blood pressure increased	血圧上昇	1 (<0.1%)	0	0		0	0	0	
Blood urea increased	血中尿素増加	0	0	0		1 (<0.1%)	0	0	
C-reactive protein increased	Ｃ－反応性蛋白増加	0	1 (<0.1%)	0		0	0	0	
Coagulation factor V level decreased	凝固第Ｖ因子量減少	1 (<0.1%)	0	0		0	0	0	
Coagulation factor X level decreased	凝固第Ｘ因子量減少	1 (<0.1%)	0	0		0	0	0	
Coagulation time prolonged	凝固時間延長	0	0	0		3 (0.1%)	1 (<0.1%)	0	
Epidermal growth factor receptor increased	上皮増殖因子受容体増加	0	0	0		1 (<0.1%)	0	0	
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (<0.1%)	0	0		0	0	0	
Haemoglobin decreased	ヘモグロビン減少	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Heart rate irregular	心拍数不整	1 (<0.1%)	0	0		0	0	0	
Hepatic enzyme increased	肝酵素上昇	3 (0.1%)	2 (<0.1%)	2 (<0.1%)		3 (0.1%)	3 (0.1%)	1 (<0.1%)	
International normalised ratio abnormal	ＩＮＲ異常	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
International normalised ratio decreased	ＩＮＲ減少	0	0	0		14 (0.6%)	2 (<0.1%)	0	
International normalised ratio fluctuation	ＩＮＲ変動	0	0	0		0	1 (<0.1%)	0	
International normalised ratio increased	ＩＮＲ増加	2 (<0.1%)	2 (<0.1%)	0		56 (2.3%)	17 (0.7%)	3 (0.1%)	
Liver function test abnormal	肝機能検査異常	5 (0.2%)	5 (0.2%)	3 (0.1%)		14 (0.6%)	3 (0.1%)	0	
Occult blood positive	便潜血陽性	4 (0.2%)	1 (<0.1%)	0		0	1 (<0.1%)	0	
Platelet count increased	血小板数増加	1 (<0.1%)	0	0		0	0	0	
Prothrombin level decreased	プロトロンビン量減少	1 (<0.1%)	0	0		0	0	0	
Prothrombin time ratio decreased	プロトロンビン時間比減少	1 (<0.1%)	0	0		0	0	0	
Prothrombin time shortened	プロトロンビン時間短縮	0	1 (<0.1%)	0		0	0	0	
Transaminases increased	トランスアミナーゼ上昇	2 (<0.1%)	1 (<0.1%)	0		4 (0.2%)	1 (<0.1%)	0	
Ultrasound liver abnormal	肝超音波検査異常	0	0	1 (<0.1%)		0	0	0	

表 2.7.4.7-8 重症度別の治験薬との因果関係が否定できない TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing
Weight increased	体重増加	2 (<0.1%)	0	0		1 (<0.1%)	0	0	
Metabolism and nutrition disorders	代謝および栄養障害	6 (0.2%)	1 (<0.1%)	0		5 (0.2%)	2 (<0.1%)	1 (<0.1%)	
Decreased appetite	食欲減退	2 (<0.1%)	0	0		2 (<0.1%)	0	0	
Gout	痛風	1 (<0.1%)	1 (<0.1%)	0		0	2 (<0.1%)	0	
Hyperlipidaemia	高脂血症	0	0	0		1 (<0.1%)	0	0	
Hypokalaemia	低カリウム血症	0	0	0		1 (<0.1%)	0	0	
Hypovolaemia	血液量減少症	0	0	0		0	0	1 (<0.1%)	
Iron deficiency	鉄欠乏	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Vitamin D deficiency	ビタミンD欠乏	1 (<0.1%)	0	0		0	0	0	
Weight loss poor	体重減少不良	1 (<0.1%)	0	0		0	0	0	
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	24 (1.0%)	5 (0.2%)	2 (<0.1%)		15 (0.6%)	11 (0.5%)	5 (0.2%)	
Arthralgia	関節痛	4 (0.2%)	2 (<0.1%)	1 (<0.1%)		1 (<0.1%)	1 (<0.1%)	0	
Arthritis	関節炎	1 (<0.1%)	0	0		0	0	0	
Flank pain	側腹部痛	0	0	0		0	1 (<0.1%)	0	
Haemarthrosis	出血性関節症	2 (<0.1%)	2 (<0.1%)	0		2 (<0.1%)	1 (<0.1%)	0	
Muscle haemorrhage	筋肉内出血	0	0	1 (<0.1%)		2 (<0.1%)	4 (0.2%)	5 (0.2%)	
Muscle spasms	筋痙縮	5 (0.2%)	0	0		5 (0.2%)	1 (<0.1%)	0	
Muscle twitching	筋攣縮	1 (<0.1%)	0	0		0	0	0	
Musculoskeletal chest pain	筋骨格系胸痛	0	0	0		1 (<0.1%)	0	0	
Musculoskeletal pain	筋骨格痛	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Myalgia	筋肉痛	4 (0.2%)	1 (<0.1%)	0		1 (<0.1%)	1 (<0.1%)	0	
Osteoarthritis	変形性関節症	1 (<0.1%)	0	0		0	0	0	
Osteorrhagia	骨出血	0	0	0		1 (<0.1%)	0	0	
Pain in extremity	四肢痛	8 (0.3%)	1 (<0.1%)	0		3 (0.1%)	2 (<0.1%)	0	
Soft tissue haemorrhage	軟部組織出血	0	0	0		1 (<0.1%)	0	0	
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）	0	0	0		2 (<0.1%)	0	0	
Lung neoplasm	肺新生物	0	0	0		1 (<0.1%)	0	0	
Tumour haemorrhage	腫瘍出血	0	0	0		1 (<0.1%)	0	0	
Nervous system disorders	神経系障害	45 (1.9%)	11 (0.5%)	5 (0.2%)		15 (0.6%)	7 (0.3%)	4 (0.2%)	

表 2.7.4.7-8 重症度別の治験薬との因果関係が否定できない TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing
Ageusia	味覚消失	1 (<0.1%)	0	0		0	0	0	
Burning sensation	灼熱感	1 (<0.1%)	0	0		0	0	0	
Cerebellar haemorrhage	小脳出血	0	0	1 (<0.1%)		0	0	0	
Cerebral haemorrhage	脳出血	0	0	0		0	1 (<0.1%)	2 (<0.1%)	
Cerebrovascular accident	脳血管発作	0	0	1 (<0.1%)		0	0	0	
Clumsiness	不器用	0	1 (<0.1%)	0		0	0	0	
Convulsion	痙攣	0	0	1 (<0.1%)		0	0	0	
Disturbance in attention	注意力障害	1 (<0.1%)	0	0		0	0	0	
Dizziness	浮動性めまい	9 (0.4%)	0	0		2 (<0.1%)	1 (<0.1%)	0	
Dysaesthesia	異常感覚	1 (<0.1%)	0	0		0	0	0	
Dysgeusia	味覚異常	3 (0.1%)	0	0		1 (<0.1%)	0	0	
Haemorrhage intracranial	頭蓋内出血	0	0	0		1 (<0.1%)	0	1 (<0.1%)	
Headache	頭痛	30 (1.2%)	5 (0.2%)	0		8 (0.3%)	2 (<0.1%)	1 (<0.1%)	
Hepatic encephalopathy	肝性脳症	0	0	1 (<0.1%)		0	0	0	
Hypoaesthesia	感覚鈍麻	2 (<0.1%)	0	0		0	0	0	
Ischaemic stroke	虚血性脳卒中	0	0	0		1 (<0.1%)	0	0	
Lethargy	嗜眠	1 (<0.1%)	0	0		0	0	0	
Loss of consciousness	意識消失	0	0	0		1 (<0.1%)	0	0	
Migraine	片頭痛	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Paraesthesia	錯感覚	3 (0.1%)	1 (<0.1%)	0		2 (<0.1%)	0	0	
Restless legs syndrome	下肢静止不能症候群	0	2 (<0.1%)	0		0	0	0	
Sciatica	坐骨神経痛	0	0	0		0	1 (<0.1%)	0	
Subarachnoid haemorrhage	くも膜下出血	0	0	0		0	1 (<0.1%)	0	
Syncope	失神	0	0	1 (<0.1%)		0	0	0	
Tension headache	緊張性頭痛	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Tremor	振戦	2 (<0.1%)	1 (<0.1%)	0		0	0	0	
Psychiatric disorders	精神障害	8 (0.3%)	2 (<0.1%)	0		4 (0.2%)	1 (<0.1%)	0	
Affective disorder	感情障害	0	1 (<0.1%)	0		0	0	0	
Anxiety	不安	2 (<0.1%)	0	0		0	0	0	
Confusional state	錯乱状態	1 (<0.1%)	0	0		0	0	0	
Depression	うつ病	1 (<0.1%)	1 (<0.1%)	0		1 (<0.1%)	0	0	

表 2.7.4.7-8 重症度別の治験薬との因果関係が否定できない TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing
Insomnia	不眠症	3 (0.1%)	0	0		1 (<0.1%)	0	0	
Loss of libido	リビド消失	0	0	0		1 (<0.1%)	0	0	
Nervousness	神経過敏	1 (<0.1%)	0	0		0	0	0	
Orgasm abnormal	オルガズム異常	0	0	0		0	1 (<0.1%)	0	
Sleep disorder	睡眠障害	0	0	0		1 (<0.1%)	0	0	
Renal and urinary disorders	腎および尿路障害	38 (1.6%)	12 (0.5%)	2 (<0.1%)		36 (1.5%)	14 (0.6%)	4 (0.2%)	
Calculus ureteric	尿管結石	0	0	0		0	1 (<0.1%)	0	
Cystitis haemorrhagic	出血性膀胱炎	0	0	0		0	1 (<0.1%)	0	
Dysuria	排尿困難	1 (<0.1%)	0	0		0	0	0	
Haematuria	血尿	35 (1.5%)	12 (0.5%)	2 (<0.1%)		37 (1.5%)	13 (0.5%)	2 (<0.1%)	
Pollakiuria	頻尿	1 (<0.1%)	0	0		0	0	0	
Renal failure	腎不全	0	0	0		0	0	1 (<0.1%)	
Renal failure acute	急性腎不全	0	0	0		0	0	1 (<0.1%)	
Renal haemorrhage	腎出血	1 (<0.1%)	0	0		0	0	0	
Urinary retention	尿閉	0	0	1 (<0.1%)		0	0	0	
Reproductive system and breast disorders	生殖系および乳房障害	52 (2.2%)	40 (1.7%)	5 (0.2%)		42 (1.7%)	14 (0.6%)	3 (0.1%)	
Amenorrhoea	無月経	0	0	0		1 (<0.1%)	0	0	
Breast haematoma	乳房血腫	1 (<0.1%)	0	0		0	0	0	
Breast mass	乳房腫瘤	0	0	0		1 (<0.1%)	0	0	
Coital bleeding	性交出血	2 (<0.1%)	0	0		0	0	0	
Dysfunctional uterine bleeding	機能障害性子宮出血	0	1 (<0.1%)	0		0	0	0	
Dysmenorrhoea	月経困難症	0	2 (<0.1%)	0		0	0	0	
Erectile dysfunction	勃起不全	1 (<0.1%)	0	0		0	0	0	
Gynaecomastia	女性化乳房	1 (<0.1%)	0	0		0	0	0	
Haemorrhagic ovarian cyst	出血性卵巣嚢胞	0	0	0		1 (<0.1%)	0	0	
Menometrorrhagia	機能性子宮出血	0	0	0		1 (<0.1%)	1 (<0.1%)	0	
Menorrhagia	月経過多	28 (1.2%)	29 (1.2%)	4 (0.2%)		25 (1.0%)	7 (0.3%)	2 (<0.1%)	
Menstruation irregular	不規則月経	0	0	0		1 (<0.1%)	0	0	
Metrorrhagia	不正子宮出血	6 (0.2%)	3 (0.1%)	1 (<0.1%)		8 (0.3%)	5 (0.2%)	1 (<0.1%)	
Penile haematoma	陰茎血腫	0	0	0		0	1 (<0.1%)	0	
Priapism	持続勃起症	0	0	0		0	1 (<0.1%)	0	

表 2.7.4.7-8 重症度別の治験薬との因果関係が否定できない TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing
Scrotal haematocoele	陰嚢血瘤	1 (<0.1%)	0	0		0	0	0	
Vaginal haemorrhage	膣出血	14 (0.6%)	5 (0.2%)	0		7 (0.3%)	1 (<0.1%)	0	
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	212 (8.8%)	28 (1.2%)	6 (0.2%)		170 (7.1%)	25 (1.0%)	6 (0.2%)	
Asthma	喘息	0	1 (<0.1%)	0		0	0	0	
Bronchial irritation	気管支刺激	1 (<0.1%)	0	0		0	0	0	
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	0	1 (<0.1%)	0		0	0	0	
Cough	咳嗽	6 (0.2%)	1 (<0.1%)	0		2 (<0.1%)	0	0	
Dyspnoea	呼吸困難	3 (0.1%)	1 (<0.1%)	0		3 (0.1%)	2 (<0.1%)	1 (<0.1%)	
Dyspnoea at rest	安静時呼吸困難	0	0	0		1 (<0.1%)	0	0	
Dyspnoea exertional	労作性呼吸困難	2 (<0.1%)	0	0		0	0	0	
Epistaxis	鼻出血	154 (6.4%)	19 (0.8%)	0		140 (5.8%)	16 (0.7%)	3 (0.1%)	
Haemoptysis	喀血	58 (2.4%)	4 (0.2%)	0		39 (1.6%)	5 (0.2%)	1 (<0.1%)	
Haemothorax	血胸	1 (<0.1%)	0	1 (<0.1%)		0	0	1 (<0.1%)	
Oropharyngeal blistering	口腔咽頭水疱形成	0	0	0		1 (<0.1%)	0	0	
Paranasal sinus haematoma	副鼻腔血腫	0	0	0		0	1 (<0.1%)	0	
Pleural effusion	胸水	0	0	0		0	1 (<0.1%)	0	
Productive cough	湿性咳嗽	2 (<0.1%)	0	0		0	0	0	
Pulmonary congestion	肺うっ血	0	0	0		0	1 (<0.1%)	0	
Pulmonary embolism	肺塞栓症	0	0	1 (<0.1%)		0	0	0	
Pulmonary haemorrhage	肺出血	0	0	1 (<0.1%)		0	0	0	
Pulmonary infarction	肺梗塞	0	0	1 (<0.1%)		0	0	0	
Pulmonary venous thrombosis	肺静脈血栓症	0	0	1 (<0.1%)		0	0	0	
Respiratory distress	呼吸窮迫	0	0	0		0	0	1 (<0.1%)	
Respiratory failure	呼吸不全	0	1 (<0.1%)	1 (<0.1%)		0	0	0	
Rhinorrhoea	鼻漏	1 (<0.1%)	0	0		0	0	0	
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	78 (3.2%)	25 (1.0%)	2 (<0.1%)		66 (2.7%)	10 (0.4%)	2 (<0.1%)	
Acne	ざ瘡	2 (<0.1%)	0	0		0	0	0	
Alopecia	脱毛症	8 (0.3%)	2 (<0.1%)	0		18 (0.7%)	2 (<0.1%)	1 (<0.1%)	
Alopecia areata	円形脱毛症	0	0	0		1 (<0.1%)	0	0	

表 2.7.4.7-8 重症度別の治験薬との因果関係が否定できない TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing
Angioedema	血管浮腫	1 (<0.1%)	0	0		0	0	0	
Blister	水疱	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Blood blister	血性水疱	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Cutaneous vasculitis	皮膚血管炎	1 (<0.1%)	0	0		0	0	0	
Dermatitis allergic	アレルギー性皮膚炎	2 (<0.1%)	2 (<0.1%)	0		0	1 (<0.1%)	0	
Dry skin	皮膚乾燥	3 (0.1%)	0	0		0	0	0	
Ecchymosis	斑状出血	10 (0.4%)	1 (<0.1%)	0		13 (0.5%)	2 (<0.1%)	0	
Eczema	湿疹	1 (<0.1%)	0	0		0	0	0	
Erythema	紅斑	2 (<0.1%)	0	0		2 (<0.1%)	0	0	
Haemorrhage subcutaneous	皮下出血	1 (<0.1%)	0	0		2 (<0.1%)	1 (<0.1%)	0	
Hair texture abnormal	毛質異常	2 (<0.1%)	0	0		0	0	0	
Hirsutism	男性型多毛症	0	0	0		1 (<0.1%)	0	0	
Hyperhidrosis	多汗症	5 (0.2%)	0	0		0	0	0	
Hyperkeratosis	過角化	1 (<0.1%)	0	0		0	0	0	
Increased tendency to bruise	内出血発生の増加傾向	3 (0.1%)	0	0		1 (<0.1%)	0	0	
Nail bed bleeding	爪床出血	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Night sweats	寝汗	1 (<0.1%)	0	0		0	1 (<0.1%)	0	
Onychomalacia	爪軟化症	1 (<0.1%)	0	0		0	0	0	
Petechiae	点状出血	2 (<0.1%)	0	0		3 (0.1%)	0	0	
Photosensitivity allergic reaction	アレルギー性光線過敏性反応	1 (<0.1%)	0	0		0	0	0	
Pruritus	そう痒症	16 (0.7%)	4 (0.2%)	1 (<0.1%)		6 (0.2%)	1 (<0.1%)	0	
Pruritus generalised	全身性そう痒症	0	0	0		1 (<0.1%)	0	0	
Psoriasis	乾癬	0	2 (<0.1%)	0		0	0	0	
Purpura	紫斑	0	1 (<0.1%)	1 (<0.1%)		1 (<0.1%)	0	0	
Rash	発疹	19 (0.8%)	11 (0.5%)	0		9 (0.4%)	1 (<0.1%)	0	
Rash erythematous	紅斑性皮疹	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Rash generalised	全身性皮疹	1 (<0.1%)	1 (<0.1%)	0		0	0	0	
Rash macular	斑状皮疹	0	0	0		1 (<0.1%)	0	0	
Rash maculo-papular	斑状丘疹状皮疹	0	0	0		1 (<0.1%)	0	0	
Rash morbilliform	麻疹様発疹	0	1 (<0.1%)	0		0	0	0	

表 2.7.4.7-8 重症度別の治験薬との因果関係が否定できない TEAE（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}		Rivaroxaban				Enoxaparin/VKA			
		MILD N=2412 (100%)	MODERATE N=2412 (100%)	SEVERE N=2412 (100%)	missing	MILD N=2405 (100%)	MODERATE N=2405 (100%)	SEVERE N=2405 (100%)	missing
Rash papular	丘疹性皮疹	2 (<0.1%)	0	0		0	0	1 (<0.1%)	
Rash pruritic	そう痒性皮疹	0	0	0		2 (<0.1%)	0	0	
Skin disorder	皮膚障害	1 (<0.1%)	0	0		0	0	0	
Skin fissures	皮膚亀裂	0	0	0		1 (<0.1%)	0	0	
Skin haemorrhage	皮膚出血	4 (0.2%)	1 (<0.1%)	0		3 (0.1%)	2 (<0.1%)	0	
Skin necrosis	皮膚壊死	0	0	0		1 (<0.1%)	0	0	
Skin ulcer	皮膚潰瘍	1 (<0.1%)	0	0		0	0	0	
Skin warm	皮膚熱感	1 (<0.1%)	0	0		0	0	0	
Swelling face	顔面腫脹	0	0	0		1 (<0.1%)	0	0	
Telangiectasia	毛細血管拡張症	0	0	0		1 (<0.1%)	0	0	
Urticaria	蕁麻疹	0	2 (<0.1%)	0		1 (<0.1%)	0	0	
Social circumstances	社会環境	0	0	1 (<0.1%)		0	0	0	
Miscarriage of partner	パートナーの自然流産	0	0	1 (<0.1%)		0	0	0	
Vascular disorders	血管障害	35 (1.5%)	11 (0.5%)	3 (0.1%)		63 (2.6%)	10 (0.4%)	4 (0.2%)	
Collateral circulation	側副血行	1 (<0.1%)	0	0		1 (<0.1%)	0	0	
Flushing	潮紅	0	0	0		1 (<0.1%)	0	0	
Haematoma	血腫	27 (1.1%)	8 (0.3%)	2 (<0.1%)		57 (2.4%)	8 (0.3%)	3 (0.1%)	
Hot flush	ほてり	1 (<0.1%)	1 (<0.1%)	0		2 (<0.1%)	0	0	
Hypertension	高血圧	5 (0.2%)	2 (<0.1%)	0		0	2 (<0.1%)	0	
Intra-abdominal haematoma	腹腔内血腫	0	0	0		1 (<0.1%)	0	1 (<0.1%)	
Intra-abdominal haemorrhage	腹腔内出血	0	0	1 (<0.1%)		0	0	0	
Peripheral coldness	末梢冷感	0	0	0		1 (<0.1%)	0	0	
Vasoconstriction	血管収縮	1 (<0.1%)	0	0		0	0	0	

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Only the most severe intensity is counted for multiple occurrences of the same AE in each subject.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-3-4.sas erjli 21MAR2013 10:12
End of table

表 2.7.4.7-9 重症度別の治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Number of subjects (%) with at least one adverse event		51 (8.6%)	9 (1.5%)	3 (0.5%)		70 (11.7%)	21 (3.5%)	7 (1.2%)	
Blood and lymphatic system disorders	血液およびリンパ系障害	0	0	0		0	1 (0.2%)	0	
Anaemia	貧血	0	0	0		0	1 (0.2%)	0	
Ear and labyrinth disorders	耳および迷路障害	1 (0.2%)	0	0		0	0	0	
Ear haemorrhage	耳出血	1 (0.2%)	0	0		0	0	0	
Eye disorders	眼障害	0	0	0		4 (0.7%)	0	0	
Cataract	白内障	0	0	0		1 (0.2%)	0	0	
Conjunctival haemorrhage	結膜出血	0	0	0		2 (0.3%)	0	0	
Ocular hyperaemia	眼充血	0	0	0		1 (0.2%)	0	0	
Gastrointestinal disorders	胃腸障害	10 (1.7%)	2 (0.3%)	0		18 (3.0%)	4 (0.7%)	1 (0.2%)	
Abdominal discomfort	腹部不快感	1 (0.2%)	0	0		1 (0.2%)	0	0	
Abdominal pain	腹痛	0	1 (0.2%)	0		0	0	0	
Abdominal pain upper	上腹部痛	0	0	0		3 (0.5%)	1 (0.2%)	0	
Diarrhoea	下痢	1 (0.2%)	0	0		0	0	0	
Dry mouth	口内乾燥	1 (0.2%)	0	0		0	0	0	
Dyspepsia	消化不良	1 (0.2%)	0	0		0	0	0	
Gastritis	胃炎	1 (0.2%)	0	0		1 (0.2%)	0	0	
Gastritis haemorrhagic	出血性胃炎	0	0	0		1 (0.2%)	0	0	
Gastrointestinal haemorrhage	胃腸出血	0	0	0		0	1 (0.2%)	1 (0.2%)	
Gingival bleeding	歯肉出血	2 (0.3%)	0	0		7 (1.2%)	0	0	
Haematochezia	血便排泄	1 (0.2%)	0	0		0	0	0	
Haemorrhoidal haemorrhage	痔出血	0	0	0		0	1 (0.2%)	0	
Intra-abdominal haematoma	腹腔内血腫	1 (0.2%)	0	0		0	0	0	
Lip haematoma	口唇血腫	0	0	0		1 (0.2%)	0	0	
Melaena	メレナ	0	0	0		1 (0.2%)	0	0	
Mouth haemorrhage	口腔内出血	0	0	0		1 (0.2%)	0	0	
Nausea	悪心	2 (0.3%)	0	0		0	0	0	
Rectal haemorrhage	直腸出血	0	1 (0.2%)	0		2 (0.3%)	1 (0.2%)	0	
Vomiting	嘔吐	1 (0.2%)	0	0		0	0	0	
General disorders and administration site conditions	一般・全身障害および投与部位の状態	2 (0.3%)	2 (0.3%)	0		7 (1.2%)	0	0	

表 2.7.4.7-9 重症度別の治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Chest pain	胸痛	0	1 (0.2%)	0		3 (0.5%)	0	0	
Fatigue	疲労	0	0	0		3 (0.5%)	0	0	
Oedema peripheral	末梢性浮腫	0	1 (0.2%)	0		1 (0.2%)	0	0	
Pyrexia	発熱	1 (0.2%)	0	0		0	0	0	
Thirst	口渇	1 (0.2%)	0	0		0	0	0	
Immune system disorders	免疫系障害	0	0	0		1 (0.2%)	0	0	
Drug hypersensitivity	薬物過敏症	0	0	0		1 (0.2%)	0	0	
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	11 (1.9%)	1 (0.2%)	0		10 (1.7%)	1 (0.2%)	0	
Anaemia postoperative	術後貧血	0	0	0		1 (0.2%)	0	0	
Contusion	挫傷	5 (0.8%)	1 (0.2%)	0		9 (1.5%)	0	0	
Eye injury	眼外傷	1 (0.2%)	0	0		0	0	0	
Periorbital haematoma	眼窩周囲血腫	1 (0.2%)	0	0		0	0	0	
Post procedural haematoma	処置後血腫	1 (0.2%)	0	0		0	0	0	
Post procedural haemorrhage	処置後出血	0	0	0		1 (0.2%)	1 (0.2%)	0	
Subcutaneous haematoma	皮下血腫	2 (0.3%)	0	0		0	0	0	
Traumatic haemorrhage	外傷性出血	0	0	0		1 (0.2%)	0	0	
Wound secretion	創部分泌	1 (0.2%)	0	0		0	0	0	
Investigations	臨床検査	4 (0.7%)	0	0		7 (1.2%)	3 (0.5%)	1 (0.2%)	
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	1 (0.2%)	0	0		2 (0.3%)	0	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	0	0	0		3 (0.5%)	0	0	
Bilirubin conjugated increased	抱合ビリルビン増加	1 (0.2%)	0	0		1 (0.2%)	0	0	
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0	0	0		0	1 (0.2%)	0	
Blood amylase increased	血中アミラーゼ増加	0	0	0		1 (0.2%)	0	0	
Blood bilirubin increased	血中ビリルビン増加	1 (0.2%)	0	0		1 (0.2%)	0	0	
Blood urine present	尿中血陽性	0	0	0		1 (0.2%)	0	0	
Haemoglobin decreased	ヘモグロビン減少	0	0	0		0	1 (0.2%)	0	
Hepatic enzyme increased	肝酵素上昇	0	0	0		1 (0.2%)	0	0	
Liver function test abnormal	肝機能検査異常	2 (0.3%)	0	0		1 (0.2%)	1 (0.2%)	1 (0.2%)	

表 2.7.4.7-9 重症度別の治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Protein S decreased	プロテインＳ減少	0	0	0		1 (0.2%)	0	0	
Prothrombin time prolonged	プロトロンビン時間延長	0	0	0		1 (0.2%)	0	0	
Metabolism and nutrition disorders	代謝および栄養障害	1 (0.2%)	0	0		0	0	0	
Gout	痛風	1 (0.2%)	0	0		0	0	0	
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	6 (1.0%)	2 (0.3%)	0		5 (0.8%)	1 (0.2%)	0	
Muscle spasms	筋痙縮	1 (0.2%)	0	0		2 (0.3%)	0	0	
Musculoskeletal pain	筋骨格痛	0	0	0		0	1 (0.2%)	0	
Osteoarthritis	骨関節炎	0	0	0		1 (0.2%)	0	0	
Pain in extremity	四肢痛	6 (1.0%)	2 (0.3%)	0		2 (0.3%)	0	0	
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）	2 (0.3%)	0	0		0	0	0	
Benign vascular neoplasm	血管の良性新生物	1 (0.2%)	0	0		0	0	0	
Naevus haemorrhage	母斑出血	1 (0.2%)	0	0		0	0	0	
Nervous system disorders	神経系障害	4 (0.7%)	0	1 (0.2%)		4 (0.7%)	3 (0.5%)	0	
Dizziness	浮動性めまい	2 (0.3%)	0	0		0	1 (0.2%)	0	
Dysgeusia	味覚異常	2 (0.3%)	0	0		0	0	0	
Haemorrhage intracranial	頭蓋内出血	0	0	1 (0.2%)		0	0	0	
Headache	頭痛	0	0	0		3 (0.5%)	2 (0.3%)	0	
Hypoaesthesia	感覚鈍麻	0	0	0		1 (0.2%)	0	0	
Somnolence	傾眠	0	0	0		1 (0.2%)	0	0	
Renal and urinary disorders	腎および尿路障害	2 (0.3%)	0	0		7 (1.2%)	1 (0.2%)	2 (0.3%)	
Cystitis haemorrhagic	出血性膀胱炎	0	0	0		0	1 (0.2%)	0	
Haematuria	血尿	1 (0.2%)	0	0		7 (1.2%)	1 (0.2%)	2 (0.3%)	
Pollakiuria	頻尿	1 (0.2%)	0	0		0	0	0	
Reproductive system and breast disorders	生殖系および乳房障害	5 (0.8%)	0	0		2 (0.3%)	4 (0.7%)	1 (0.2%)	
Menometrorrhagia	機能性子宮出血	0	0	0		0	0	1 (0.2%)	
Menorrhagia	月経過多	2 (0.3%)	0	0		1 (0.2%)	4 (0.7%)	0	
Metrorrhagia	不正子宮出血	0	0	0		1 (0.2%)	1 (0.2%)	0	
Postmenopausal haemorrhage	閉経後出血	1 (0.2%)	0	0		0	0	0	
Vaginal haemorrhage	膣出血	2 (0.3%)	0	0		0	1 (0.2%)	0	

表 2.7.4.7-9 重症度別の治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	14 (2.4%)	0	1 (0.2%)		19 (3.2%)	2 (0.3%)	0	
Cough	咳嗽	2 (0.3%)	0	0		2 (0.3%)	0	0	
Dyspnoea exertional	労作性呼吸困難	2 (0.3%)	0	0		1 (0.2%)	0	0	
Epistaxis	鼻出血	9 (1.5%)	0	0		15 (2.5%)	2 (0.3%)	0	
Haemoptysis	喀血	1 (0.2%)	0	0		1 (0.2%)	0	0	
Oropharyngeal pain	口腔咽頭痛	1 (0.2%)	0	0		0	0	0	
Pulmonary embolism	肺塞栓症	0	0	1 (0.2%)		0	0	0	
Tachypnoea	頻呼吸	0	0	0		1 (0.2%)	0	0	
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	5 (0.8%)	1 (0.2%)	0		7 (1.2%)	1 (0.2%)	1 (0.2%)	
Acne	ざ瘡	0	0	0		3 (0.5%)	0	1 (0.2%)	
Alopecia	脱毛症	1 (0.2%)	0	0		1 (0.2%)	0	0	
Dermatitis allergic	アレルギー性皮膚炎	1 (0.2%)	0	0		0	0	0	
Dry skin	皮膚乾燥	0	0	0		1 (0.2%)	0	0	
Ecchymosis	斑状出血	1 (0.2%)	0	0		1 (0.2%)	0	0	
Erythema	紅斑	1 (0.2%)	0	0		0	0	0	
Onychoclasis	爪破損	1 (0.2%)	0	0		0	0	0	
Petechiae	点状出血	0	0	0		1 (0.2%)	0	0	
Plantar erythema	足底紅斑	1 (0.2%)	0	0		0	0	0	
Rash	発疹	0	0	0		1 (0.2%)	0	0	
Skin lesion	皮膚病変	1 (0.2%)	0	0		0	0	0	
Skin ulcer	皮膚潰瘍	0	1 (0.2%)	0		0	0	0	
Urticaria	蕁麻疹	0	0	0		0	1 (0.2%)	0	
Vascular disorders	血管障害	8 (1.4%)	1 (0.2%)	1 (0.2%)		9 (1.5%)	2 (0.3%)	1 (0.2%)	
Bleeding varicose vein	出血性静脈瘤	0	0	0		1 (0.2%)	0	0	
Circulatory collapse	循環虚脱	0	0	0		0	0	1 (0.2%)	
Flushing	潮紅	1 (0.2%)	0	0		0	0	0	
Haematoma	血腫	3 (0.5%)	1 (0.2%)	0		5 (0.8%)	1 (0.2%)	0	
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	0	0	1 (0.2%)		0	0	0	
Thrombophlebitis	血栓性静脈炎	1 (0.2%)	0	0		0	0	0	
Thrombophlebitis superficial	表在性血栓性静脈炎	1 (0.2%)	0	0		0	0	0	

表 2.7.4.7-9 重症度別の治験薬との因果関係が否定できない TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{12.0}		Placebo				BAY 59-7939			
		MILD N=590 (100%)	MODERATE N=590 (100%)	SEVERE N=590 (100%)	missing	MILD N=598 (100%)	MODERATE N=598 (100%)	SEVERE N=598 (100%)	missing
Vascular rupture	血管破裂	0	0	0		1 (0.2%)	0	0	
Vein disorder	静脈障害	0	0	0		1 (0.2%)	0	0	
Wound haemorrhage	創傷出血	2 (0.3%)	0	0		1 (0.2%)	1 (0.2%)	0	

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Only the most severe intensity is counted for multiple occurrences of the same AE in each subject.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-3-4.sas erjli 21MAR2013 10:13
End of table

表 2.7.4.7-10　全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		1718 (100%)	1718 (100%)	1649 (100%)	1620 (100%)	1718 (100%)	1599 (100%)	1252 (100%)	328 (100%)
Gastrointestinal disorders	胃腸障害	183 (10.7%)	116 (6.8%)	31 (1.9%)	15 (0.9%)	158 (9.2%)	24 (1.5%)	5 (0.4%)	3 (0.9%)
Constipation	便秘	45 (2.6%)	32 (1.9%)	4 (0.2%)	4 (0.2%)	40 (2.3%)	2 (0.1%)	1 (<0.1%)	2 (0.6%)
Diarrhoea	下痢	51 (3.0%)	27 (1.6%)	11 (0.7%)	5 (0.3%)	43 (2.5%)	7 (0.4%)	1 (<0.1%)	
Gingival bleeding	歯肉出血	36 (2.1%)	17 (1.0%)	8 (0.5%)	2 (0.1%)	27 (1.6%)	5 (0.3%)	3 (0.2%)	1 (0.3%)
Nausea	悪心	45 (2.6%)	33 (1.9%)	5 (0.3%)	1 (<0.1%)	39 (2.3%)	6 (0.4%)		
Rectal haemorrhage	直腸出血	36 (2.1%)	21 (1.2%)	5 (0.3%)	5 (0.3%)	31 (1.8%)	5 (0.3%)		
General disorders and administration site conditions	一般・全身障害および投与部位の状態	78 (4.5%)	28 (1.6%)	13 (0.8%)	8 (0.5%)	49 (2.9%)	24 (1.5%)	3 (0.2%)	3 (0.9%)
Oedema peripheral	末梢性浮腫	40 (2.3%)	9 (0.5%)	8 (0.5%)	6 (0.4%)	23 (1.3%)	13 (0.8%)	2 (0.2%)	2 (0.6%)
Pyrexia	発熱	40 (2.3%)	20 (1.2%)	5 (0.3%)	2 (0.1%)	27 (1.6%)	11 (0.7%)	1 (<0.1%)	1 (0.3%)
Infections and infestations	感染症および寄生虫症	149 (8.7%)	47 (2.7%)	37 (2.2%)	22 (1.4%)	105 (6.1%)	35 (2.2%)	8 (0.6%)	6 (1.8%)
Influenza	インフルエンザ	36 (2.1%)	9 (0.5%)	8 (0.5%)	5 (0.3%)	22 (1.3%)	9 (0.6%)	3 (0.2%)	2 (0.6%)
Nasopharyngitis	鼻咽頭炎	84 (4.9%)	23 (1.3%)	18 (1.1%)	15 (0.9%)	56 (3.3%)	22 (1.4%)	4 (0.3%)	2 (0.6%)
Urinary tract infection	尿路感染	36 (2.1%)	15 (0.9%)	11 (0.7%)	2 (0.1%)	28 (1.6%)	5 (0.3%)	1 (<0.1%)	2 (0.6%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	53 (3.1%)	20 (1.2%)	12 (0.7%)	7 (0.4%)	39 (2.3%)	8 (0.5%)	6 (0.5%)	
Contusion	挫傷	53 (3.1%)	20 (1.2%)	12 (0.7%)	7 (0.4%)	39 (2.3%)	8 (0.5%)	6 (0.5%)	
Investigations	臨床検査	21 (1.2%)	9 (0.5%)	4 (0.2%)	1 (<0.1%)	14 (0.8%)	3 (0.2%)	3 (0.2%)	1 (0.3%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	20 (1.2%)	8 (0.5%)	4 (0.2%)	1 (<0.1%)	13 (0.8%)	3 (0.2%)	3 (0.2%)	1 (0.3%)
International normalised ratio increased	ＩＮＲ増加	1 (<0.1%)	1 (<0.1%)			1 (<0.1%)			
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	136 (7.9%)	54 (3.1%)	27 (1.6%)	12 (0.7%)	90 (5.2%)	38 (2.4%)	10 (0.8%)	4 (1.2%)
Arthralgia	関節痛	37 (2.2%)	13 (0.8%)	7 (0.4%)	4 (0.2%)	24 (1.4%)	8 (0.5%)	4 (0.3%)	1 (0.3%)
Back pain	背部痛	47 (2.7%)	15 (0.9%)	9 (0.5%)	3 (0.2%)	27 (1.6%)	13 (0.8%)	5 (0.4%)	2 (0.6%)
Pain in extremity	四肢痛	66 (3.8%)	30 (1.7%)	11 (0.7%)	5 (0.3%)	46 (2.7%)	18 (1.1%)	1 (<0.1%)	1 (0.3%)
Nervous system disorders	神経系障害	111 (6.5%)	65 (3.8%)	12 (0.7%)	10 (0.6%)	85 (4.9%)	21 (1.3%)	6 (0.5%)	1 (0.3%)
Dizziness	浮動性めまい	35 (2.0%)	24 (1.4%)	2 (0.1%)	2 (0.1%)	28 (1.6%)	6 (0.4%)	1 (<0.1%)	

表 2.7.4.7-10 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Headache	頭痛	82 (4.8%)	42 (2.4%)	10 (0.6%)	8 (0.5%)	60 (3.5%)	16 (1.0%)	5 (0.4%)	1 (0.3%)
Renal and urinary disorders	腎および尿路障害	38 (2.2%)	25 (1.5%)	4 (0.2%)	3 (0.2%)	32 (1.9%)	3 (0.2%)	1 (<0.1%)	2 (0.6%)
Haematuria	血尿	38 (2.2%)	25 (1.5%)	4 (0.2%)	3 (0.2%)	32 (1.9%)	3 (0.2%)	1 (<0.1%)	2 (0.6%)
Reproductive system and breast disorders	生殖系および乳房障害	49 (2.9%)	39 (2.3%)	3 (0.2%)	3 (0.2%)	45 (2.6%)	4 (0.3%)		
Menorrhagia	月経過多	49 (2.9%)	39 (2.3%)	3 (0.2%)	3 (0.2%)	45 (2.6%)	4 (0.3%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	147 (8.6%)	66 (3.8%)	27 (1.6%)	12 (0.7%)	105 (6.1%)	35 (2.2%)	7 (0.6%)	4 (1.2%)
Cough	咳嗽	65 (3.8%)	23 (1.3%)	12 (0.7%)	5 (0.3%)	40 (2.3%)	19 (1.2%)	5 (0.4%)	1 (0.3%)
Epistaxis	鼻出血	89 (5.2%)	44 (2.6%)	15 (0.9%)	7 (0.4%)	66 (3.8%)	18 (1.1%)	2 (0.2%)	3 (0.9%)
Vascular disorders	血管障害	69 (4.0%)	26 (1.5%)	6 (0.4%)	7 (0.4%)	39 (2.3%)	21 (1.3%)	7 (0.6%)	2 (0.6%)
Haematoma	血腫	37 (2.2%)	11 (0.6%)	3 (0.2%)	5 (0.3%)	19 (1.1%)	13 (0.8%)	4 (0.3%)	1 (0.3%)
Hypertension	高血圧	32 (1.9%)	15 (0.9%)	3 (0.2%)	2 (0.1%)	20 (1.2%)	8 (0.5%)	3 (0.2%)	1 (0.3%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:18

表 2.7.4.7-10　全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		1711 (100%)	1711 (100%)	1608 (100%)	1570 (100%)	1711 (100%)	1538 (100%)	1147 (100%)	317 (100%)
Gastrointestinal disorders	胃腸障害	149 (8.7%)	77 (4.5%)	28 (1.7%)	13 (0.8%)	114 (6.7%)	27 (1.8%)	10 (0.9%)	3 (0.9%)
Constipation	便秘	41 (2.4%)	29 (1.7%)	4 (0.2%)		33 (1.9%)	4 (0.3%)	3 (0.3%)	1 (0.3%)
Diarrhoea	下痢	38 (2.2%)	17 (1.0%)	9 (0.6%)	4 (0.3%)	30 (1.8%)	8 (0.5%)		
Gingival bleeding	歯肉出血	28 (1.6%)	5 (0.3%)	7 (0.4%)	4 (0.3%)	16 (0.9%)	7 (0.5%)	3 (0.3%)	2 (0.6%)
Nausea	悪心	37 (2.2%)	20 (1.2%)	5 (0.3%)	5 (0.3%)	30 (1.8%)	5 (0.3%)	2 (0.2%)	
Rectal haemorrhage	直腸出血	19 (1.1%)	8 (0.5%)	4 (0.2%)	1 (<0.1%)	13 (0.8%)	3 (0.2%)	3 (0.3%)	
General disorders and administration site conditions	一般・全身障害および投与部位の状態	71 (4.1%)	32 (1.9%)	13 (0.8%)	12 (0.8%)	55 (3.2%)	12 (0.8%)	2 (0.2%)	
Oedema peripheral	末梢性浮腫	35 (2.0%)	9 (0.5%)	9 (0.6%)	7 (0.4%)	25 (1.5%)	8 (0.5%)	2 (0.2%)	
Pyrexia	発熱	38 (2.2%)	23 (1.3%)	4 (0.2%)	5 (0.3%)	32 (1.9%)	4 (0.3%)		
Infections and infestations	感染症および寄生虫症	138 (8.1%)	40 (2.3%)	21 (1.3%)	18 (1.1%)	76 (4.4%)	40 (2.6%)	14 (1.2%)	9 (2.8%)
Influenza	インフルエンザ	36 (2.1%)	7 (0.4%)	7 (0.4%)	5 (0.3%)	19 (1.1%)	9 (0.6%)	7 (0.6%)	1 (0.3%)
Nasopharyngitis	鼻咽頭炎	76 (4.4%)	22 (1.3%)	9 (0.6%)	8 (0.5%)	39 (2.3%)	24 (1.6%)	6 (0.5%)	7 (2.2%)
Urinary tract infection	尿路感染	32 (1.9%)	11 (0.6%)	5 (0.3%)	5 (0.3%)	21 (1.2%)	9 (0.6%)	1 (<0.1%)	1 (0.3%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	68 (4.0%)	42 (2.5%)	4 (0.2%)	4 (0.3%)	50 (2.9%)	14 (0.9%)	3 (0.3%)	
Contusion	挫傷	68 (4.0%)	42 (2.5%)	4 (0.2%)	4 (0.3%)	50 (2.9%)	14 (0.9%)	3 (0.3%)	
Investigations	臨床検査	88 (5.1%)	63 (3.7%)	3 (0.2%)	2 (0.1%)	68 (4.0%)	13 (0.8%)	5 (0.4%)	3 (0.9%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	52 (3.0%)	41 (2.4%)	2 (0.1%)		43 (2.5%)	5 (0.3%)	2 (0.2%)	2 (0.6%)
International normalised ratio increased	ＩＮＲ増加	37 (2.2%)	22 (1.3%)	1 (<0.1%)	2 (0.1%)	25 (1.5%)	8 (0.5%)	3 (0.3%)	1 (0.3%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	113 (6.6%)	48 (2.8%)	21 (1.3%)	14 (0.9%)	81 (4.7%)	31 (2.0%)	3 (0.3%)	2 (0.6%)
Arthralgia	関節痛	33 (1.9%)	11 (0.6%)	4 (0.2%)	3 (0.2%)	18 (1.1%)	12 (0.8%)	2 (0.2%)	1 (0.3%)
Back pain	背部痛	30 (1.8%)	12 (0.7%)	1 (<0.1%)	6 (0.4%)	19 (1.1%)	9 (0.6%)	1 (<0.1%)	
Pain in extremity	四肢痛	62 (3.6%)	26 (1.5%)	16 (1.0%)	7 (0.4%)	49 (2.9%)	12 (0.8%)		1 (0.3%)
Nervous system disorders	神経系障害	75 (4.4%)	40 (2.3%)	13 (0.8%)	9 (0.6%)	60 (3.5%)	13 (0.8%)	1 (<0.1%)	2 (0.6%)
Dizziness	浮動性めまい	19 (1.1%)	10 (0.6%)	2 (0.1%)	2 (0.1%)	14 (0.8%)	3 (0.2%)		2 (0.6%)

表 2.7.4.7-10　全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Headache	頭痛	63 (3.7%)	33 (1.9%)	11 (0.7%)	8 (0.5%)	52 (3.0%)	10 (0.7%)	1 (<0.1%)	
Renal and urinary disorders	腎および尿路障害	41 (2.4%)	19 (1.1%)	4 (0.2%)	6 (0.4%)	29 (1.7%)	6 (0.4%)	3 (0.3%)	3 (0.9%)
Haematuria	血尿	41 (2.4%)	19 (1.1%)	4 (0.2%)	6 (0.4%)	29 (1.7%)	6 (0.4%)	3 (0.3%)	3 (0.9%)
Reproductive system and breast disorders	生殖系および乳房障害	19 (1.1%)	7 (0.4%)		8 (0.5%)	15 (0.9%)	4 (0.3%)		
Menorrhagia	月経過多	19 (1.1%)	7 (0.4%)		8 (0.5%)	15 (0.9%)	4 (0.3%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	121 (7.1%)	50 (2.9%)	23 (1.4%)	7 (0.4%)	80 (4.7%)	33 (2.1%)	5 (0.4%)	3 (0.9%)
Cough	咳嗽	48 (2.8%)	24 (1.4%)	10 (0.6%)	2 (0.1%)	36 (2.1%)	9 (0.6%)	2 (0.2%)	1 (0.3%)
Epistaxis	鼻出血	74 (4.3%)	27 (1.6%)	13 (0.8%)	5 (0.3%)	45 (2.6%)	24 (1.6%)	3 (0.3%)	2 (0.6%)
Vascular disorders	血管障害	98 (5.7%)	45 (2.6%)	8 (0.5%)	11 (0.7%)	64 (3.7%)	23 (1.5%)	5 (0.4%)	6 (1.9%)
Haematoma	血腫	59 (3.4%)	33 (1.9%)	2 (0.1%)	7 (0.4%)	42 (2.5%)	11 (0.7%)	3 (0.3%)	3 (0.9%)
Hypertension	高血圧	39 (2.3%)	12 (0.7%)	6 (0.4%)	4 (0.3%)	22 (1.3%)	12 (0.8%)	2 (0.2%)	3 (0.9%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas　erjli　21MAR2013 10:18

表 2.7.4.7-10 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		207 (100%)	207 (100%)	198 (100%)	191 (100%)	207 (100%)	186 (100%)		
Gastrointestinal disorders	胃腸障害	18 (8.7%)	16 (7.7%)	2 (1.0%)		18 (8.7%)			
Diarrhoea	下痢	8 (3.9%)	6 (2.9%)	2 (1.0%)		8 (3.9%)			
Gingival bleeding	歯肉出血	3 (1.4%)	3 (1.4%)			3 (1.4%)			
Nausea	悪心	8 (3.9%)	8 (3.9%)			8 (3.9%)			
General disorders and administration site conditions	一般・全身障害および投与部位の状態	6 (2.9%)	5 (2.4%)		1 (0.5%)	6 (2.9%)			
Oedema peripheral	末梢性浮腫	2 (1.0%)	1 (0.5%)		1 (0.5%)	2 (1.0%)			
Pyrexia	発熱	4 (1.9%)	4 (1.9%)			4 (1.9%)			
Infections and infestations	感染症および寄生虫症	9 (4.3%)	3 (1.4%)	6 (3.0%)		9 (4.3%)			
Nasopharyngitis	鼻咽頭炎	6 (2.9%)	2 (1.0%)	4 (2.0%)		6 (2.9%)			
Urinary tract infection	尿路感染	3 (1.4%)	1 (0.5%)	2 (1.0%)		3 (1.4%)			
Investigations	臨床検査	1 (0.5%)		1 (0.5%)		1 (0.5%)			
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	1 (0.5%)		1 (0.5%)		1 (0.5%)			
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	8 (3.9%)	5 (2.4%)	1 (0.5%)	1 (0.5%)	7 (3.4%)	1 (0.5%)		
Pain in extremity	四肢痛	8 (3.9%)	5 (2.4%)	1 (0.5%)	1 (0.5%)	7 (3.4%)	1 (0.5%)		
Nervous system disorders	神経系障害	7 (3.4%)	5 (2.4%)	1 (0.5%)	1 (0.5%)	7 (3.4%)			
Headache	頭痛	7 (3.4%)	5 (2.4%)	1 (0.5%)	1 (0.5%)	7 (3.4%)			
Renal and urinary disorders	腎および尿路障害	6 (2.9%)	6 (2.9%)			6 (2.9%)			
Haematuria	血尿	6 (2.9%)	6 (2.9%)			6 (2.9%)			
Reproductive system and breast disorders	生殖系および乳房障害	6 (2.9%)	5 (2.4%)		1 (0.5%)	6 (2.9%)			
Menorrhagia	月経過多	6 (2.9%)	5 (2.4%)		1 (0.5%)	6 (2.9%)			
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	10 (4.8%)	8 (3.9%)	2 (1.0%)		10 (4.8%)			
Epistaxis	鼻出血	10 (4.8%)	8 (3.9%)	2 (1.0%)		10 (4.8%)			
Vascular disorders	血管障害	5 (2.4%)	3 (1.4%)		2 (1.0%)	5 (2.4%)			
Haematoma	血腫	5 (2.4%)	3 (1.4%)		2 (1.0%)	5 (2.4%)			

表 2.7.4.7-10 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{13.0}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:18

表 2.7.4.7-10 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		201 (100%)	201 (100%)	187 (100%)	183 (100%)	201 (100%)	171 (100%)		
Gastrointestinal disorders	胃腸障害	12 (6.0%)	6 (3.0%)	3 (1.6%)	3 (1.6%)	12 (6.0%)	1 (0.6%)		
Diarrhoea	下痢	1 (0.5%)	1 (0.5%)			1 (0.5%)			
Gingival bleeding	歯肉出血	7 (3.5%)	1 (0.5%)	3 (1.6%)	2 (1.1%)	6 (3.0%)	1 (0.6%)		
Nausea	悪心	5 (2.5%)	4 (2.0%)		1 (0.5%)	5 (2.5%)			
General disorders and administration site conditions	一般・全身障害および投与部位の状態	11 (5.5%)	4 (2.0%)	3 (1.6%)	2 (1.1%)	9 (4.5%)	1 (0.6%)		
Oedema peripheral	末梢性浮腫	5 (2.5%)	1 (0.5%)	2 (1.1%)	1 (0.5%)	4 (2.0%)	1 (0.6%)		
Pyrexia	発熱	6 (3.0%)	3 (1.5%)	1 (0.5%)	1 (0.5%)	5 (2.5%)			
Infections and infestations	感染症および寄生虫症	14 (7.0%)	9 (4.5%)	2 (1.1%)	3 (1.6%)	14 (7.0%)			
Nasopharyngitis	鼻咽頭炎	7 (3.5%)	3 (1.5%)	2 (1.1%)	2 (1.1%)	7 (3.5%)			
Urinary tract infection	尿路感染	7 (3.5%)	6 (3.0%)		1 (0.5%)	7 (3.5%)			
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	9 (4.5%)	8 (4.0%)			8 (4.0%)	1 (0.6%)		
Contusion	挫傷	9 (4.5%)	8 (4.0%)			8 (4.0%)	1 (0.6%)		
Investigations	臨床検査	14 (7.0%)	11 (5.5%)	2 (1.1%)		13 (6.5%)	1 (0.6%)		
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	9 (4.5%)	7 (3.5%)	1 (0.5%)		8 (4.0%)	1 (0.6%)		
Hepatic enzyme increased	肝酵素上昇	5 (2.5%)	4 (2.0%)	1 (0.5%)		5 (2.5%)			
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	8 (4.0%)	5 (2.5%)	2 (1.1%)	1 (0.5%)	8 (4.0%)			
Pain in extremity	四肢痛	8 (4.0%)	5 (2.5%)	2 (1.1%)	1 (0.5%)	8 (4.0%)			
Nervous system disorders	神経系障害	13 (6.5%)	8 (4.0%)	3 (1.6%)	1 (0.5%)	12 (6.0%)	1 (0.6%)		
Headache	頭痛	13 (6.5%)	8 (4.0%)	3 (1.6%)	1 (0.5%)	12 (6.0%)	1 (0.6%)		
Renal and urinary disorders	腎および尿路障害	4 (2.0%)	4 (2.0%)			4 (2.0%)			
Haematuria	血尿	4 (2.0%)	4 (2.0%)			4 (2.0%)			
Reproductive system and breast disorders	生殖系および乳房障害	4 (2.0%)	1 (0.5%)		3 (1.6%)	4 (2.0%)			
Menorrhagia	月経過多	4 (2.0%)	1 (0.5%)		3 (1.6%)	4 (2.0%)			

表 2.7.4.7-10 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	6 (3.0%)	2 (1.0%)	1 (0.5%)	2 (1.1%)	5 (2.5%)	1 (0.6%)		
Epistaxis	鼻出血	6 (3.0%)	2 (1.0%)	1 (0.5%)	2 (1.1%)	5 (2.5%)	1 (0.6%)		
Vascular disorders	血管障害	8 (4.0%)	7 (3.5%)	1 (0.5%)		8 (4.0%)			
Haematoma	血腫	8 (4.0%)	7 (3.5%)	1 (0.5%)		8 (4.0%)			

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:18

表 2.7.4.7-10 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		1074 (100%)	1074 (100%)	1024 (100%)	1007 (100%)	1074 (100%)	996 (100%)	852 (100%)	
Gastrointestinal disorders	胃腸障害	88 (8.2%)	53 (4.9%)	16 (1.6%)	10 (1.0%)	76 (7.1%)	15 (1.5%)		
Constipation	便秘	28 (2.6%)	21 (2.0%)	3 (0.3%)	2 (0.2%)	26 (2.4%)	2 (0.2%)		
Diarrhoea	下痢	25 (2.3%)	14 (1.3%)	5 (0.5%)	3 (0.3%)	22 (2.0%)	3 (0.3%)		
Nausea	悪心	23 (2.1%)	12 (1.1%)	5 (0.5%)	1 (<0.1%)	18 (1.7%)	5 (0.5%)		
Rectal haemorrhage	直腸出血	27 (2.5%)	14 (1.3%)	4 (0.4%)	4 (0.4%)	22 (2.0%)	5 (0.5%)		
General disorders and administration site conditions	一般・全身障害および投与部位の状態	69 (6.4%)	30 (2.8%)	12 (1.2%)	10 (1.0%)	52 (4.8%)	19 (1.9%)		
Chest pain	胸痛	24 (2.2%)	15 (1.4%)	1 (<0.1%)	4 (0.4%)	20 (1.9%)	4 (0.4%)		
Oedema peripheral	末梢性浮腫	27 (2.5%)	5 (0.5%)	8 (0.8%)	5 (0.5%)	18 (1.7%)	9 (0.9%)		
Pyrexia	発熱	21 (2.0%)	10 (0.9%)	3 (0.3%)	1 (<0.1%)	14 (1.3%)	7 (0.7%)		
Infections and infestations	感染症および寄生虫症	74 (6.9%)	25 (2.3%)	19 (1.9%)	10 (1.0%)	53 (4.9%)	20 (2.0%)	1 (0.1%)	
Nasopharyngitis	鼻咽頭炎	50 (4.7%)	13 (1.2%)	11 (1.1%)	9 (0.9%)	33 (3.1%)	16 (1.6%)	1 (0.1%)	
Urinary tract infection	尿路感染	25 (2.3%)	12 (1.1%)	8 (0.8%)	1 (<0.1%)	21 (2.0%)	4 (0.4%)		
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	38 (3.5%)	14 (1.3%)	10 (1.0%)	6 (0.6%)	30 (2.8%)	7 (0.7%)	1 (0.1%)	
Contusion	挫傷	38 (3.5%)	14 (1.3%)	10 (1.0%)	6 (0.6%)	30 (2.8%)	7 (0.7%)	1 (0.1%)	
Investigations	臨床検査	12 (1.1%)	6 (0.6%)	3 (0.3%)	1 (<0.1%)	10 (0.9%)	2 (0.2%)		
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	12 (1.1%)	6 (0.6%)	3 (0.3%)	1 (<0.1%)	10 (0.9%)	2 (0.2%)		
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	87 (8.1%)	35 (3.3%)	20 (2.0%)	10 (1.0%)	63 (5.9%)	27 (2.7%)	2 (0.2%)	
Arthralgia	関節痛	20 (1.9%)	7 (0.7%)	4 (0.4%)	3 (0.3%)	14 (1.3%)	6 (0.6%)		
Back pain	背部痛	34 (3.2%)	13 (1.2%)	7 (0.7%)	3 (0.3%)	23 (2.1%)	9 (0.9%)	2 (0.2%)	
Pain in extremity	四肢痛	43 (4.0%)	18 (1.7%)	9 (0.9%)	4 (0.4%)	31 (2.9%)	12 (1.2%)		
Nervous system disorders	神経系障害	60 (5.6%)	33 (3.1%)	8 (0.8%)	4 (0.4%)	45 (4.2%)	12 (1.2%)	3 (0.4%)	
Headache	頭痛	60 (5.6%)	33 (3.1%)	8 (0.8%)	4 (0.4%)	45 (4.2%)	12 (1.2%)	3 (0.4%)	
Renal and urinary disorders	腎および尿路障害	23 (2.1%)	17 (1.6%)	2 (0.2%)	2 (0.2%)	21 (2.0%)	2 (0.2%)		
Haematuria	血尿	23 (2.1%)	17 (1.6%)	2 (0.2%)	2 (0.2%)	21 (2.0%)	2 (0.2%)		

表 2.7.4.7-10 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Reproductive system and breast disorders	生殖系および乳房障害	34 (3.2%)	28 (2.6%)	2 (0.2%)	1 (<0.1%)	31 (2.9%)	3 (0.3%)		
Menorrhagia	月経過多	34 (3.2%)	28 (2.6%)	2 (0.2%)	1 (<0.1%)	31 (2.9%)	3 (0.3%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	107 (10.0%)	50 (4.7%)	22 (2.1%)	11 (1.1%)	81 (7.5%)	27 (2.7%)	2 (0.2%)	
Cough	咳嗽	43 (4.0%)	15 (1.4%)	9 (0.9%)	4 (0.4%)	28 (2.6%)	13 (1.3%)	2 (0.2%)	
Dyspnoea	呼吸困難	23 (2.1%)	14 (1.3%)	3 (0.3%)	3 (0.3%)	20 (1.9%)	3 (0.3%)		
Epistaxis	鼻出血	51 (4.7%)	24 (2.2%)	10 (1.0%)	4 (0.4%)	38 (3.5%)	13 (1.3%)		
Vascular disorders	血管障害	35 (3.3%)	15 (1.4%)	2 (0.2%)	3 (0.3%)	20 (1.9%)	14 (1.4%)	1 (0.1%)	
Haematoma	血腫	20 (1.9%)	8 (0.7%)	2 (0.2%)	2 (0.2%)	12 (1.1%)	8 (0.8%)		
Hypertension	高血圧	15 (1.4%)	7 (0.7%)		1 (<0.1%)	8 (0.7%)	6 (0.6%)	1 (0.1%)	

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:18

表 2.7.4.7-10 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		1079 (100%)	1079 (100%)	1011 (100%)	984 (100%)	1079 (100%)	968 (100%)	765 (100%)	
Gastrointestinal disorders	胃腸障害	83 (7.7%)	47 (4.4%)	18 (1.8%)	7 (0.7%)	69 (6.4%)	15 (1.5%)	2 (0.3%)	
Constipation	便秘	29 (2.7%)	23 (2.1%)	3 (0.3%)		26 (2.4%)	3 (0.3%)		
Diarrhoea	下痢	26 (2.4%)	9 (0.8%)	8 (0.8%)	4 (0.4%)	21 (1.9%)	5 (0.5%)		
Nausea	悪心	21 (1.9%)	10 (0.9%)	4 (0.4%)	3 (0.3%)	17 (1.6%)	4 (0.4%)		
Rectal haemorrhage	直腸出血	17 (1.6%)	7 (0.6%)	4 (0.4%)	1 (0.1%)	12 (1.1%)	3 (0.3%)	2 (0.3%)	
General disorders and administration site conditions	一般・全身障害および投与部位の状態	58 (5.4%)	30 (2.8%)	10 (1.0%)	7 (0.7%)	46 (4.3%)	12 (1.2%)		
Chest pain	胸痛	17 (1.6%)	9 (0.8%)	5 (0.5%)		14 (1.3%)	3 (0.3%)		
Oedema peripheral	末梢性浮腫	20 (1.9%)	8 (0.7%)	2 (0.2%)	4 (0.4%)	14 (1.3%)	6 (0.6%)		
Pyrexia	発熱	23 (2.1%)	13 (1.2%)	3 (0.3%)	3 (0.3%)	19 (1.8%)	3 (0.3%)		
Infections and infestations	感染症および寄生虫症	60 (5.6%)	18 (1.7%)	10 (1.0%)	7 (0.7%)	35 (3.2%)	25 (2.6%)		
Nasopharyngitis	鼻咽頭炎	43 (4.0%)	14 (1.3%)	6 (0.6%)	4 (0.4%)	24 (2.2%)	19 (2.0%)		
Urinary tract infection	尿路感染	17 (1.6%)	4 (0.4%)	4 (0.4%)	3 (0.3%)	11 (1.0%)	6 (0.6%)		
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	37 (3.4%)	26 (2.4%)	3 (0.3%)	1 (0.1%)	30 (2.8%)	7 (0.7%)		
Contusion	挫傷	37 (3.4%)	26 (2.4%)	3 (0.3%)	1 (0.1%)	30 (2.8%)	7 (0.7%)		
Investigations	臨床検査	27 (2.5%)	24 (2.2%)			24 (2.2%)	2 (0.2%)	1 (0.1%)	
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	27 (2.5%)	24 (2.2%)			24 (2.2%)	2 (0.2%)	1 (0.1%)	
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	76 (7.0%)	32 (3.0%)	14 (1.4%)	10 (1.0%)	54 (5.0%)	22 (2.3%)	1 (0.1%)	
Arthralgia	関節痛	24 (2.2%)	10 (0.9%)	3 (0.3%)	2 (0.2%)	15 (1.4%)	8 (0.8%)	1 (0.1%)	
Back pain	背部痛	19 (1.8%)	8 (0.7%)	1 (<0.1%)	5 (0.5%)	14 (1.3%)	5 (0.5%)		
Pain in extremity	四肢痛	39 (3.6%)	15 (1.4%)	10 (1.0%)	4 (0.4%)	29 (2.7%)	10 (1.0%)		
Nervous system disorders	神経系障害	36 (3.3%)	20 (1.9%)	5 (0.5%)	5 (0.5%)	30 (2.8%)	6 (0.6%)		
Headache	頭痛	36 (3.3%)	20 (1.9%)	5 (0.5%)	5 (0.5%)	30 (2.8%)	6 (0.6%)		
Renal and urinary disorders	腎および尿路障害	21 (1.9%)	10 (0.9%)	2 (0.2%)	4 (0.4%)	16 (1.5%)	5 (0.5%)		
Haematuria	血尿	21 (1.9%)	10 (0.9%)	2 (0.2%)	4 (0.4%)	16 (1.5%)	5 (0.5%)		

表 2.7.4.7-10 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Reproductive system and breast disorders	生殖系および乳房障害	9 (0.8%)	5 (0.5%)		2 (0.2%)	7 (0.6%)	2 (0.2%)		
Menorrhagia	月経過多	9 (0.8%)	5 (0.5%)		2 (0.2%)	7 (0.6%)	2 (0.2%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	94 (8.7%)	43 (4.0%)	23 (2.3%)	4 (0.4%)	70 (6.5%)	25 (2.6%)		
Cough	咳嗽	30 (2.8%)	12 (1.1%)	8 (0.8%)	2 (0.2%)	22 (2.0%)	8 (0.8%)		
Dyspnoea	呼吸困難	23 (2.1%)	15 (1.4%)	4 (0.4%)		19 (1.8%)	4 (0.4%)		
Epistaxis	鼻出血	45 (4.2%)	18 (1.7%)	11 (1.1%)	2 (0.2%)	31 (2.9%)	14 (1.4%)		
Vascular disorders	血管障害	63 (5.8%)	33 (3.1%)	3 (0.3%)	7 (0.7%)	43 (4.0%)	19 (2.0%)	1 (0.1%)	
Haematoma	血腫	41 (3.8%)	24 (2.2%)	1 (<0.1%)	5 (0.5%)	30 (2.8%)	10 (1.0%)	1 (0.1%)	
Hypertension	高血圧	22 (2.0%)	9 (0.8%)	2 (0.2%)	2 (0.2%)	13 (1.2%)	9 (0.9%)		

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:18

表 2.7.4.7-10 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		437 (100%)	437 (100%)	427 (100%)	422 (100%)	437 (100%)	417 (100%)	400 (100%)	328 (100%)
Blood and lymphatic system disorders	血液およびリンパ系障害	11 (2.5%)	5 (1.1%)	1 (0.2%)	1 (0.2%)	7 (1.6%)	2 (0.5%)	1 (0.3%)	1 (0.3%)
Anaemia	貧血	11 (2.5%)	5 (1.1%)	1 (0.2%)	1 (0.2%)	7 (1.6%)	2 (0.5%)	1 (0.3%)	1 (0.3%)
Gastrointestinal disorders	胃腸障害	50 (11.4%)	30 (6.9%)	8 (1.9%)	2 (0.5%)	39 (8.9%)	6 (1.4%)	5 (1.3%)	3 (0.9%)
Constipation	便秘	13 (3.0%)	8 (1.8%)	1 (0.2%)	1 (0.2%)	10 (2.3%)		1 (0.3%)	2 (0.6%)
Diarrhoea	下痢	18 (4.1%)	7 (1.6%)	4 (0.9%)	2 (0.5%)	13 (3.0%)	4 (1.0%)	1 (0.3%)	
Gingival bleeding	歯肉出血	12 (2.7%)	3 (0.7%)	3 (0.7%)		6 (1.4%)	2 (0.5%)	3 (0.8%)	1 (0.3%)
Nausea	悪心	14 (3.2%)	13 (3.0%)			13 (3.0%)	1 (0.2%)		
General disorders and administration site conditions	一般・全身障害および投与部位の状態	33 (7.6%)	9 (2.1%)	2 (0.5%)	2 (0.5%)	13 (3.0%)	10 (2.4%)	5 (1.3%)	5 (1.5%)
Chest pain	胸痛	8 (1.8%)	1 (0.2%)		1 (0.2%)	2 (0.5%)	2 (0.5%)	2 (0.5%)	2 (0.6%)
Oedema peripheral	末梢性浮腫	11 (2.5%)	3 (0.7%)			3 (0.7%)	4 (1.0%)	2 (0.5%)	2 (0.6%)
Pyrexia	発熱	15 (3.4%)	6 (1.4%)	2 (0.5%)	1 (0.2%)	9 (2.1%)	4 (1.0%)	1 (0.3%)	1 (0.3%)
Infections and infestations	感染症および寄生虫症	41 (9.4%)	12 (2.7%)	6 (1.4%)	6 (1.4%)	24 (5.5%)	8 (1.9%)	7 (1.8%)	5 (1.5%)
Bronchitis	気管支炎	4 (0.9%)	1 (0.2%)			1 (0.2%)		2 (0.5%)	1 (0.3%)
Influenza	インフルエンザ	12 (2.7%)	3 (0.7%)	3 (0.7%)		6 (1.4%)	2 (0.5%)	2 (0.5%)	2 (0.6%)
Nasopharyngitis	鼻咽頭炎	28 (6.4%)	8 (1.8%)	3 (0.7%)	6 (1.4%)	17 (3.9%)	6 (1.4%)	3 (0.8%)	2 (0.6%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	16 (3.7%)	6 (1.4%)	2 (0.5%)	1 (0.2%)	9 (2.1%)	3 (0.7%)	5 (1.3%)	
Contusion	挫傷	15 (3.4%)	6 (1.4%)	2 (0.5%)	1 (0.2%)	9 (2.1%)	1 (0.2%)	5 (1.3%)	
Wound haemorrhage	創傷出血	3 (0.7%)					2 (0.5%)	1 (0.3%)	
Investigations	臨床検査	7 (1.6%)	2 (0.5%)			2 (0.5%)	1 (0.2%)	3 (0.8%)	1 (0.3%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	7 (1.6%)	2 (0.5%)			2 (0.5%)	1 (0.2%)	3 (0.8%)	1 (0.3%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	37 (8.5%)	11 (2.5%)	4 (0.9%)	1 (0.2%)	16 (3.7%)	10 (2.4%)	8 (2.0%)	4 (1.2%)
Arthralgia	関節痛	15 (3.4%)	5 (1.1%)	2 (0.5%)	1 (0.2%)	8 (1.8%)	2 (0.5%)	4 (1.0%)	1 (0.3%)
Back pain	背部痛	10 (2.3%)		1 (0.2%)		1 (0.2%)	4 (1.0%)	3 (0.8%)	2 (0.6%)
Pain in extremity	四肢痛	15 (3.4%)	7 (1.6%)	1 (0.2%)		8 (1.8%)	5 (1.2%)	1 (0.3%)	1 (0.3%)

表 2.7.4.7-10 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Nervous system disorders	神経系障害	25 (5.7%)	11 (2.5%)	1 (0.2%)	4 (0.9%)	16 (3.7%)	8 (1.9%)	2 (0.5%)	1 (0.3%)
Dizziness	浮動性めまい	13 (3.0%)	8 (1.8%)		1 (0.2%)	9 (2.1%)	4 (1.0%)		
Headache	頭痛	15 (3.4%)	4 (0.9%)	1 (0.2%)	3 (0.7%)	8 (1.8%)	4 (1.0%)	2 (0.5%)	1 (0.3%)
Renal and urinary disorders	腎および尿路障害	9 (2.1%)	2 (0.5%)	2 (0.5%)	1 (0.2%)	5 (1.1%)	1 (0.2%)	1 (0.3%)	2 (0.6%)
Haematuria	血尿	9 (2.1%)	2 (0.5%)	2 (0.5%)	1 (0.2%)	5 (1.1%)	1 (0.2%)	1 (0.3%)	2 (0.6%)
Reproductive system and breast disorders	生殖系および乳房障害	9 (2.1%)	6 (1.4%)	1 (0.2%)	1 (0.2%)	8 (1.8%)	1 (0.2%)		
Menorrhagia	月経過多	9 (2.1%)	6 (1.4%)	1 (0.2%)	1 (0.2%)	8 (1.8%)	1 (0.2%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	45 (10.3%)	19 (4.3%)	5 (1.2%)	4 (0.9%)	28 (6.4%)	10 (2.4%)	5 (1.3%)	4 (1.2%)
Cough	咳嗽	20 (4.6%)	7 (1.6%)	2 (0.5%)	1 (0.2%)	10 (2.3%)	6 (1.4%)	3 (0.8%)	1 (0.3%)
Epistaxis	鼻出血	28 (6.4%)	12 (2.7%)	3 (0.7%)	3 (0.7%)	18 (4.1%)	5 (1.2%)	2 (0.5%)	3 (0.9%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	6 (1.4%)	5 (1.1%)			5 (1.1%)		1 (0.3%)	
Pruritus	そう痒症	6 (1.4%)	5 (1.1%)			5 (1.1%)		1 (0.3%)	
Vascular disorders	血管障害	27 (6.2%)	8 (1.8%)	2 (0.5%)	2 (0.5%)	12 (2.7%)	7 (1.7%)	6 (1.5%)	2 (0.6%)
Haematoma	血腫	12 (2.7%)		1 (0.2%)	1 (0.2%)	2 (0.5%)	5 (1.2%)	4 (1.0%)	1 (0.3%)
Hypertension	高血圧	15 (3.4%)	8 (1.8%)	1 (0.2%)	1 (0.2%)	10 (2.3%)	2 (0.5%)	2 (0.5%)	1 (0.3%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:18

表 2.7.4.7-10　全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		431 (100%)	431 (100%)	410 (100%)	403 (100%)	431 (100%)	399 (100%)	382 (100%)	317 (100%)
Blood and lymphatic system disorders	血液およびリンパ系障害	1 (0.2%)							1 (0.3%)
Anaemia	貧血	1 (0.2%)							1 (0.3%)
Gastrointestinal disorders	胃腸障害	38 (8.8%)	17 (3.9%)	4 (1.0%)	2 (0.5%)	22 (5.1%)	7 (1.8%)	7 (1.8%)	3 (0.9%)
Constipation	便秘	8 (1.9%)	2 (0.5%)	1 (0.2%)		3 (0.7%)	1 (0.3%)	3 (0.8%)	1 (0.3%)
Diarrhoea	下痢	11 (2.6%)	7 (1.6%)	1 (0.2%)		8 (1.9%)	3 (0.8%)		
Gingival bleeding	歯肉出血	11 (2.6%)	2 (0.5%)	1 (0.2%)	1 (0.2%)	4 (0.9%)	2 (0.5%)	3 (0.8%)	2 (0.6%)
Nausea	悪心	11 (2.6%)	6 (1.4%)	1 (0.2%)	1 (0.2%)	8 (1.9%)	1 (0.3%)	2 (0.5%)	
General disorders and administration site conditions	一般・全身障害および投与部位の状態	27 (6.3%)	13 (3.0%)	5 (1.2%)	4 (1.0%)	21 (4.9%)	5 (1.3%)	2 (0.5%)	1 (0.3%)
Chest pain	胸痛	11 (2.6%)	6 (1.4%)		1 (0.2%)	7 (1.6%)	3 (0.8%)		1 (0.3%)
Oedema peripheral	末梢性浮腫	10 (2.3%)		5 (1.2%)	2 (0.5%)	7 (1.6%)	1 (0.3%)	2 (0.5%)	
Pyrexia	発熱	9 (2.1%)	7 (1.6%)		1 (0.2%)	8 (1.9%)	1 (0.3%)		
Infections and infestations	感染症および寄生虫症	47 (10.9%)	8 (1.9%)	5 (1.2%)	3 (0.7%)	16 (3.7%)	10 (2.5%)	13 (3.4%)	10 (3.2%)
Bronchitis	気管支炎	13 (3.0%)	2 (0.5%)	1 (0.2%)	1 (0.2%)	4 (0.9%)	3 (0.8%)	3 (0.8%)	2 (0.6%)
Influenza	インフルエンザ	12 (2.8%)	2 (0.5%)	3 (0.7%)		5 (1.2%)	2 (0.5%)	4 (1.0%)	1 (0.3%)
Nasopharyngitis	鼻咽頭炎	26 (6.0%)	5 (1.2%)	1 (0.2%)	2 (0.5%)	8 (1.9%)	5 (1.3%)	6 (1.6%)	7 (2.2%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	26 (6.0%)	11 (2.6%)	1 (0.2%)	4 (1.0%)	16 (3.7%)	8 (2.0%)	3 (0.8%)	1 (0.3%)
Contusion	挫傷	22 (5.1%)	8 (1.9%)	1 (0.2%)	3 (0.7%)	12 (2.8%)	6 (1.5%)	3 (0.8%)	
Wound haemorrhage	創傷出血	9 (2.1%)	4 (0.9%)		1 (0.2%)	5 (1.2%)	2 (0.5%)	1 (0.3%)	1 (0.3%)
Investigations	臨床検査	28 (6.5%)	18 (4.2%)	1 (0.2%)		19 (4.4%)	3 (0.8%)	4 (1.0%)	3 (0.9%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	16 (3.7%)	10 (2.3%)	1 (0.2%)		11 (2.6%)	2 (0.5%)	1 (0.3%)	2 (0.6%)
International normalised ratio increased	ＩＮＲ増加	13 (3.0%)	8 (1.9%)			8 (1.9%)	1 (0.3%)	3 (0.8%)	1 (0.3%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	26 (6.0%)	8 (1.9%)	5 (1.2%)	3 (0.7%)	16 (3.7%)	8 (2.0%)	2 (0.5%)	2 (0.6%)
Arthralgia	関節痛	7 (1.6%)		1 (0.2%)	1 (0.2%)	2 (0.5%)	3 (0.8%)	1 (0.3%)	1 (0.3%)

表 2.7.4.7-10 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Back pain	背部痛	9 (2.1%)	2 (0.5%)		1 (0.2%)	3 (0.7%)	4 (1.0%)	1 (0.3%)	
Pain in extremity	四肢痛	15 (3.5%)	6 (1.4%)	4 (1.0%)	2 (0.5%)	12 (2.8%)	2 (0.5%)		1 (0.3%)
Nervous system disorders	神経系障害	18 (4.2%)	8 (1.9%)	3 (0.7%)	2 (0.5%)	13 (3.0%)	3 (0.8%)	1 (0.3%)	2 (0.6%)
Dizziness	浮動性めまい	6 (1.4%)	4 (0.9%)			4 (0.9%)			2 (0.6%)
Headache	頭痛	14 (3.2%)	5 (1.2%)	3 (0.7%)	2 (0.5%)	10 (2.3%)	3 (0.8%)	1 (0.3%)	
Renal and urinary disorders	腎および尿路障害	16 (3.7%)	5 (1.2%)	2 (0.5%)	2 (0.5%)	9 (2.1%)	1 (0.3%)	3 (0.8%)	3 (0.9%)
Haematuria	血尿	16 (3.7%)	5 (1.2%)	2 (0.5%)	2 (0.5%)	9 (2.1%)	1 (0.3%)	3 (0.8%)	3 (0.9%)
Reproductive system and breast disorders	生殖系および乳房障害	6 (1.4%)	1 (0.2%)		3 (0.7%)	4 (0.9%)	2 (0.5%)		
Menorrhagia	月経過多	6 (1.4%)	1 (0.2%)		3 (0.7%)	4 (0.9%)	2 (0.5%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	37 (8.6%)	15 (3.5%)	3 (0.7%)	1 (0.2%)	19 (4.4%)	10 (2.5%)	5 (1.3%)	3 (0.9%)
Cough	咳嗽	14 (3.2%)	8 (1.9%)	2 (0.5%)		10 (2.3%)	1 (0.3%)	2 (0.5%)	1 (0.3%)
Epistaxis	鼻出血	23 (5.3%)	7 (1.6%)	1 (0.2%)	1 (0.2%)	9 (2.1%)	9 (2.3%)	3 (0.8%)	2 (0.6%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	10 (2.3%)	3 (0.7%)	4 (1.0%)		7 (1.6%)		1 (0.3%)	2 (0.6%)
Pruritus	そう痒症	10 (2.3%)	3 (0.7%)	4 (1.0%)		7 (1.6%)		1 (0.3%)	2 (0.6%)
Vascular disorders	血管障害	25 (5.8%)	5 (1.2%)	3 (0.7%)	4 (1.0%)	12 (2.8%)	3 (0.8%)	4 (1.0%)	6 (1.9%)
Haematoma	血腫	10 (2.3%)	2 (0.5%)		2 (0.5%)	4 (0.9%)	1 (0.3%)	2 (0.5%)	3 (0.9%)
Hypertension	高血圧	15 (3.5%)	3 (0.7%)	3 (0.7%)	2 (0.5%)	8 (1.9%)	2 (0.5%)	2 (0.5%)	3 (0.9%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:18
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表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		2412 (100%)	2412 (100%)	2289 (100%)	2258 (100%)	2412 (100%)	2241 (100%)	1885 (100%)	712 (100%)
Blood and lymphatic system disorders	血液およびリンパ系障害	52 (2.2%)	22 (0.9%)	5 (0.2%)	5 (0.2%)	32 (1.3%)	14 (0.6%)	3 (0.2%)	3 (0.4%)
Anaemia	貧血	52 (2.2%)	22 (0.9%)	5 (0.2%)	5 (0.2%)	32 (1.3%)	14 (0.6%)	3 (0.2%)	3 (0.4%)
Gastrointestinal disorders	胃腸障害	419 (17.4%)	287 (11.9%)	37 (1.6%)	26 (1.2%)	335 (13.9%)	69 (3.1%)	17 (0.9%)	14 (2.0%)
Constipation	便秘	132 (5.5%)	112 (4.6%)	4 (0.2%)	3 (0.1%)	119 (4.9%)	11 (0.5%)		1 (0.1%)
Diarrhoea	下痢	114 (4.7%)	69 (2.9%)	4 (0.2%)	7 (0.3%)	80 (3.3%)	20 (0.9%)	9 (0.5%)	5 (0.7%)
Gingival bleeding	歯肉出血	57 (2.4%)	36 (1.5%)	7 (0.3%)	2 (<0.1%)	45 (1.9%)	9 (0.4%)		3 (0.4%)
Nausea	悪心	102 (4.2%)	71 (2.9%)	8 (0.3%)	7 (0.3%)	86 (3.6%)	11 (0.5%)	3 (0.2%)	2 (0.3%)
Rectal haemorrhage	直腸出血	57 (2.4%)	22 (0.9%)	8 (0.3%)	3 (0.1%)	33 (1.4%)	19 (0.8%)	3 (0.2%)	2 (0.3%)
Vomiting	嘔吐	50 (2.1%)	28 (1.2%)	10 (0.4%)	4 (0.2%)	42 (1.7%)	3 (0.1%)	3 (0.2%)	2 (0.3%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	321 (13.3%)	142 (5.9%)	50 (2.2%)	31 (1.4%)	218 (9.0%)	82 (3.7%)	27 (1.4%)	12 (1.7%)
Chest pain	胸痛	164 (6.8%)	67 (2.8%)	24 (1.0%)	14 (0.6%)	105 (4.4%)	40 (1.8%)	12 (0.6%)	6 (0.8%)
Fatigue	疲労	53 (2.2%)	19 (0.8%)	5 (0.2%)	7 (0.3%)	31 (1.3%)	14 (0.6%)	4 (0.2%)	3 (0.4%)
Oedema peripheral	末梢性浮腫	77 (3.2%)	27 (1.1%)	15 (0.7%)	8 (0.4%)	50 (2.1%)	17 (0.8%)	9 (0.5%)	1 (0.1%)
Pyrexia	発熱	64 (2.7%)	33 (1.4%)	8 (0.3%)	4 (0.2%)	45 (1.9%)	13 (0.6%)	3 (0.2%)	3 (0.4%)
Infections and infestations	感染症および寄生虫症	389 (16.1%)	91 (3.8%)	61 (2.7%)	47 (2.1%)	198 (8.2%)	122 (5.4%)	45 (2.4%)	39 (5.5%)
Bronchitis	気管支炎	100 (4.1%)	26 (1.1%)	19 (0.8%)	9 (0.4%)	54 (2.2%)	30 (1.3%)	10 (0.5%)	6 (0.8%)
Influenza	インフルエンザ	56 (2.3%)	10 (0.4%)	6 (0.3%)	5 (0.2%)	21 (0.9%)	23 (1.0%)	6 (0.3%)	6 (0.8%)
Nasopharyngitis	鼻咽頭炎	168 (7.0%)	21 (0.9%)	23 (1.0%)	24 (1.1%)	68 (2.8%)	55 (2.5%)	23 (1.2%)	22 (3.1%)
Urinary tract infection	尿路感染	88 (3.6%)	35 (1.5%)	13 (0.6%)	9 (0.4%)	57 (2.4%)	19 (0.8%)	7 (0.4%)	5 (0.7%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	92 (3.8%)	29 (1.2%)	11 (0.5%)	14 (0.6%)	54 (2.2%)	22 (1.0%)	12 (0.6%)	4 (0.6%)
Contusion	挫傷	92 (3.8%)	29 (1.2%)	11 (0.5%)	14 (0.6%)	54 (2.2%)	22 (1.0%)	12 (0.6%)	4 (0.6%)
Investigations	臨床検査	57 (2.4%)	25 (1.0%)	4 (0.2%)	5 (0.2%)	34 (1.4%)	16 (0.7%)	5 (0.3%)	2 (0.3%)

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	51 (2.1%)	22 (0.9%)	3 (0.1%)	5 (0.2%)	30 (1.2%)	14 (0.6%)	5 (0.3%)	2 (0.3%)
International normalised ratio increased	ＩＮＲ増加	6 (0.2%)	3 (0.1%)	1 (<0.1%)		4 (0.2%)	2 (<0.1%)		
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	262 (10.9%)	91 (3.8%)	43 (1.9%)	26 (1.2%)	159 (6.6%)	66 (2.9%)	34 (1.8%)	16 (2.2%)
Arthralgia	関節痛	66 (2.7%)	14 (0.6%)	7 (0.3%)	11 (0.5%)	32 (1.3%)	19 (0.8%)	7 (0.4%)	8 (1.1%)
Back pain	背部痛	80 (3.3%)	27 (1.1%)	12 (0.5%)	5 (0.2%)	44 (1.8%)	24 (1.1%)	9 (0.5%)	3 (0.4%)
Pain in extremity	四肢痛	137 (5.7%)	52 (2.2%)	26 (1.1%)	10 (0.4%)	88 (3.6%)	24 (1.1%)	19 (1.0%)	5 (0.7%)
Nervous system disorders	神経系障害	218 (9.0%)	127 (5.3%)	23 (1.0%)	23 (1.0%)	169 (7.0%)	36 (1.6%)	9 (0.5%)	5 (0.7%)
Dizziness	浮動性めまい	56 (2.3%)	29 (1.2%)	8 (0.3%)	8 (0.4%)	45 (1.9%)	10 (0.4%)	1 (<0.1%)	
Headache	頭痛	176 (7.3%)	104 (4.3%)	16 (0.7%)	15 (0.7%)	135 (5.6%)	27 (1.2%)	8 (0.4%)	5 (0.7%)
Psychiatric disorders	精神障害	122 (5.1%)	76 (3.2%)	15 (0.7%)	7 (0.3%)	97 (4.0%)	21 (0.9%)	4 (0.2%)	1 (0.1%)
Anxiety	不安	72 (3.0%)	41 (1.7%)	10 (0.4%)	3 (0.1%)	54 (2.2%)	15 (0.7%)	3 (0.2%)	
Insomnia	不眠症	58 (2.4%)	38 (1.6%)	7 (0.3%)	4 (0.2%)	49 (2.0%)	6 (0.3%)	1 (<0.1%)	1 (0.1%)
Renal and urinary disorders	腎および尿路障害	72 (3.0%)	45 (1.9%)	9 (0.4%)	5 (0.2%)	59 (2.4%)	8 (0.4%)	2 (0.1%)	3 (0.4%)
Haematuria	血尿	72 (3.0%)	45 (1.9%)	9 (0.4%)	5 (0.2%)	59 (2.4%)	8 (0.4%)	2 (0.1%)	3 (0.4%)
Reproductive system and breast disorders	生殖系および乳房障害	72 (3.0%)	45 (1.9%)	11 (0.5%)	4 (0.2%)	60 (2.5%)	11 (0.5%)	1 (<0.1%)	
Menorrhagia	月経過多	72 (3.0%)	45 (1.9%)	11 (0.5%)	4 (0.2%)	60 (2.5%)	11 (0.5%)	1 (<0.1%)	
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	481 (19.9%)	243 (10.1%)	45 (2.0%)	54 (2.4%)	330 (13.7%)	120 (5.4%)	40 (2.1%)	22 (3.1%)
Cough	咳嗽	132 (5.5%)	55 (2.3%)	8 (0.3%)	21 (0.9%)	84 (3.5%)	36 (1.6%)	7 (0.4%)	5 (0.7%)
Dyspnoea	呼吸困難	146 (6.1%)	55 (2.3%)	17 (0.7%)	13 (0.6%)	85 (3.5%)	42 (1.9%)	17 (0.9%)	2 (0.3%)
Epistaxis	鼻出血	218 (9.0%)	114 (4.7%)	19 (0.8%)	16 (0.7%)	149 (6.2%)	42 (1.9%)	17 (0.9%)	10 (1.4%)
Haemoptysis	喀血	81 (3.4%)	47 (1.9%)	6 (0.3%)	7 (0.3%)	60 (2.5%)	12 (0.5%)	1 (<0.1%)	8 (1.1%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	64 (2.7%)	34 (1.4%)	8 (0.3%)	9 (0.4%)	51 (2.1%)	11 (0.5%)	2 (0.1%)	
Rash	発疹	64 (2.7%)	34 (1.4%)	8 (0.3%)	9 (0.4%)	51 (2.1%)	11 (0.5%)	2 (0.1%)	

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Vascular disorders	血管障害	160 (6.6%)	62 (2.6%)	16 (0.7%)	20 (0.9%)	98 (4.1%)	36 (1.6%)	13 (0.7%)	12 (1.7%)
Haematoma	血腫	57 (2.4%)	13 (0.5%)	5 (0.2%)	9 (0.4%)	27 (1.1%)	19 (0.8%)	3 (0.2%)	8 (1.1%)
Hypertension	高血圧	104 (4.3%)	49 (2.0%)	11 (0.5%)	11 (0.5%)	71 (2.9%)	17 (0.8%)	10 (0.5%)	4 (0.6%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:31

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		2405 (100%)	2405 (100%)	2289 (100%)	2244 (100%)	2405 (100%)	2215 (100%)	1798 (100%)	690 (100%)
Blood and lymphatic system disorders	血液およびリンパ系障害	35 (1.5%)	19 (0.8%)	4 (0.2%)	2 (<0.1%)	25 (1.0%)	5 (0.2%)	3 (0.2%)	2 (0.3%)
Anaemia	貧血	35 (1.5%)	19 (0.8%)	4 (0.2%)	2 (<0.1%)	25 (1.0%)	5 (0.2%)	3 (0.2%)	2 (0.3%)
Gastrointestinal disorders	胃腸障害	421 (17.5%)	286 (11.9%)	49 (2.1%)	38 (1.7%)	352 (14.6%)	55 (2.5%)	23 (1.3%)	17 (2.5%)
Constipation	便秘	131 (5.4%)	107 (4.4%)	7 (0.3%)	6 (0.3%)	120 (5.0%)	5 (0.2%)	3 (0.2%)	3 (0.4%)
Diarrhoea	下痢	119 (4.9%)	63 (2.6%)	10 (0.4%)	12 (0.5%)	85 (3.5%)	22 (1.0%)	8 (0.4%)	4 (0.6%)
Gingival bleeding	歯肉出血	76 (3.2%)	37 (1.5%)	13 (0.6%)	9 (0.4%)	59 (2.5%)	11 (0.5%)	3 (0.2%)	3 (0.4%)
Nausea	悪心	116 (4.8%)	77 (3.2%)	10 (0.4%)	12 (0.5%)	99 (4.1%)	14 (0.6%)	1 (<0.1%)	2 (0.3%)
Rectal haemorrhage	直腸出血	41 (1.7%)	20 (0.8%)	6 (0.3%)	4 (0.2%)	30 (1.2%)	6 (0.3%)	2 (0.1%)	3 (0.4%)
Vomiting	嘔吐	72 (3.0%)	36 (1.5%)	7 (0.3%)	3 (0.1%)	46 (1.9%)	11 (0.5%)	9 (0.5%)	6 (0.9%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	311 (12.9%)	154 (6.4%)	53 (2.3%)	27 (1.2%)	224 (9.3%)	70 (3.2%)	14 (0.8%)	20 (2.9%)
Chest pain	胸痛	168 (7.0%)	77 (3.2%)	27 (1.2%)	15 (0.7%)	119 (4.9%)	36 (1.6%)	5 (0.3%)	8 (1.2%)
Fatigue	疲労	43 (1.8%)	24 (1.0%)	6 (0.3%)	4 (0.2%)	34 (1.4%)	7 (0.3%)	1 (<0.1%)	
Oedema peripheral	末梢性浮腫	79 (3.3%)	23 (1.0%)	14 (0.6%)	8 (0.4%)	45 (1.9%)	21 (0.9%)	4 (0.2%)	8 (1.2%)
Pyrexia	発熱	68 (2.8%)	41 (1.7%)	6 (0.3%)	2 (<0.1%)	49 (2.0%)	11 (0.5%)	4 (0.2%)	4 (0.6%)
Infections and infestations	感染症および寄生虫症	363 (15.1%)	100 (4.2%)	52 (2.3%)	51 (2.3%)	197 (8.2%)	111 (5.0%)	38 (2.1%)	36 (5.2%)
Bronchitis	気管支炎	81 (3.4%)	18 (0.7%)	9 (0.4%)	16 (0.7%)	43 (1.8%)	21 (0.9%)	5 (0.3%)	12 (1.7%)
Influenza	インフルエンザ	46 (1.9%)	6 (0.2%)	7 (0.3%)	7 (0.3%)	20 (0.8%)	16 (0.7%)	7 (0.4%)	3 (0.4%)
Nasopharyngitis	鼻咽頭炎	177 (7.4%)	36 (1.5%)	29 (1.3%)	19 (0.8%)	84 (3.5%)	55 (2.5%)	19 (1.1%)	19 (2.8%)
Urinary tract infection	尿路感染	93 (3.9%)	41 (1.7%)	7 (0.3%)	11 (0.5%)	59 (2.5%)	21 (0.9%)	8 (0.4%)	5 (0.7%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	128 (5.3%)	71 (3.0%)	10 (0.4%)	7 (0.3%)	88 (3.7%)	28 (1.3%)	10 (0.6%)	1 (0.1%)
Contusion	挫傷	128 (5.3%)	71 (3.0%)	10 (0.4%)	7 (0.3%)	88 (3.7%)	28 (1.3%)	10 (0.6%)	1 (0.1%)
Investigations	臨床検査	153 (6.4%)	116 (4.8%)	5 (0.2%)	6 (0.3%)	127 (5.3%)	13 (0.6%)	10 (0.6%)	5 (0.7%)

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION Treatment Group: Enoxaparin/VKA									
Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	76 (3.2%)	63 (2.6%)	3 (0.1%)		66 (2.7%)	6 (0.3%)	1 (<0.1%)	3 (0.4%)
International normalised ratio increased	ＩＮＲ増加	82 (3.4%)	55 (2.3%)	2 (<0.1%)	6 (0.3%)	63 (2.6%)	8 (0.4%)	9 (0.5%)	2 (0.3%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	275 (11.4%)	113 (4.7%)	39 (1.7%)	27 (1.2%)	172 (7.2%)	83 (3.7%)	17 (0.9%)	19 (2.8%)
Arthralgia	関節痛	64 (2.7%)	21 (0.9%)	5 (0.2%)	6 (0.3%)	32 (1.3%)	23 (1.0%)	3 (0.2%)	6 (0.9%)
Back pain	背部痛	123 (5.1%)	48 (2.0%)	17 (0.7%)	11 (0.5%)	76 (3.2%)	30 (1.4%)	9 (0.5%)	7 (1.0%)
Pain in extremity	四肢痛	129 (5.4%)	53 (2.2%)	18 (0.8%)	11 (0.5%)	82 (3.4%)	35 (1.6%)	6 (0.3%)	6 (0.9%)
Nervous system disorders	神経系障害	220 (9.1%)	125 (5.2%)	22 (1.0%)	14 (0.6%)	159 (6.6%)	41 (1.9%)	15 (0.8%)	8 (1.2%)
Dizziness	浮動性めまい	78 (3.2%)	38 (1.6%)	9 (0.4%)	4 (0.2%)	51 (2.1%)	19 (0.9%)	5 (0.3%)	2 (0.3%)
Headache	頭痛	160 (6.7%)	96 (4.0%)	15 (0.7%)	10 (0.4%)	121 (5.0%)	23 (1.0%)	10 (0.6%)	6 (0.9%)
Psychiatric disorders	精神障害	126 (5.2%)	91 (3.8%)	14 (0.6%)	2 (<0.1%)	106 (4.4%)	15 (0.7%)	4 (0.2%)	4 (0.6%)
Anxiety	不安	65 (2.7%)	40 (1.7%)	10 (0.4%)	2 (<0.1%)	52 (2.2%)	7 (0.3%)	3 (0.2%)	3 (0.4%)
Insomnia	不眠症	68 (2.8%)	53 (2.2%)	4 (0.2%)		57 (2.4%)	9 (0.4%)	1 (<0.1%)	1 (0.1%)
Renal and urinary disorders	腎および尿路障害	71 (3.0%)	39 (1.6%)	3 (0.1%)	5 (0.2%)	47 (2.0%)	15 (0.7%)	5 (0.3%)	4 (0.6%)
Haematuria	血尿	71 (3.0%)	39 (1.6%)	3 (0.1%)	5 (0.2%)	47 (2.0%)	15 (0.7%)	5 (0.3%)	4 (0.6%)
Reproductive system and breast disorders	生殖系および乳房障害	45 (1.9%)	22 (0.9%)	10 (0.4%)	1 (<0.1%)	33 (1.4%)	8 (0.4%)	3 (0.2%)	1 (0.1%)
Menorrhagia	月経過多	45 (1.9%)	22 (0.9%)	10 (0.4%)	1 (<0.1%)	33 (1.4%)	8 (0.4%)	3 (0.2%)	1 (0.1%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	455 (18.9%)	246 (10.2%)	77 (3.4%)	41 (1.8%)	340 (14.1%)	85 (3.8%)	36 (2.0%)	17 (2.5%)
Cough	咳嗽	144 (6.0%)	77 (3.2%)	20 (0.9%)	9 (0.4%)	106 (4.4%)	25 (1.1%)	7 (0.4%)	6 (0.9%)
Dyspnoea	呼吸困難	122 (5.1%)	54 (2.2%)	24 (1.0%)	10 (0.4%)	88 (3.7%)	20 (0.9%)	12 (0.7%)	
Epistaxis	鼻出血	197 (8.2%)	85 (3.5%)	31 (1.4%)	19 (0.8%)	135 (5.6%)	39 (1.8%)	15 (0.8%)	8 (1.2%)
Haemoptysis	喀血	81 (3.4%)	55 (2.3%)	8 (0.3%)	5 (0.2%)	68 (2.8%)	7 (0.3%)	3 (0.2%)	3 (0.4%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	57 (2.4%)	33 (1.4%)	4 (0.2%)	8 (0.4%)	45 (1.9%)	12 (0.5%)		
Rash	発疹	57 (2.4%)	33 (1.4%)	4 (0.2%)	8 (0.4%)	45 (1.9%)	12 (0.5%)		

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Vascular disorders	血管障害	168 (7.0%)	75 (3.1%)	25 (1.1%)	14 (0.6%)	113 (4.7%)	35 (1.6%)	11 (0.6%)	10 (1.4%)
Haematoma	血腫	92 (3.8%)	44 (1.8%)	9 (0.4%)	6 (0.3%)	59 (2.5%)	18 (0.8%)	8 (0.4%)	7 (1.0%)
Hypertension	高血圧	80 (3.3%)	32 (1.3%)	16 (0.7%)	8 (0.4%)	56 (2.3%)	18 (0.8%)	3 (0.2%)	3 (0.4%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:31

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		125 (100%)	125 (100%)	113 (100%)	111 (100%)	125 (100%)	110 (100%)		
Gastrointestinal disorders	胃腸障害	21 (16.8%)	16 (12.8%)	3 (2.7%)	2 (1.8%)	20 (16.0%)	1 (0.9%)		
Abdominal pain	腹痛	3 (2.4%)	1 (0.8%)	1 (0.9%)	1 (0.9%)	3 (2.4%)			
Abdominal pain upper	上腹部痛	3 (2.4%)	2 (1.6%)	1 (0.9%)		3 (2.4%)			
Constipation	便秘	8 (6.4%)	8 (6.4%)			8 (6.4%)			
Diarrhoea	下痢	2 (1.6%)	2 (1.6%)			2 (1.6%)			
Nausea	悪心	5 (4.0%)	4 (3.2%)		1 (0.9%)	5 (4.0%)			
Vomiting	嘔吐	5 (4.0%)	3 (2.4%)	1 (0.9%)		4 (3.2%)	1 (0.9%)		
General disorders and administration site conditions	一般・全身障害および投与部位の状態	14 (11.2%)	11 (8.8%)	2 (1.8%)		12 (9.6%)	2 (1.8%)		
Chest pain	胸痛	7 (5.6%)	5 (4.0%)	1 (0.9%)		6 (4.8%)	1 (0.9%)		
Oedema peripheral	末梢性浮腫	3 (2.4%)	1 (0.8%)	1 (0.9%)		2 (1.6%)	1 (0.9%)		
Pyrexia	発熱	5 (4.0%)	5 (4.0%)			5 (4.0%)			
Hepatobiliary disorders	肝胆道系障害	3 (2.4%)	2 (1.6%)	1 (0.9%)		3 (2.4%)			
Cholelithiasis	胆石症	3 (2.4%)	2 (1.6%)	1 (0.9%)		3 (2.4%)			
Infections and infestations	感染症および寄生虫症	13 (10.4%)	9 (7.2%)	3 (2.7%)	1 (0.9%)	13 (10.4%)			
Bronchitis	気管支炎	4 (3.2%)	3 (2.4%)	1 (0.9%)		4 (3.2%)			
Nasopharyngitis	鼻咽頭炎	3 (2.4%)	1 (0.8%)	1 (0.9%)	1 (0.9%)	3 (2.4%)			
Upper respiratory tract infection	上気道感染	3 (2.4%)	3 (2.4%)			3 (2.4%)			
Urinary tract infection	尿路感染	3 (2.4%)	2 (1.6%)	1 (0.9%)		3 (2.4%)			
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	1 (0.8%)		1 (0.9%)		1 (0.8%)			
Contusion	挫傷	1 (0.8%)		1 (0.9%)		1 (0.8%)			
Investigations	臨床検査	3 (2.4%)	3 (2.4%)			3 (2.4%)			
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	3 (2.4%)	3 (2.4%)			3 (2.4%)			

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3 (2.4%)	3 (2.4%)			3 (2.4%)			
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	5 (4.0%)	1 (0.8%)	3 (2.7%)	1 (0.9%)	5 (4.0%)			
Pain in extremity	四肢痛	5 (4.0%)	1 (0.8%)	3 (2.7%)	1 (0.9%)	5 (4.0%)			
Nervous system disorders	神経系障害	6 (4.8%)	2 (1.6%)	1 (0.9%)	2 (1.8%)	5 (4.0%)	1 (0.9%)		
Dizziness	浮動性めまい	1 (0.8%)	1 (0.8%)			1 (0.8%)			
Headache	頭痛	5 (4.0%)	1 (0.8%)	1 (0.9%)	2 (1.8%)	4 (3.2%)	1 (0.9%)		
Psychiatric disorders	精神障害	8 (6.4%)	6 (4.8%)	1 (0.9%)	1 (0.9%)	8 (6.4%)			
Anxiety	不安	6 (4.8%)	5 (4.0%)	1 (0.9%)		6 (4.8%)			
Insomnia	不眠症	2 (1.6%)	1 (0.8%)		1 (0.9%)	2 (1.6%)			
Renal and urinary disorders	腎および尿路障害	4 (3.2%)	3 (2.4%)		1 (0.9%)	4 (3.2%)			
Haematuria	血尿	4 (3.2%)	3 (2.4%)		1 (0.9%)	4 (3.2%)			
Reproductive system and breast disorders	生殖系および乳房障害	3 (2.4%)	3 (2.4%)			3 (2.4%)			
Menorrhagia	月経過多	3 (2.4%)	3 (2.4%)			3 (2.4%)			
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	15 (12.0%)	11 (8.8%)	1 (0.9%)	2 (1.8%)	14 (11.2%)	1 (0.9%)		
Cough	咳嗽	7 (5.6%)	4 (3.2%)	1 (0.9%)	2 (1.8%)	7 (5.6%)			
Dyspnoea	呼吸困難	7 (5.6%)	6 (4.8%)			6 (4.8%)	1 (0.9%)		
Epistaxis	鼻出血	4 (3.2%)	4 (3.2%)			4 (3.2%)			
Vascular disorders	血管障害	2 (1.6%)	1 (0.8%)	1 (0.9%)		2 (1.6%)			
Hypertension	高血圧	2 (1.6%)	1 (0.8%)	1 (0.9%)		2 (1.6%)			

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:31

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS Treatment Group: Enoxaparin/VKA									
Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		122 (100%)	122 (100%)	115 (100%)	110 (100%)	122 (100%)	101 (100%)		
Gastrointestinal disorders	胃腸障害	18 (14.8%)	14 (11.5%)	3 (2.6%)	1 (0.9%)	17 (13.9%)	1 (1.0%)		
Abdominal pain upper	上腹部痛	1 (0.8%)	1 (0.8%)			1 (0.8%)			
Constipation	便秘	9 (7.4%)	8 (6.6%)	1 (0.9%)		9 (7.4%)			
Diarrhoea	下痢	4 (3.3%)	2 (1.6%)	2 (1.7%)		4 (3.3%)			
Haematochezia	血便排泄	3 (2.5%)	1 (0.8%)		1 (0.9%)	2 (1.6%)	1 (1.0%)		
Nausea	悪心	3 (2.5%)	3 (2.5%)			3 (2.5%)			
Vomiting	嘔吐	2 (1.6%)	1 (0.8%)	1 (0.9%)		2 (1.6%)			
General disorders and administration site conditions	一般・全身障害および投与部位の状態	16 (13.1%)	11 (9.0%)	3 (2.6%)	1 (0.9%)	15 (12.3%)	1 (1.0%)		
Chest pain	胸痛	10 (8.2%)	8 (6.6%)		1 (0.9%)	9 (7.4%)	1 (1.0%)		
Fatigue	疲労	4 (3.3%)	3 (2.5%)	1 (0.9%)		4 (3.3%)			
Oedema peripheral	末梢性浮腫	2 (1.6%)		2 (1.7%)		2 (1.6%)			
Pyrexia	発熱	3 (2.5%)	3 (2.5%)			3 (2.5%)			
Infections and infestations	感染症および寄生虫症	12 (9.8%)	6 (4.9%)	5 (4.3%)	2 (1.8%)	12 (9.8%)			
Bronchitis	気管支炎	3 (2.5%)	2 (1.6%)	1 (0.9%)		3 (2.5%)			
Nasopharyngitis	鼻咽頭炎	7 (5.7%)	2 (1.6%)	4 (3.5%)	1 (0.9%)	7 (5.7%)			
Upper respiratory tract infection	上気道感染	2 (1.6%)	2 (1.6%)			2 (1.6%)			
Urinary tract infection	尿路感染	1 (0.8%)			1 (0.9%)	1 (0.8%)			
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	4 (3.3%)	2 (1.6%)	2 (1.7%)		4 (3.3%)			
Contusion	挫傷	4 (3.3%)	2 (1.6%)	2 (1.7%)		4 (3.3%)			
Investigations	臨床検査	5 (4.1%)	5 (4.1%)			5 (4.1%)			
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	5 (4.1%)	5 (4.1%)			5 (4.1%)			

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1 (0.8%)	1 (0.8%)			1 (0.8%)			
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	2 (1.6%)	2 (1.6%)			2 (1.6%)			
Pain in extremity	四肢痛	2 (1.6%)	2 (1.6%)			2 (1.6%)			
Nervous system disorders	神経系障害	11 (9.0%)	9 (7.4%)	2 (1.7%)		10 (8.2%)			
Dizziness	浮動性めまい	3 (2.5%)	2 (1.6%)			2 (1.6%)			
Headache	頭痛	9 (7.4%)	7 (5.7%)	2 (1.7%)		9 (7.4%)			
Psychiatric disorders	精神障害	4 (3.3%)	4 (3.3%)			4 (3.3%)			
Insomnia	不眠症	4 (3.3%)	4 (3.3%)			4 (3.3%)			
Renal and urinary disorders	腎および尿路障害	4 (3.3%)	3 (2.5%)			3 (2.5%)	1 (1.0%)		
Haematuria	血尿	4 (3.3%)	3 (2.5%)			3 (2.5%)	1 (1.0%)		
Reproductive system and breast disorders	生殖系および乳房障害	4 (3.3%)	3 (2.5%)	1 (0.9%)		4 (3.3%)			
Menorrhagia	月経過多	4 (3.3%)	3 (2.5%)	1 (0.9%)		4 (3.3%)			
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	11 (9.0%)	4 (3.3%)	7 (6.1%)	1 (0.9%)	11 (9.0%)			
Cough	咳嗽	7 (5.7%)	2 (1.6%)	5 (4.3%)		7 (5.7%)			
Dyspnoea	呼吸困難	2 (1.6%)	1 (0.8%)	1 (0.9%)		2 (1.6%)			
Epistaxis	鼻出血	5 (4.1%)	2 (1.6%)	2 (1.7%)	1 (0.9%)	5 (4.1%)			
Vascular disorders	血管障害	4 (3.3%)	4 (3.3%)			4 (3.3%)			
Hypertension	高血圧	4 (3.3%)	4 (3.3%)			4 (3.3%)			

表 2.7.4.7-11　全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{14.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas　erjli　21MAR2013 10:31

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		1383 (100%)	1383 (100%)	1310 (100%)	1291 (100%)	1383 (100%)	1282 (100%)	1070 (100%)	
Cardiac disorders	心臓障害	29 (2.1%)	16 (1.2%)	4 (0.3%)	3 (0.2%)	23 (1.7%)	5 (0.4%)	1 (<0.1%)	
Tachycardia	頻脈	29 (2.1%)	16 (1.2%)	4 (0.3%)	3 (0.2%)	23 (1.7%)	5 (0.4%)	1 (<0.1%)	
Gastrointestinal disorders	胃腸障害	232 (16.8%)	164 (11.9%)	19 (1.5%)	20 (1.5%)	193 (14.0%)	45 (3.5%)	2 (0.2%)	
Constipation	便秘	74 (5.4%)	61 (4.4%)	3 (0.2%)	2 (0.2%)	66 (4.8%)	8 (0.6%)		
Diarrhoea	下痢	62 (4.5%)	42 (3.0%)	2 (0.2%)	5 (0.4%)	49 (3.5%)	12 (0.9%)	1 (<0.1%)	
Gingival bleeding	歯肉出血	27 (2.0%)	19 (1.4%)	1 (<0.1%)	1 (<0.1%)	21 (1.5%)	6 (0.5%)		
Nausea	悪心	60 (4.3%)	41 (3.0%)	6 (0.5%)	6 (0.5%)	53 (3.8%)	7 (0.5%)		
Rectal haemorrhage	直腸出血	37 (2.7%)	17 (1.2%)	5 (0.4%)	2 (0.2%)	24 (1.7%)	13 (1.0%)		
Vomiting	嘔吐	27 (2.0%)	15 (1.1%)	5 (0.4%)	4 (0.3%)	24 (1.7%)	2 (0.2%)	1 (<0.1%)	
General disorders and administration site conditions	一般・全身障害および投与部位の状態	182 (13.2%)	86 (6.2%)	36 (2.7%)	19 (1.5%)	138 (10.0%)	48 (3.7%)	5 (0.5%)	
Chest pain	胸痛	89 (6.4%)	43 (3.1%)	16 (1.2%)	6 (0.5%)	65 (4.7%)	21 (1.6%)	3 (0.3%)	
Fatigue	疲労	31 (2.2%)	13 (0.9%)	4 (0.3%)	6 (0.5%)	23 (1.7%)	6 (0.5%)	1 (<0.1%)	
Oedema peripheral	末梢性浮腫	45 (3.3%)	15 (1.1%)	12 (0.9%)	6 (0.5%)	33 (2.4%)	11 (0.9%)	1 (<0.1%)	
Pyrexia	発熱	38 (2.7%)	18 (1.3%)	6 (0.5%)	3 (0.2%)	27 (2.0%)	11 (0.9%)		
Infections and infestations	感染症および寄生虫症	178 (12.9%)	57 (4.1%)	32 (2.4%)	25 (1.9%)	113 (8.2%)	64 (5.0%)	4 (0.4%)	
Bronchitis	気管支炎	43 (3.1%)	13 (0.9%)	10 (0.8%)	7 (0.5%)	30 (2.2%)	13 (1.0%)		
Influenza	インフルエンザ	29 (2.1%)	8 (0.6%)	3 (0.2%)	2 (0.2%)	13 (0.9%)	16 (1.2%)		
Nasopharyngitis	鼻咽頭炎	63 (4.6%)	13 (0.9%)	12 (0.9%)	12 (0.9%)	37 (2.7%)	24 (1.9%)	2 (0.2%)	
Urinary tract infection	尿路感染	49 (3.5%)	24 (1.7%)	7 (0.5%)	4 (0.3%)	35 (2.5%)	12 (0.9%)	2 (0.2%)	
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	40 (2.9%)	15 (1.1%)	8 (0.6%)	3 (0.2%)	26 (1.9%)	12 (0.9%)	2 (0.2%)	
Contusion	挫傷	40 (2.9%)	15 (1.1%)	8 (0.6%)	3 (0.2%)	26 (1.9%)	12 (0.9%)	2 (0.2%)	
Investigations	臨床検査	28 (2.0%)	14 (1.0%)	3 (0.2%)	2 (0.2%)	19 (1.4%)	7 (0.5%)	2 (0.2%)	
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	23 (1.7%)	11 (0.8%)	3 (0.2%)	2 (0.2%)	16 (1.2%)	5 (0.4%)	2 (0.2%)	

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS Treatment Group: Rivaroxaban									
Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
International normalised ratio increased	ＩＮＲ増加	5 (0.4%)	3 (0.2%)			3 (0.2%)	2 (0.2%)		
Metabolism and nutrition disorders	代謝および栄養障害	25 (1.8%)	16 (1.2%)	2 (0.2%)	2 (0.2%)	20 (1.4%)	5 (0.4%)		
Hypokalaemia	低カリウム血症	25 (1.8%)	16 (1.2%)	2 (0.2%)	2 (0.2%)	20 (1.4%)	5 (0.4%)		
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	129 (9.3%)	49 (3.5%)	24 (1.8%)	17 (1.3%)	89 (6.4%)	42 (3.3%)	3 (0.3%)	
Arthralgia	関節痛	27 (2.0%)	6 (0.4%)	3 (0.2%)	7 (0.5%)	16 (1.2%)	10 (0.8%)	1 (<0.1%)	
Back pain	背部痛	39 (2.8%)	17 (1.2%)	6 (0.5%)	3 (0.2%)	26 (1.9%)	13 (1.0%)		
Pain in extremity	四肢痛	71 (5.1%)	27 (2.0%)	15 (1.1%)	7 (0.5%)	49 (3.5%)	20 (1.6%)	2 (0.2%)	
Nervous system disorders	神経系障害	136 (9.8%)	91 (6.6%)	12 (0.9%)	13 (1.0%)	112 (8.1%)	23 (1.8%)	1 (<0.1%)	
Dizziness	浮動性めまい	40 (2.9%)	23 (1.7%)	6 (0.5%)	6 (0.5%)	35 (2.5%)	5 (0.4%)		
Headache	頭痛	107 (7.7%)	73 (5.3%)	6 (0.5%)	7 (0.5%)	86 (6.2%)	19 (1.5%)	1 (<0.1%)	
Psychiatric disorders	精神障害	65 (4.7%)	47 (3.4%)	5 (0.4%)	4 (0.3%)	55 (4.0%)	10 (0.8%)		
Anxiety	不安	40 (2.9%)	27 (2.0%)	5 (0.4%)	2 (0.2%)	34 (2.5%)	6 (0.5%)		
Insomnia	不眠症	29 (2.1%)	22 (1.6%)		2 (0.2%)	24 (1.7%)	4 (0.3%)		
Renal and urinary disorders	腎および尿路障害	37 (2.7%)	26 (1.9%)	4 (0.3%)	3 (0.2%)	33 (2.4%)	4 (0.3%)		
Haematuria	血尿	37 (2.7%)	26 (1.9%)	4 (0.3%)	3 (0.2%)	33 (2.4%)	4 (0.3%)		
Reproductive system and breast disorders	生殖系および乳房障害	43 (3.1%)	31 (2.2%)	5 (0.4%)		36 (2.6%)	7 (0.5%)		
Menorrhagia	月経過多	43 (3.1%)	31 (2.2%)	5 (0.4%)		36 (2.6%)	7 (0.5%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	264 (19.1%)	140 (10.1%)	33 (2.5%)	36 (2.8%)	201 (14.5%)	67 (5.2%)	6 (0.6%)	
Cough	咳嗽	70 (5.1%)	34 (2.5%)	4 (0.3%)	12 (0.9%)	50 (3.6%)	20 (1.6%)		
Dyspnoea	呼吸困難	81 (5.9%)	29 (2.1%)	15 (1.1%)	10 (0.8%)	54 (3.9%)	24 (1.9%)	3 (0.3%)	
Epistaxis	鼻出血	116 (8.4%)	63 (4.6%)	14 (1.1%)	12 (0.9%)	89 (6.4%)	24 (1.9%)	3 (0.3%)	
Haemoptysis	喀血	41 (3.0%)	27 (2.0%)	4 (0.3%)	4 (0.3%)	35 (2.5%)	6 (0.5%)		
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	58 (4.2%)	34 (2.5%)	4 (0.3%)	6 (0.5%)	44 (3.2%)	15 (1.2%)	1 (<0.1%)	
Pruritus	そう痒症	29 (2.1%)	16 (1.2%)	2 (0.2%)	1 (<0.1%)	19 (1.4%)	9 (0.7%)	1 (<0.1%)	

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Rash	発疹	35 (2.5%)	21 (1.5%)	2 (0.2%)	5 (0.4%)	28 (2.0%)	7 (0.5%)		
Vascular disorders	血管障害	71 (5.1%)	31 (2.2%)	10 (0.8%)	10 (0.8%)	51 (3.7%)	17 (1.3%)	2 (0.2%)	
Haematoma	血腫	22 (1.6%)	7 (0.5%)	2 (0.2%)	4 (0.3%)	13 (0.9%)	9 (0.7%)		
Hypertension	高血圧	49 (3.5%)	24 (1.7%)	8 (0.6%)	6 (0.5%)	38 (2.7%)	8 (0.6%)	2 (0.2%)	

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:31

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		1382 (100%)	1382 (100%)	1315 (100%)	1283 (100%)	1382 (100%)	1273 (100%)	989 (100%)	
Cardiac disorders	心臓障害	21 (1.5%)	7 (0.5%)	4 (0.3%)	2 (0.2%)	13 (0.9%)	7 (0.5%)	1 (0.1%)	
Tachycardia	頻脈	21 (1.5%)	7 (0.5%)	4 (0.3%)	2 (0.2%)	13 (0.9%)	7 (0.5%)	1 (0.1%)	
Gastrointestinal disorders	胃腸障害	240 (17.4%)	182 (13.2%)	28 (2.1%)	22 (1.7%)	218 (15.8%)	30 (2.4%)	1 (0.1%)	
Constipation	便秘	73 (5.3%)	66 (4.8%)	1 (<0.1%)	5 (0.4%)	72 (5.2%)	1 (<0.1%)		
Diarrhoea	下痢	60 (4.3%)	34 (2.5%)	5 (0.4%)	7 (0.5%)	46 (3.3%)	14 (1.1%)		
Gingival bleeding	歯肉出血	45 (3.3%)	24 (1.7%)	9 (0.7%)	5 (0.4%)	38 (2.7%)	7 (0.5%)		
Nausea	悪心	76 (5.5%)	56 (4.1%)	6 (0.5%)	6 (0.5%)	68 (4.9%)	8 (0.6%)		
Rectal haemorrhage	直腸出血	20 (1.4%)	12 (0.9%)	4 (0.3%)	1 (<0.1%)	17 (1.2%)	3 (0.2%)		
Vomiting	嘔吐	40 (2.9%)	25 (1.8%)	5 (0.4%)	2 (0.2%)	32 (2.3%)	7 (0.5%)	1 (0.1%)	
General disorders and administration site conditions	一般・全身障害および投与部位の状態	175 (12.7%)	92 (6.7%)	32 (2.4%)	15 (1.2%)	133 (9.6%)	45 (3.5%)	3 (0.3%)	
Chest pain	胸痛	92 (6.7%)	42 (3.0%)	18 (1.4%)	8 (0.6%)	68 (4.9%)	23 (1.8%)	1 (0.1%)	
Fatigue	疲労	28 (2.0%)	18 (1.3%)	4 (0.3%)	1 (<0.1%)	23 (1.7%)	5 (0.4%)		
Oedema peripheral	末梢性浮腫	38 (2.7%)	12 (0.9%)	6 (0.5%)	6 (0.5%)	24 (1.7%)	13 (1.0%)	1 (0.1%)	
Pyrexia	発熱	38 (2.7%)	24 (1.7%)	4 (0.3%)	1 (<0.1%)	29 (2.1%)	8 (0.6%)	1 (0.1%)	
Infections and infestations	感染症および寄生虫症	179 (13.0%)	63 (4.6%)	30 (2.3%)	27 (2.1%)	117 (8.5%)	64 (5.0%)	4 (0.4%)	
Bronchitis	気管支炎	41 (3.0%)	11 (0.8%)	6 (0.5%)	10 (0.8%)	27 (2.0%)	14 (1.1%)		
Influenza	インフルエンザ	26 (1.9%)	3 (0.2%)	5 (0.4%)	3 (0.2%)	11 (0.8%)	12 (0.9%)	3 (0.3%)	
Nasopharyngitis	鼻咽頭炎	70 (5.1%)	22 (1.6%)	15 (1.1%)	7 (0.5%)	44 (3.2%)	25 (2.0%)	1 (0.1%)	
Urinary tract infection	尿路感染	54 (3.9%)	28 (2.0%)	4 (0.3%)	7 (0.5%)	39 (2.8%)	15 (1.2%)		
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	72 (5.2%)	45 (3.3%)	4 (0.3%)	4 (0.3%)	53 (3.8%)	16 (1.3%)	2 (0.2%)	
Contusion	挫傷	72 (5.2%)	45 (3.3%)	4 (0.3%)	4 (0.3%)	53 (3.8%)	16 (1.3%)	2 (0.2%)	
Investigations	臨床検査	81 (5.9%)	67 (4.8%)	3 (0.2%)	2 (0.2%)	72 (5.2%)	9 (0.7%)		
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	44 (3.2%)	38 (2.7%)	2 (0.2%)		40 (2.9%)	4 (0.3%)		

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
International normalised ratio increased	ＩＮＲ増加	40 (2.9%)	31 (2.2%)	1 (<0.1%)	2 (0.2%)	34 (2.5%)	6 (0.5%)		
Metabolism and nutrition disorders	代謝および栄養障害	30 (2.2%)	21 (1.5%)	2 (0.2%)	4 (0.3%)	27 (2.0%)	2 (0.2%)	1 (0.1%)	
Hypokalaemia	低カリウム血症	30 (2.2%)	21 (1.5%)	2 (0.2%)	4 (0.3%)	27 (2.0%)	2 (0.2%)	1 (0.1%)	
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	143 (10.3%)	64 (4.6%)	21 (1.6%)	18 (1.4%)	98 (7.1%)	46 (3.6%)	2 (0.2%)	
Arthralgia	関節痛	35 (2.5%)	14 (1.0%)	1 (<0.1%)	6 (0.5%)	21 (1.5%)	14 (1.1%)		
Back pain	背部痛	55 (4.0%)	23 (1.7%)	7 (0.5%)	7 (0.5%)	37 (2.7%)	18 (1.4%)		
Pain in extremity	四肢痛	71 (5.1%)	34 (2.5%)	13 (1.0%)	6 (0.5%)	53 (3.8%)	16 (1.3%)	2 (0.2%)	
Nervous system disorders	神経系障害	121 (8.8%)	76 (5.5%)	13 (1.0%)	10 (0.8%)	98 (7.1%)	20 (1.6%)	5 (0.5%)	
Dizziness	浮動性めまい	47 (3.4%)	26 (1.9%)	6 (0.5%)	3 (0.2%)	35 (2.5%)	11 (0.9%)	1 (0.1%)	
Headache	頭痛	89 (6.4%)	59 (4.3%)	9 (0.7%)	7 (0.5%)	75 (5.4%)	10 (0.8%)	4 (0.4%)	
Psychiatric disorders	精神障害	82 (5.9%)	61 (4.4%)	10 (0.8%)	2 (0.2%)	72 (5.2%)	10 (0.8%)	2 (0.2%)	
Anxiety	不安	44 (3.2%)	28 (2.0%)	8 (0.6%)	2 (0.2%)	38 (2.7%)	4 (0.3%)	2 (0.2%)	
Insomnia	不眠症	43 (3.1%)	35 (2.5%)	2 (0.2%)		37 (2.7%)	6 (0.5%)		
Renal and urinary disorders	腎および尿路障害	45 (3.3%)	27 (2.0%)	3 (0.2%)	4 (0.3%)	34 (2.5%)	11 (0.9%)		
Haematuria	血尿	45 (3.3%)	27 (2.0%)	3 (0.2%)	4 (0.3%)	34 (2.5%)	11 (0.9%)		
Reproductive system and breast disorders	生殖系および乳房障害	28 (2.0%)	14 (1.0%)	7 (0.5%)	1 (<0.1%)	22 (1.6%)	5 (0.4%)	1 (0.1%)	
Menorrhagia	月経過多	28 (2.0%)	14 (1.0%)	7 (0.5%)	1 (<0.1%)	22 (1.6%)	5 (0.4%)	1 (0.1%)	
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	250 (18.1%)	154 (11.1%)	44 (3.3%)	24 (1.9%)	210 (15.2%)	48 (3.8%)	4 (0.4%)	
Cough	咳嗽	77 (5.6%)	44 (3.2%)	13 (1.0%)	5 (0.4%)	62 (4.5%)	15 (1.2%)		
Dyspnoea	呼吸困難	62 (4.5%)	33 (2.4%)	11 (0.8%)	6 (0.5%)	50 (3.6%)	12 (0.9%)		
Epistaxis	鼻出血	103 (7.5%)	54 (3.9%)	17 (1.3%)	11 (0.9%)	82 (5.9%)	17 (1.3%)	4 (0.4%)	
Haemoptysis	喀血	53 (3.8%)	40 (2.9%)	6 (0.5%)	2 (0.2%)	48 (3.5%)	5 (0.4%)		
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	44 (3.2%)	32 (2.3%)	3 (0.2%)	3 (0.2%)	38 (2.7%)	7 (0.5%)		

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Pruritus	そう痒症	17 (1.2%)	13 (0.9%)	2 (0.2%)		15 (1.1%)	2 (0.2%)		
Rash	発疹	28 (2.0%)	19 (1.4%)	1 (<0.1%)	3 (0.2%)	23 (1.7%)	5 (0.4%)		
Vascular disorders	血管障害	81 (5.9%)	41 (3.0%)	15 (1.1%)	8 (0.6%)	64 (4.6%)	17 (1.3%)		
Haematoma	血腫	46 (3.3%)	31 (2.2%)	4 (0.3%)	2 (0.2%)	37 (2.7%)	9 (0.7%)		
Hypertension	高血圧	36 (2.6%)	11 (0.8%)	11 (0.8%)	6 (0.5%)	28 (2.0%)	8 (0.6%)		

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:31

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		904 (100%)	904 (100%)	866 (100%)	856 (100%)	904 (100%)	849 (100%)	815 (100%)	712 (100%)
Blood and lymphatic system disorders	血液およびリンパ系障害	24 (2.7%)	9 (1.0%)	3 (0.3%)	1 (0.1%)	13 (1.4%)	5 (0.6%)	3 (0.4%)	3 (0.4%)
Anaemia	貧血	24 (2.7%)	9 (1.0%)	3 (0.3%)	1 (0.1%)	13 (1.4%)	5 (0.6%)	3 (0.4%)	3 (0.4%)
Ear and labyrinth disorders	耳および迷路障害	19 (2.1%)	7 (0.8%)	1 (0.1%)	1 (0.1%)	9 (1.0%)	6 (0.7%)	2 (0.2%)	2 (0.3%)
Vertigo	回転性めまい	19 (2.1%)	7 (0.8%)	1 (0.1%)	1 (0.1%)	9 (1.0%)	6 (0.7%)	2 (0.2%)	2 (0.3%)
Gastrointestinal disorders	胃腸障害	204 (22.6%)	124 (13.7%)	20 (2.3%)	8 (0.9%)	143 (15.8%)	32 (3.8%)	24 (2.9%)	23 (3.2%)
Abdominal pain	腹痛	19 (2.1%)	10 (1.1%)	3 (0.3%)	1 (0.1%)	14 (1.5%)	2 (0.2%)	1 (0.1%)	2 (0.3%)
Abdominal pain upper	上腹部痛	21 (2.3%)	10 (1.1%)	2 (0.2%)	2 (0.2%)	14 (1.5%)	2 (0.2%)	2 (0.2%)	3 (0.4%)
Constipation	便秘	50 (5.5%)	43 (4.8%)	1 (0.1%)	1 (0.1%)	45 (5.0%)	3 (0.4%)		1 (0.1%)
Diarrhoea	下痢	50 (5.5%)	25 (2.8%)	2 (0.2%)	2 (0.2%)	29 (3.2%)	8 (0.9%)	8 (1.0%)	5 (0.7%)
Gingival bleeding	歯肉出血	28 (3.1%)	16 (1.8%)	5 (0.6%)	1 (0.1%)	22 (2.4%)	3 (0.4%)		3 (0.4%)
Nausea	悪心	37 (4.1%)	26 (2.9%)	2 (0.2%)		28 (3.1%)	4 (0.5%)	3 (0.4%)	2 (0.3%)
Rectal haemorrhage	直腸出血	20 (2.2%)	5 (0.6%)	3 (0.3%)	1 (0.1%)	9 (1.0%)	6 (0.7%)	3 (0.4%)	2 (0.3%)
Toothache	歯痛	20 (2.2%)	4 (0.4%)			4 (0.4%)	6 (0.7%)	6 (0.7%)	4 (0.6%)
Vomiting	嘔吐	18 (2.0%)	10 (1.1%)	4 (0.5%)		14 (1.5%)		2 (0.2%)	2 (0.3%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	125 (13.8%)	45 (5.0%)	12 (1.4%)	12 (1.4%)	68 (7.5%)	32 (3.8%)	22 (2.7%)	12 (1.7%)
Chest pain	胸痛	68 (7.5%)	19 (2.1%)	7 (0.8%)	8 (0.9%)	34 (3.8%)	18 (2.1%)	9 (1.1%)	6 (0.8%)
Fatigue	疲労	22 (2.4%)	6 (0.7%)	1 (0.1%)	1 (0.1%)	8 (0.9%)	8 (0.9%)	3 (0.4%)	3 (0.4%)
Oedema peripheral	末梢性浮腫	29 (3.2%)	11 (1.2%)	2 (0.2%)	2 (0.2%)	15 (1.7%)	5 (0.6%)	8 (1.0%)	1 (0.1%)
Pyrexia	発熱	21 (2.3%)	10 (1.1%)	2 (0.2%)	1 (0.1%)	13 (1.4%)	2 (0.2%)	3 (0.4%)	3 (0.4%)
Hepatobiliary disorders	肝胆道系障害	32 (3.5%)	28 (3.1%)	1 (0.1%)	1 (0.1%)	30 (3.3%)			2 (0.3%)
Hepatic steatosis	脂肪肝	32 (3.5%)	28 (3.1%)	1 (0.1%)	1 (0.1%)	30 (3.3%)			2 (0.3%)
Infections and infestations	感染症および寄生虫症	236 (26.1%)	40 (4.4%)	28 (3.2%)	27 (3.2%)	94 (10.4%)	66 (7.8%)	50 (6.1%)	46 (6.5%)
Bronchitis	気管支炎	53 (5.9%)	10 (1.1%)	8 (0.9%)	2 (0.2%)	20 (2.2%)	17 (2.0%)	10 (1.2%)	6 (0.8%)
Gastroenteritis	胃腸炎	15 (1.7%)	6 (0.7%)		2 (0.2%)	8 (0.9%)	3 (0.4%)	1 (0.1%)	3 (0.4%)
Influenza	インフルエンザ	25 (2.8%)	2 (0.2%)	1 (0.1%)	3 (0.4%)	6 (0.7%)	7 (0.8%)	6 (0.7%)	6 (0.8%)

表 2.7.4.7-11　全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Nasopharyngitis	鼻咽頭炎	102 (11.3%)	7 (0.8%)	10 (1.2%)	11 (1.3%)	28 (3.1%)	31 (3.7%)	21 (2.6%)	22 (3.1%)
Pneumonia	肺炎	13 (1.4%)	6 (0.7%)	1 (0.1%)	2 (0.2%)	9 (1.0%)		3 (0.4%)	1 (0.1%)
Upper respiratory tract infection	上気道感染	21 (2.3%)	1 (0.1%)	3 (0.3%)	2 (0.2%)	6 (0.7%)	5 (0.6%)	6 (0.7%)	3 (0.4%)
Urinary tract infection	尿路感染	36 (4.0%)	9 (1.0%)	5 (0.6%)	5 (0.6%)	19 (2.1%)	7 (0.8%)	5 (0.6%)	5 (0.7%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	84 (9.3%)	22 (2.4%)	5 (0.6%)	16 (1.9%)	42 (4.6%)	21 (2.5%)	18 (2.2%)	8 (1.1%)
Contusion	挫傷	51 (5.6%)	14 (1.5%)	2 (0.2%)	11 (1.3%)	27 (3.0%)	10 (1.2%)	10 (1.2%)	4 (0.6%)
Subcutaneous haematoma	皮下血腫	21 (2.3%)	6 (0.7%)	1 (0.1%)	2 (0.2%)	9 (1.0%)	7 (0.8%)	2 (0.2%)	3 (0.4%)
Wound haemorrhage	創傷出血	19 (2.1%)	3 (0.3%)	2 (0.2%)	3 (0.4%)	8 (0.9%)	4 (0.5%)	6 (0.7%)	1 (0.1%)
Investigations	臨床検査	26 (2.9%)	8 (0.9%)	1 (0.1%)	3 (0.4%)	12 (1.3%)	9 (1.1%)	3 (0.4%)	2 (0.3%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	25 (2.8%)	8 (0.9%)		3 (0.4%)	11 (1.2%)	9 (1.1%)	3 (0.4%)	2 (0.3%)
International normalised ratio increased	ＩＮＲ増加	1 (0.1%)		1 (0.1%)		1 (0.1%)			
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	137 (15.2%)	41 (4.5%)	18 (2.1%)	7 (0.8%)	66 (7.3%)	29 (3.4%)	36 (4.4%)	18 (2.5%)
Arthralgia	関節痛	37 (4.1%)	8 (0.9%)	3 (0.3%)	3 (0.4%)	14 (1.5%)	9 (1.1%)	6 (0.7%)	8 (1.1%)
Back pain	背部痛	39 (4.3%)	9 (1.0%)	5 (0.6%)	2 (0.2%)	16 (1.8%)	11 (1.3%)	9 (1.1%)	3 (0.4%)
Muscle spasms	筋痙縮	15 (1.7%)	1 (0.1%)	2 (0.2%)		3 (0.3%)	5 (0.6%)	5 (0.6%)	2 (0.3%)
Pain in extremity	四肢痛	61 (6.7%)	24 (2.7%)	8 (0.9%)	2 (0.2%)	34 (3.8%)	4 (0.5%)	17 (2.1%)	5 (0.7%)
Nervous system disorders	神経系障害	76 (8.4%)	34 (3.8%)	10 (1.2%)	8 (0.9%)	52 (5.8%)	12 (1.4%)	8 (1.0%)	5 (0.7%)
Dizziness	浮動性めまい	15 (1.7%)	5 (0.6%)	2 (0.2%)	2 (0.2%)	9 (1.0%)	5 (0.6%)	1 (0.1%)	
Headache	頭痛	64 (7.1%)	30 (3.3%)	9 (1.0%)	6 (0.7%)	45 (5.0%)	7 (0.8%)	7 (0.9%)	5 (0.7%)
Psychiatric disorders	精神障害	49 (5.4%)	23 (2.5%)	9 (1.0%)	2 (0.2%)	34 (3.8%)	11 (1.3%)	4 (0.5%)	1 (0.1%)
Anxiety	不安	26 (2.9%)	9 (1.0%)	4 (0.5%)	1 (0.1%)	14 (1.5%)	9 (1.1%)	3 (0.4%)	
Insomnia	不眠症	27 (3.0%)	15 (1.7%)	7 (0.8%)	1 (0.1%)	23 (2.5%)	2 (0.2%)	1 (0.1%)	1 (0.1%)
Renal and urinary disorders	腎および尿路障害	43 (4.8%)	23 (2.5%)	5 (0.6%)	2 (0.2%)	30 (3.3%)	6 (0.7%)	4 (0.5%)	3 (0.4%)
Haematuria	血尿	31 (3.4%)	16 (1.8%)	5 (0.6%)	1 (0.1%)	22 (2.4%)	4 (0.5%)	2 (0.2%)	3 (0.4%)

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Renal cyst	腎嚢胞	12 (1.3%)	7 (0.8%)		1 (0.1%)	8 (0.9%)	2 (0.2%)	2 (0.2%)	
Reproductive system and breast disorders	生殖系および乳房障害	26 (2.9%)	11 (1.2%)	6 (0.7%)	4 (0.5%)	21 (2.3%)	4 (0.5%)	1 (0.1%)	
Menorrhagia	月経過多	26 (2.9%)	11 (1.2%)	6 (0.7%)	4 (0.5%)	21 (2.3%)	4 (0.5%)	1 (0.1%)	
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	200 (22.1%)	90 (10.0%)	11 (1.3%)	16 (1.9%)	113 (12.5%)	52 (6.1%)	34 (4.2%)	22 (3.1%)
Cough	咳嗽	55 (6.1%)	17 (1.9%)	3 (0.3%)	7 (0.8%)	27 (3.0%)	16 (1.9%)	7 (0.9%)	5 (0.7%)
Dyspnoea	呼吸困難	58 (6.4%)	20 (2.2%)	2 (0.2%)	3 (0.4%)	25 (2.8%)	17 (2.0%)	14 (1.7%)	2 (0.3%)
Epistaxis	鼻出血	98 (10.8%)	47 (5.2%)	5 (0.6%)	4 (0.5%)	56 (6.2%)	18 (2.1%)	14 (1.7%)	10 (1.4%)
Haemoptysis	喀血	38 (4.2%)	18 (2.0%)	2 (0.2%)	3 (0.4%)	23 (2.5%)	6 (0.7%)	1 (0.1%)	8 (1.1%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	27 (3.0%)	13 (1.4%)	5 (0.6%)	3 (0.4%)	21 (2.3%)	4 (0.5%)	2 (0.2%)	
Rash	発疹	27 (3.0%)	13 (1.4%)	5 (0.6%)	3 (0.4%)	21 (2.3%)	4 (0.5%)	2 (0.2%)	
Vascular disorders	血管障害	87 (9.6%)	30 (3.3%)	5 (0.6%)	10 (1.2%)	45 (5.0%)	19 (2.2%)	11 (1.3%)	12 (1.7%)
Haematoma	血腫	35 (3.9%)	6 (0.7%)	3 (0.3%)	5 (0.6%)	14 (1.5%)	10 (1.2%)	3 (0.4%)	8 (1.1%)
Hypertension	高血圧	53 (5.9%)	24 (2.7%)	2 (0.2%)	5 (0.6%)	31 (3.4%)	9 (1.1%)	8 (1.0%)	4 (0.6%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:31

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		901 (100%)	901 (100%)	859 (100%)	851 (100%)	901 (100%)	841 (100%)	809 (100%)	690 (100%)
Blood and lymphatic system disorders	血液およびリンパ系障害	16 (1.8%)	7 (0.8%)	2 (0.2%)		9 (1.0%)	2 (0.2%)	3 (0.4%)	2 (0.3%)
Anaemia	貧血	16 (1.8%)	7 (0.8%)	2 (0.2%)		9 (1.0%)	2 (0.2%)	3 (0.4%)	2 (0.3%)
Ear and labyrinth disorders	耳および迷路障害	21 (2.3%)	2 (0.2%)	5 (0.6%)	4 (0.5%)	11 (1.2%)	1 (0.1%)	6 (0.7%)	3 (0.4%)
Vertigo	回転性めまい	21 (2.3%)	2 (0.2%)	5 (0.6%)	4 (0.5%)	11 (1.2%)	1 (0.1%)	6 (0.7%)	3 (0.4%)
Gastrointestinal disorders	胃腸障害	191 (21.2%)	94 (10.4%)	19 (2.2%)	17 (2.0%)	124 (13.8%)	37 (4.4%)	31 (3.8%)	21 (3.0%)
Abdominal pain	腹痛	15 (1.7%)	4 (0.4%)	1 (0.1%)		5 (0.6%)	6 (0.7%)	2 (0.2%)	2 (0.3%)
Abdominal pain upper	上腹部痛	16 (1.8%)	4 (0.4%)		1 (0.1%)	5 (0.6%)	6 (0.7%)	1 (0.1%)	4 (0.6%)
Constipation	便秘	49 (5.4%)	33 (3.7%)	5 (0.6%)	1 (0.1%)	39 (4.3%)	4 (0.5%)	3 (0.4%)	3 (0.4%)
Diarrhoea	下痢	55 (6.1%)	27 (3.0%)	3 (0.3%)	5 (0.6%)	35 (3.9%)	8 (1.0%)	8 (1.0%)	4 (0.6%)
Gingival bleeding	歯肉出血	29 (3.2%)	11 (1.2%)	4 (0.5%)	4 (0.5%)	19 (2.1%)	4 (0.5%)	3 (0.4%)	3 (0.4%)
Nausea	悪心	37 (4.1%)	18 (2.0%)	4 (0.5%)	6 (0.7%)	28 (3.1%)	6 (0.7%)	1 (0.1%)	2 (0.3%)
Rectal haemorrhage	直腸出血	21 (2.3%)	8 (0.9%)	2 (0.2%)	3 (0.4%)	13 (1.4%)	3 (0.4%)	2 (0.2%)	3 (0.4%)
Toothache	歯痛	15 (1.7%)	1 (0.1%)	1 (0.1%)	1 (0.1%)	3 (0.3%)	3 (0.4%)	8 (1.0%)	1 (0.1%)
Vomiting	嘔吐	30 (3.3%)	10 (1.1%)	1 (0.1%)	1 (0.1%)	12 (1.3%)	4 (0.5%)	8 (1.0%)	6 (0.9%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	120 (13.3%)	51 (5.7%)	18 (2.1%)	11 (1.3%)	76 (8.4%)	24 (2.9%)	11 (1.4%)	20 (2.9%)
Chest pain	胸痛	66 (7.3%)	27 (3.0%)	9 (1.0%)	6 (0.7%)	42 (4.7%)	12 (1.4%)	4 (0.5%)	8 (1.2%)
Fatigue	疲労	11 (1.2%)	3 (0.3%)	1 (0.1%)	3 (0.4%)	7 (0.8%)	2 (0.2%)	1 (0.1%)	
Oedema peripheral	末梢性浮腫	39 (4.3%)	11 (1.2%)	6 (0.7%)	2 (0.2%)	19 (2.1%)	8 (1.0%)	3 (0.4%)	8 (1.2%)
Pyrexia	発熱	27 (3.0%)	14 (1.6%)	2 (0.2%)	1 (0.1%)	17 (1.9%)	3 (0.4%)	3 (0.4%)	4 (0.6%)
Hepatobiliary disorders	肝胆道系障害	28 (3.1%)	23 (2.6%)	1 (0.1%)		24 (2.7%)	1 (0.1%)	1 (0.1%)	2 (0.3%)
Hepatic steatosis	脂肪肝	28 (3.1%)	23 (2.6%)	1 (0.1%)		24 (2.7%)	1 (0.1%)	1 (0.1%)	2 (0.3%)
Infections and infestations	感染症および寄生虫症	212 (23.5%)	47 (5.2%)	25 (2.9%)	24 (2.8%)	92 (10.2%)	56 (6.7%)	45 (5.6%)	44 (6.4%)
Bronchitis	気管支炎	37 (4.1%)	5 (0.6%)	2 (0.2%)	6 (0.7%)	13 (1.4%)	7 (0.8%)	5 (0.6%)	12 (1.7%)
Gastroenteritis	胃腸炎	19 (2.1%)	5 (0.6%)		1 (0.1%)	6 (0.7%)	6 (0.7%)	4 (0.5%)	3 (0.4%)
Influenza	インフルエンザ	20 (2.2%)	3 (0.3%)	2 (0.2%)	4 (0.5%)	9 (1.0%)	4 (0.5%)	4 (0.5%)	3 (0.4%)

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Nasopharyngitis	鼻咽頭炎	100 (11.1%)	12 (1.3%)	10 (1.2%)	11 (1.3%)	33 (3.7%)	30 (3.6%)	18 (2.2%)	19 (2.8%)
Pneumonia	肺炎	20 (2.2%)	7 (0.8%)	5 (0.6%)		12 (1.3%)	5 (0.6%)	2 (0.2%)	1 (0.1%)
Upper respiratory tract infection	上気道感染	19 (2.1%)	4 (0.4%)	3 (0.3%)	1 (0.1%)	8 (0.9%)	2 (0.2%)	5 (0.6%)	4 (0.6%)
Urinary tract infection	尿路感染	38 (4.2%)	13 (1.4%)	3 (0.3%)	3 (0.4%)	19 (2.1%)	6 (0.7%)	8 (1.0%)	5 (0.7%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	86 (9.5%)	31 (3.4%)	8 (0.9%)	5 (0.6%)	42 (4.7%)	19 (2.3%)	18 (2.2%)	10 (1.4%)
Contusion	挫傷	52 (5.8%)	24 (2.7%)	4 (0.5%)	3 (0.4%)	31 (3.4%)	12 (1.4%)	8 (1.0%)	1 (0.1%)
Subcutaneous haematoma	皮下血腫	22 (2.4%)	4 (0.4%)	3 (0.3%)	1 (0.1%)	8 (0.9%)	4 (0.5%)	5 (0.6%)	5 (0.7%)
Wound haemorrhage	創傷出血	20 (2.2%)	5 (0.6%)	1 (0.1%)	1 (0.1%)	7 (0.8%)	4 (0.5%)	5 (0.6%)	4 (0.6%)
Investigations	臨床検査	67 (7.4%)	44 (4.9%)	2 (0.2%)	4 (0.5%)	50 (5.5%)	4 (0.5%)	10 (1.2%)	5 (0.7%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	27 (3.0%)	20 (2.2%)	1 (0.1%)		21 (2.3%)	2 (0.2%)	1 (0.1%)	3 (0.4%)
International normalised ratio increased	ＩＮＲ増加	42 (4.7%)	24 (2.7%)	1 (0.1%)	4 (0.5%)	29 (3.2%)	2 (0.2%)	9 (1.1%)	2 (0.3%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	141 (15.6%)	51 (5.7%)	19 (2.2%)	11 (1.3%)	79 (8.8%)	41 (4.9%)	15 (1.9%)	24 (3.5%)
Arthralgia	関節痛	29 (3.2%)	7 (0.8%)	4 (0.5%)		11 (1.2%)	9 (1.1%)	3 (0.4%)	6 (0.9%)
Back pain	背部痛	66 (7.3%)	24 (2.7%)	10 (1.2%)	4 (0.5%)	38 (4.2%)	12 (1.4%)	9 (1.1%)	7 (1.0%)
Muscle spasms	筋痙縮	19 (2.1%)	5 (0.6%)	1 (0.1%)	2 (0.2%)	8 (0.9%)	5 (0.6%)		5 (0.7%)
Pain in extremity	四肢痛	56 (6.2%)	17 (1.9%)	5 (0.6%)	5 (0.6%)	27 (3.0%)	19 (2.3%)	4 (0.5%)	6 (0.9%)
Nervous system disorders	神経系障害	88 (9.8%)	40 (4.4%)	7 (0.8%)	4 (0.5%)	51 (5.7%)	21 (2.5%)	10 (1.2%)	8 (1.2%)
Dizziness	浮動性めまい	28 (3.1%)	10 (1.1%)	3 (0.3%)	1 (0.1%)	14 (1.6%)	8 (1.0%)	4 (0.5%)	2 (0.3%)
Headache	頭痛	62 (6.9%)	30 (3.3%)	4 (0.5%)	3 (0.4%)	37 (4.1%)	13 (1.5%)	6 (0.7%)	6 (0.9%)
Psychiatric disorders	精神障害	40 (4.4%)	26 (2.9%)	4 (0.5%)		30 (3.3%)	5 (0.6%)	2 (0.2%)	4 (0.6%)
Anxiety	不安	21 (2.3%)	12 (1.3%)	2 (0.2%)		14 (1.6%)	3 (0.4%)	1 (0.1%)	3 (0.4%)
Insomnia	不眠症	21 (2.3%)	14 (1.6%)	2 (0.2%)		16 (1.8%)	3 (0.4%)	1 (0.1%)	1 (0.1%)
Renal and urinary disorders	腎および尿路障害	43 (4.8%)	30 (3.3%)		1 (0.1%)	31 (3.4%)	3 (0.4%)	5 (0.6%)	4 (0.6%)
Haematuria	血尿	22 (2.4%)	9 (1.0%)		1 (0.1%)	10 (1.1%)	3 (0.4%)	5 (0.6%)	4 (0.6%)

表 2.7.4.7-11 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Renal cyst	腎嚢胞	21 (2.3%)	21 (2.3%)			21 (2.3%)			
Reproductive system and breast disorders	生殖系および乳房障害	13 (1.4%)	5 (0.6%)	2 (0.2%)		7 (0.8%)	3 (0.4%)	2 (0.2%)	1 (0.1%)
Menorrhagia	月経過多	13 (1.4%)	5 (0.6%)	2 (0.2%)		7 (0.8%)	3 (0.4%)	2 (0.2%)	1 (0.1%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	193 (21.4%)	87 (9.7%)	26 (3.0%)	16 (1.9%)	118 (13.1%)	37 (4.4%)	32 (4.0%)	17 (2.5%)
Cough	咳嗽	60 (6.7%)	31 (3.4%)	2 (0.2%)	4 (0.5%)	37 (4.1%)	10 (1.2%)	7 (0.9%)	6 (0.9%)
Dyspnoea	呼吸困難	58 (6.4%)	20 (2.2%)	12 (1.4%)	4 (0.5%)	36 (4.0%)	8 (1.0%)	12 (1.5%)	
Epistaxis	鼻出血	89 (9.9%)	29 (3.2%)	12 (1.4%)	7 (0.8%)	48 (5.3%)	22 (2.6%)	11 (1.4%)	8 (1.2%)
Haemoptysis	喀血	26 (2.9%)	14 (1.6%)	1 (0.1%)	3 (0.4%)	18 (2.0%)	2 (0.2%)	3 (0.4%)	3 (0.4%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	27 (3.0%)	12 (1.3%)	3 (0.3%)	5 (0.6%)	20 (2.2%)	7 (0.8%)		
Rash	発疹	27 (3.0%)	12 (1.3%)	3 (0.3%)	5 (0.6%)	20 (2.2%)	7 (0.8%)		
Vascular disorders	血管障害	81 (9.0%)	28 (3.1%)	10 (1.2%)	6 (0.7%)	43 (4.8%)	18 (2.1%)	11 (1.4%)	10 (1.4%)
Haematoma	血腫	44 (4.9%)	11 (1.2%)	5 (0.6%)	4 (0.5%)	20 (2.2%)	9 (1.1%)	8 (1.0%)	7 (1.0%)
Hypertension	高血圧	40 (4.4%)	17 (1.9%)	5 (0.6%)	2 (0.2%)	24 (2.7%)	10 (1.2%)	3 (0.4%)	3 (0.4%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:31
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表 2.7.4.7-12　全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）

Intended treatment duration: ALL DURATION
Treatment Group: BAY 59-7939

Primary System Organ Class Preferred Term MedDRA version{12.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		598 (100%)	594 (100%)	572 (100%)	559 (100%)	594 (100%)	551 (100%)	398 (100%)	97 (100%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	25 (4.2%)	9 (1.5%)	7 (1.2%)	3 (0.5%)	19 (3.2%)	4 (0.7%)		2 (2.1%)
Chest pain	胸痛	14 (2.3%)	4 (0.7%)	5 (0.9%)	3 (0.5%)	12 (2.0%)	1 (0.2%)		1 (1.0%)
Oedema peripheral	末梢性浮腫	12 (2.0%)	6 (1.0%)	2 (0.3%)		8 (1.3%)	3 (0.5%)		1 (1.0%)
Infections and infestations	感染症および寄生虫症	46 (7.7%)	14 (2.4%)	4 (0.7%)	7 (1.3%)	25 (4.2%)	16 (2.9%)	4 (1.0%)	1 (1.0%)
Bronchitis	気管支炎	7 (1.2%)	1 (0.2%)		1 (0.2%)	2 (0.3%)	4 (0.7%)	1 (0.3%)	
Influenza	インフルエンザ	11 (1.8%)	4 (0.7%)		2 (0.4%)	6 (1.0%)	3 (0.5%)	2 (0.5%)	
Nasopharyngitis	鼻咽頭炎	29 (4.8%)	10 (1.7%)	4 (0.7%)	4 (0.7%)	18 (3.0%)	9 (1.6%)	1 (0.3%)	1 (1.0%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	19 (3.2%)	6 (1.0%)	3 (0.5%)	3 (0.5%)	12 (2.0%)	3 (0.5%)	2 (0.5%)	2 (2.1%)
Contusion	挫傷	19 (3.2%)	6 (1.0%)	3 (0.5%)	3 (0.5%)	12 (2.0%)	3 (0.5%)	2 (0.5%)	2 (2.1%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	54 (9.0%)	25 (4.2%)	10 (1.7%)	8 (1.4%)	39 (6.6%)	10 (1.8%)	5 (1.3%)	2 (2.1%)
Arthralgia	関節痛	16 (2.7%)	9 (1.5%)	2 (0.3%)	2 (0.4%)	13 (2.2%)	1 (0.2%)	1 (0.3%)	1 (1.0%)
Back pain	背部痛	20 (3.3%)	3 (0.5%)	6 (1.0%)	3 (0.5%)	12 (2.0%)	4 (0.7%)	3 (0.8%)	1 (1.0%)
Pain in extremity	四肢痛	26 (4.3%)	15 (2.5%)	2 (0.3%)	3 (0.5%)	20 (3.4%)	5 (0.9%)	1 (0.3%)	
Nervous system disorders	神経系障害	16 (2.7%)	10 (1.7%)	2 (0.3%)	1 (0.2%)	13 (2.2%)	2 (0.4%)		1 (1.0%)
Headache	頭痛	16 (2.7%)	10 (1.7%)	2 (0.3%)	1 (0.2%)	13 (2.2%)	2 (0.4%)		1 (1.0%)
Renal and urinary disorders	腎および尿路障害	13 (2.2%)	4 (0.7%)	5 (0.9%)	1 (0.2%)	10 (1.7%)	2 (0.4%)	1 (0.3%)	
Haematuria	血尿	13 (2.2%)	4 (0.7%)	5 (0.9%)	1 (0.2%)	10 (1.7%)	2 (0.4%)	1 (0.3%)	
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	37 (6.2%)	9 (1.5%)	5 (0.9%)	5 (0.9%)	19 (3.2%)	12 (2.2%)	5 (1.3%)	1 (1.0%)
Cough	咳嗽	13 (2.2%)	2 (0.3%)	1 (0.2%)	3 (0.5%)	6 (1.0%)	5 (0.9%)	2 (0.5%)	
Epistaxis	鼻出血	24 (4.0%)	7 (1.2%)	4 (0.7%)	2 (0.4%)	13 (2.2%)	7 (1.3%)	3 (0.8%)	1 (1.0%)

表 2.7.4.7-12　全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: BAY 59-7939

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas　erjli　21MAR2013 10:48

表 2.7.4.7-12 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Placebo

Primary System Organ Class Preferred Term MedDRA version{12.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		590 (100%)	587 (100%)	576 (100%)	555 (100%)	587 (100%)	536 (100%)	385 (100%)	96 (100%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	27 (4.6%)	6 (1.0%)	6 (1.0%)	7 (1.3%)	18 (3.1%)	7 (1.3%)	2 (0.5%)	1 (1.0%)
Chest pain	胸痛	14 (2.4%)	2 (0.3%)	3 (0.5%)	4 (0.7%)	9 (1.5%)	4 (0.7%)		1 (1.0%)
Oedema peripheral	末梢性浮腫	15 (2.5%)	4 (0.7%)	3 (0.5%)	3 (0.5%)	10 (1.7%)	3 (0.6%)	2 (0.5%)	
Infections and infestations	感染症および寄生虫症	54 (9.2%)	19 (3.2%)	8 (1.4%)	5 (0.9%)	32 (5.5%)	15 (2.8%)	7 (1.8%)	1 (1.0%)
Bronchitis	気管支炎	16 (2.7%)	4 (0.7%)	4 (0.7%)	1 (0.2%)	9 (1.5%)	3 (0.6%)	4 (1.0%)	
Influenza	インフルエンザ	12 (2.0%)	4 (0.7%)	2 (0.3%)		6 (1.0%)	6 (1.1%)		
Nasopharyngitis	鼻咽頭炎	28 (4.7%)	12 (2.0%)	2 (0.3%)	4 (0.7%)	18 (3.1%)	6 (1.1%)	3 (0.8%)	1 (1.0%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	16 (2.7%)	6 (1.0%)		2 (0.4%)	8 (1.4%)	5 (0.9%)	2 (0.5%)	1 (1.0%)
Contusion	挫傷	16 (2.7%)	6 (1.0%)		2 (0.4%)	8 (1.4%)	5 (0.9%)	2 (0.5%)	1 (1.0%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	49 (8.3%)	20 (3.4%)	9 (1.6%)	7 (1.3%)	35 (6.0%)	9 (1.7%)	4 (1.0%)	1 (1.0%)
Arthralgia	関節痛	13 (2.2%)	3 (0.5%)	1 (0.2%)	3 (0.5%)	7 (1.2%)	5 (0.9%)		1 (1.0%)
Back pain	背部痛	6 (1.0%)	3 (0.5%)	1 (0.2%)		4 (0.7%)		2 (0.5%)	
Pain in extremity	四肢痛	32 (5.4%)	14 (2.4%)	7 (1.2%)	4 (0.7%)	25 (4.3%)	5 (0.9%)	2 (0.5%)	
Nervous system disorders	神経系障害	13 (2.2%)	7 (1.2%)	2 (0.3%)	1 (0.2%)	10 (1.7%)	2 (0.4%)	1 (0.3%)	
Headache	頭痛	13 (2.2%)	7 (1.2%)	2 (0.3%)	1 (0.2%)	10 (1.7%)	2 (0.4%)	1 (0.3%)	
Renal and urinary disorders	腎および尿路障害	2 (0.3%)	1 (0.2%)		1 (0.2%)	2 (0.3%)			
Haematuria	血尿	2 (0.3%)	1 (0.2%)		1 (0.2%)	2 (0.3%)			
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	29 (4.9%)	8 (1.4%)	6 (1.0%)	6 (1.1%)	20 (3.4%)	5 (0.9%)	2 (0.5%)	2 (2.1%)
Cough	咳嗽	18 (3.1%)	5 (0.9%)	3 (0.5%)	3 (0.5%)	11 (1.9%)	4 (0.7%)	1 (0.3%)	2 (2.1%)
Epistaxis	鼻出血	11 (1.9%)	3 (0.5%)	3 (0.5%)	3 (0.5%)	9 (1.5%)	1 (0.2%)	1 (0.3%)	

表 2.7.4.7-12　全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Placebo

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas　erjli　21MAR2013 10:48

表 2.7.4.7-12 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: BAY 59-7939

Primary System Organ Class Preferred Term MedDRA version{12.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		359 (100%)	357 (100%)	343 (100%)	339 (100%)	357 (100%)	335 (100%)	230 (100%)	
General disorders and administration site conditions	一般・全身障害および投与部位の状態	14 (3.9%)	5 (1.4%)	4 (1.2%)	2 (0.6%)	11 (3.1%)	3 (0.9%)		
Chest pain	胸痛	8 (2.2%)	2 (0.6%)	3 (0.9%)	2 (0.6%)	7 (2.0%)	1 (0.3%)		
Oedema peripheral	末梢性浮腫	6 (1.7%)	3 (0.8%)	1 (0.3%)		4 (1.1%)	2 (0.6%)		
Infections and infestations	感染症および寄生虫症	19 (5.3%)	3 (0.8%)	1 (0.3%)	4 (1.2%)	8 (2.2%)	11 (3.3%)		
Influenza	インフルエンザ	4 (1.1%)			1 (0.3%)	1 (0.3%)	3 (0.9%)		
Nasopharyngitis	鼻咽頭炎	15 (4.2%)	3 (0.8%)	1 (0.3%)	3 (0.9%)	7 (2.0%)	8 (2.4%)		
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	25 (7.0%)	12 (3.4%)	7 (2.0%)	6 (1.8%)	21 (5.9%)	3 (0.9%)	2 (0.9%)	
Arthralgia	関節痛	9 (2.5%)	4 (1.1%)	2 (0.6%)	2 (0.6%)	8 (2.2%)		1 (0.4%)	
Back pain	背部痛	10 (2.8%)	1 (0.3%)	4 (1.2%)	2 (0.6%)	7 (2.0%)	2 (0.6%)	1 (0.4%)	
Pain in extremity	四肢痛	11 (3.1%)	7 (2.0%)	1 (0.3%)	2 (0.6%)	10 (2.8%)	1 (0.3%)		
Nervous system disorders	神経系障害	11 (3.1%)	6 (1.7%)	2 (0.6%)	1 (0.3%)	9 (2.5%)	2 (0.6%)		
Headache	頭痛	11 (3.1%)	6 (1.7%)	2 (0.6%)	1 (0.3%)	9 (2.5%)	2 (0.6%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	20 (5.6%)	3 (0.8%)	2 (0.6%)	5 (1.5%)	10 (2.8%)	9 (2.7%)	1 (0.4%)	
Cough	咳嗽	9 (2.5%)	1 (0.3%)	1 (0.3%)	3 (0.9%)	5 (1.4%)	3 (0.9%)	1 (0.4%)	
Epistaxis	鼻出血	11 (3.1%)	2 (0.6%)	1 (0.3%)	2 (0.6%)	5 (1.4%)	6 (1.8%)		
Vascular disorders	血管障害	8 (2.2%)	3 (0.8%)		2 (0.6%)	5 (1.4%)	3 (0.9%)		
Wound haemorrhage	創傷出血	8 (2.2%)	3 (0.8%)		2 (0.6%)	5 (1.4%)	3 (0.9%)		

表 2.7.4.7-12　全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: BAY 59-7939

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas　erjli　21MAR2013 10:48

表 2.7.4.7-12　全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Placebo

Primary System Organ Class Preferred Term MedDRA version{12.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		353 (100%)	351 (100%)	346 (100%)	334 (100%)	351 (100%)	321 (100%)	225 (100%)	
General disorders and administration site conditions	一般・全身障害および投与部位の状態	14 (4.0%)	3 (0.9%)	4 (1.2%)	5 (1.5%)	11 (3.1%)	3 (0.9%)		
Chest pain	胸痛	7 (2.0%)		2 (0.6%)	3 (0.9%)	5 (1.4%)	2 (0.6%)		
Oedema peripheral	末梢性浮腫	8 (2.3%)	3 (0.9%)	2 (0.6%)	2 (0.6%)	7 (2.0%)	1 (0.3%)		
Infections and infestations	感染症および寄生虫症	19 (5.4%)	7 (2.0%)	1 (0.3%)	4 (1.2%)	12 (3.4%)	6 (1.9%)	1 (0.4%)	
Influenza	インフルエンザ	8 (2.3%)	3 (0.9%)	1 (0.3%)		4 (1.1%)	4 (1.2%)		
Nasopharyngitis	鼻咽頭炎	12 (3.4%)	5 (1.4%)		4 (1.2%)	9 (2.6%)	2 (0.6%)	1 (0.4%)	
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	26 (7.4%)	11 (3.1%)	6 (1.7%)	4 (1.2%)	20 (5.7%)	5 (1.6%)	1 (0.4%)	
Arthralgia	関節痛	5 (1.4%)	2 (0.6%)		1 (0.3%)	3 (0.9%)	2 (0.6%)		
Back pain	背部痛	4 (1.1%)	2 (0.6%)	1 (0.3%)		3 (0.9%)		1 (0.4%)	
Pain in extremity	四肢痛	18 (5.1%)	7 (2.0%)	5 (1.4%)	3 (0.9%)	15 (4.3%)	3 (0.9%)		
Nervous system disorders	神経系障害	9 (2.5%)	5 (1.4%)	1 (0.3%)	1 (0.3%)	7 (2.0%)	2 (0.6%)		
Headache	頭痛	9 (2.5%)	5 (1.4%)	1 (0.3%)	1 (0.3%)	7 (2.0%)	2 (0.6%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	14 (4.0%)	2 (0.6%)	5 (1.4%)	4 (1.2%)	11 (3.1%)	2 (0.6%)	1 (0.4%)	
Cough	咳嗽	8 (2.3%)	1 (0.3%)	3 (0.9%)	2 (0.6%)	6 (1.7%)	1 (0.3%)	1 (0.4%)	
Epistaxis	鼻出血	6 (1.7%)	1 (0.3%)	2 (0.6%)	2 (0.6%)	5 (1.4%)	1 (0.3%)		
Vascular disorders	血管障害	4 (1.1%)	2 (0.6%)			2 (0.6%)	2 (0.6%)		
Wound haemorrhage	創傷出血	4 (1.1%)	2 (0.6%)			2 (0.6%)	2 (0.6%)		

表 2.7.4.7-12　全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Placebo

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas　erjli　21MAR2013 10:48

表 2.7.4.7-12 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: BAY 59-7939

Primary System Organ Class Preferred Term MedDRA version{12.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		239 (100%)	237 (100%)	229 (100%)	220 (100%)	237 (100%)	216 (100%)	168 (100%)	97 (100%)
Gastrointestinal disorders	胃腸障害	11 (4.6%)	3 (1.3%)		5 (2.3%)	8 (3.4%)	3 (1.4%)	1 (0.6%)	
Dyspepsia	消化不良	7 (2.9%)	1 (0.4%)		4 (1.8%)	5 (2.1%)	2 (0.9%)		
Gingival bleeding	歯肉出血	5 (2.1%)	2 (0.8%)		1 (0.5%)	3 (1.3%)	1 (0.5%)	1 (0.6%)	
General disorders and administration site conditions	一般・全身障害および投与部位の状態	11 (4.6%)	4 (1.7%)	3 (1.3%)	1 (0.5%)	8 (3.4%)	1 (0.5%)		2 (2.1%)
Chest pain	胸痛	6 (2.5%)	2 (0.8%)	2 (0.9%)	1 (0.5%)	5 (2.1%)			1 (1.0%)
Oedema peripheral	末梢性浮腫	6 (2.5%)	3 (1.3%)	1 (0.4%)		4 (1.7%)	1 (0.5%)		1 (1.0%)
Infections and infestations	感染症および寄生虫症	26 (10.9%)	11 (4.6%)	3 (1.3%)	3 (1.4%)	17 (7.2%)	3 (1.4%)	4 (2.4%)	2 (2.1%)
Bronchitis	気管支炎	4 (1.7%)			1 (0.5%)	1 (0.4%)	2 (0.9%)	1 (0.6%)	
Influenza	インフルエンザ	7 (2.9%)	4 (1.7%)		1 (0.5%)	5 (2.1%)		2 (1.2%)	
Nasopharyngitis	鼻咽頭炎	14 (5.9%)	7 (3.0%)	3 (1.3%)	1 (0.5%)	11 (4.6%)	1 (0.5%)	1 (0.6%)	1 (1.0%)
Upper respiratory tract infection	上気道感染	2 (0.8%)	1 (0.4%)			1 (0.4%)			1 (1.0%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	14 (5.9%)	4 (1.7%)	2 (0.9%)	1 (0.5%)	7 (3.0%)	3 (1.4%)	2 (1.2%)	2 (2.1%)
Contusion	挫傷	14 (5.9%)	4 (1.7%)	2 (0.9%)	1 (0.5%)	7 (3.0%)	3 (1.4%)	2 (1.2%)	2 (2.1%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	35 (14.6%)	14 (5.9%)	3 (1.3%)	3 (1.4%)	20 (8.4%)	7 (3.2%)	4 (2.4%)	5 (5.2%)
Arthralgia	関節痛	7 (2.9%)	5 (2.1%)			5 (2.1%)	1 (0.5%)		1 (1.0%)
Back pain	背部痛	10 (4.2%)	2 (0.8%)	2 (0.9%)	1 (0.5%)	5 (2.1%)	2 (0.9%)	2 (1.2%)	1 (1.0%)
Osteoarthritis	骨関節炎	7 (2.9%)	1 (0.4%)		1 (0.5%)	2 (0.8%)	1 (0.5%)	1 (0.6%)	3 (3.1%)
Pain in extremity	四肢痛	15 (6.3%)	8 (3.4%)	1 (0.4%)	1 (0.5%)	10 (4.2%)	4 (1.9%)	1 (0.6%)	
Nervous system disorders	神経系障害	5 (2.1%)	4 (1.7%)			4 (1.7%)			1 (1.0%)
Headache	頭痛	5 (2.1%)	4 (1.7%)			4 (1.7%)			1 (1.0%)
Renal and urinary disorders	腎および尿路障害	6 (2.5%)	2 (0.8%)	2 (0.9%)	1 (0.5%)	5 (2.1%)		1 (0.6%)	
Haematuria	血尿	6 (2.5%)	2 (0.8%)	2 (0.9%)	1 (0.5%)	5 (2.1%)		1 (0.6%)	
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	21 (8.8%)	7 (3.0%)	3 (1.3%)	1 (0.5%)	11 (4.6%)	4 (1.9%)	5 (3.0%)	1 (1.0%)

表 2.7.4.7-12 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: BAY 59-7939

Primary System Organ Class Preferred Term MedDRA version{12.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Cough	咳嗽	4 (1.7%)	1 (0.4%)			1 (0.4%)	2 (0.9%)	1 (0.6%)	
Dyspnoea	呼吸困難	4 (1.7%)	1 (0.4%)		1 (0.5%)	2 (0.8%)	1 (0.5%)	1 (0.6%)	
Epistaxis	鼻出血	13 (5.4%)	5 (2.1%)	3 (1.3%)		8 (3.4%)	1 (0.5%)	3 (1.8%)	1 (1.0%)
Vascular disorders	血管障害	2 (0.8%)		1 (0.4%)		1 (0.4%)		1 (0.6%)	
Hypertension	高血圧	2 (0.8%)		1 (0.4%)		1 (0.4%)		1 (0.6%)	

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:48
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表 2.7.4.7-12 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Placebo

Primary System Organ Class Preferred Term MedDRA version{12.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		237 (100%)	236 (100%)	230 (100%)	221 (100%)	236 (100%)	215 (100%)	160 (100%)	96 (100%)
Gastrointestinal disorders	胃腸障害	3 (1.3%)			1 (0.5%)	1 (0.4%)	1 (0.5%)	1 (0.6%)	
Dyspepsia	消化不良	2 (0.8%)			1 (0.5%)	1 (0.4%)		1 (0.6%)	
Gingival bleeding	歯肉出血	1 (0.4%)					1 (0.5%)		
General disorders and administration site conditions	一般・全身障害および投与部位の状態	13 (5.5%)	3 (1.3%)	2 (0.9%)	2 (0.9%)	7 (3.0%)	4 (1.9%)	2 (1.3%)	1 (1.0%)
Chest pain	胸痛	7 (3.0%)	2 (0.8%)	1 (0.4%)	1 (0.5%)	4 (1.7%)	2 (0.9%)		1 (1.0%)
Oedema peripheral	末梢性浮腫	7 (3.0%)	1 (0.4%)	1 (0.4%)	1 (0.5%)	3 (1.3%)	2 (0.9%)	2 (1.3%)	
Infections and infestations	感染症および寄生虫症	42 (17.7%)	13 (5.5%)	9 (3.9%)	1 (0.5%)	23 (9.7%)	12 (5.6%)	6 (3.8%)	2 (2.1%)
Bronchitis	気管支炎	10 (4.2%)	1 (0.4%)	3 (1.3%)	1 (0.5%)	5 (2.1%)	2 (0.9%)	3 (1.9%)	
Gastroenteritis	胃腸炎	8 (3.4%)	2 (0.8%)	2 (0.9%)		4 (1.7%)	3 (1.4%)	1 (0.6%)	
Influenza	インフルエンザ	4 (1.7%)	1 (0.4%)	1 (0.4%)		2 (0.8%)	2 (0.9%)		
Nasopharyngitis	鼻咽頭炎	16 (6.8%)	7 (3.0%)	2 (0.9%)		9 (3.8%)	4 (1.9%)	2 (1.3%)	1 (1.0%)
Upper respiratory tract infection	上気道感染	5 (2.1%)	2 (0.8%)	1 (0.4%)		3 (1.3%)	1 (0.5%)		1 (1.0%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	10 (4.2%)	3 (1.3%)		2 (0.9%)	5 (2.1%)	2 (0.9%)	2 (1.3%)	1 (1.0%)
Contusion	挫傷	10 (4.2%)	3 (1.3%)		2 (0.9%)	5 (2.1%)	2 (0.9%)	2 (1.3%)	1 (1.0%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	26 (11.0%)	11 (4.7%)	3 (1.3%)	3 (1.4%)	17 (7.2%)	5 (2.3%)	3 (1.9%)	1 (1.0%)
Arthralgia	関節痛	8 (3.4%)	1 (0.4%)	1 (0.4%)	2 (0.9%)	4 (1.7%)	3 (1.4%)		1 (1.0%)
Back pain	背部痛	2 (0.8%)	1 (0.4%)			1 (0.4%)		1 (0.6%)	
Osteoarthritis	骨関節炎	3 (1.3%)	2 (0.8%)			2 (0.8%)	1 (0.5%)		
Pain in extremity	四肢痛	14 (5.9%)	7 (3.0%)	2 (0.9%)	1 (0.5%)	10 (4.2%)	2 (0.9%)	2 (1.3%)	
Nervous system disorders	神経系障害	4 (1.7%)	2 (0.8%)	1 (0.4%)		3 (1.3%)		1 (0.6%)	
Headache	頭痛	4 (1.7%)	2 (0.8%)	1 (0.4%)		3 (1.3%)		1 (0.6%)	
Renal and urinary disorders	腎および尿路障害	1 (0.4%)	1 (0.4%)			1 (0.4%)			
Haematuria	血尿	1 (0.4%)	1 (0.4%)			1 (0.4%)			

表 2.7.4.7-12 全期間で合計 2%以上に認められた TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Placebo

Primary System Organ Class Preferred Term MedDRA version{12.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	20 (8.4%)	8 (3.4%)	2 (0.9%)	2 (0.9%)	12 (5.1%)	4 (1.9%)	1 (0.6%)	3 (3.1%)
Cough	咳嗽	10 (4.2%)	4 (1.7%)		1 (0.5%)	5 (2.1%)	3 (1.4%)		2 (2.1%)
Dyspnoea	呼吸困難	6 (2.5%)	2 (0.8%)	1 (0.4%)		3 (1.3%)	1 (0.5%)		2 (2.1%)
Epistaxis	鼻出血	5 (2.1%)	2 (0.8%)	1 (0.4%)	1 (0.5%)	4 (1.7%)		1 (0.6%)	
Vascular disorders	血管障害	5 (2.1%)	2 (0.8%)	1 (0.4%)		3 (1.3%)		2 (1.3%)	
Hypertension	高血圧	5 (2.1%)	2 (0.8%)	1 (0.4%)		3 (1.3%)		2 (1.3%)	

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:48

表 2.7.4.7-13 全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		1718 (100%)	1718 (100%)	1649 (100%)	1620 (100%)	1718 (100%)	1599 (100%)	1252 (100%)	328 (100%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	28 (1.6%)	10 (0.6%)	9 (0.5%)	4 (0.2%)	23 (1.3%)	4 (0.3%)	1 (<0.1%)	
Contusion	挫傷	28 (1.6%)	10 (0.6%)	9 (0.5%)	4 (0.2%)	23 (1.3%)	4 (0.3%)	1 (<0.1%)	
Reproductive system and breast disorders	生殖系および乳房障害	40 (2.3%)	31 (1.8%)	2 (0.1%)	2 (0.1%)	35 (2.0%)	4 (0.3%)		1 (0.3%)
Menorrhagia	月経過多	40 (2.3%)	31 (1.8%)	2 (0.1%)	2 (0.1%)	35 (2.0%)	4 (0.3%)		1 (0.3%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	67 (3.9%)	32 (1.9%)	13 (0.8%)	5 (0.3%)	50 (2.9%)	12 (0.8%)	2 (0.2%)	3 (0.9%)
Epistaxis	鼻出血	67 (3.9%)	32 (1.9%)	13 (0.8%)	5 (0.3%)	50 (2.9%)	12 (0.8%)	2 (0.2%)	3 (0.9%)
Vascular disorders	血管障害	25 (1.5%)	7 (0.4%)	2 (0.1%)	3 (0.2%)	12 (0.7%)	9 (0.6%)	3 (0.2%)	1 (0.3%)
Haematoma	血腫	25 (1.5%)	7 (0.4%)	2 (0.1%)	3 (0.2%)	12 (0.7%)	9 (0.6%)	3 (0.2%)	1 (0.3%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:26

表 2.7.4.7-13　全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		1711 (100%)	1711 (100%)	1608 (100%)	1570 (100%)	1711 (100%)	1538 (100%)	1147 (100%)	317 (100%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	40 (2.3%)	29 (1.7%)	2 (0.1%)	2 (0.1%)	33 (1.9%)	6 (0.4%)	1 (<0.1%)	
Contusion	挫傷	40 (2.3%)	29 (1.7%)	2 (0.1%)	2 (0.1%)	33 (1.9%)	6 (0.4%)	1 (<0.1%)	
Reproductive system and breast disorders	生殖系および乳房障害	16 (0.9%)	4 (0.2%)		8 (0.5%)	12 (0.7%)	4 (0.3%)		
Menorrhagia	月経過多	16 (0.9%)	4 (0.2%)		8 (0.5%)	12 (0.7%)	4 (0.3%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	56 (3.3%)	19 (1.1%)	8 (0.5%)	4 (0.3%)	31 (1.8%)	22 (1.4%)	2 (0.2%)	1 (0.3%)
Epistaxis	鼻出血	56 (3.3%)	19 (1.1%)	8 (0.5%)	4 (0.3%)	31 (1.8%)	22 (1.4%)	2 (0.2%)	1 (0.3%)
Vascular disorders	血管障害	38 (2.2%)	25 (1.5%)	1 (<0.1%)	2 (0.1%)	28 (1.6%)	7 (0.5%)	1 (<0.1%)	2 (0.6%)
Haematoma	血腫	38 (2.2%)	25 (1.5%)	1 (<0.1%)	2 (0.1%)	28 (1.6%)	7 (0.5%)	1 (<0.1%)	2 (0.6%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas　erjli　21MAR2013 10:26

表 2.7.4.7-13 全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		207 (100%)	207 (100%)	198 (100%)	191 (100%)	207 (100%)			
Gastrointestinal disorders	胃腸障害	3 (1.4%)	3 (1.4%)			3 (1.4%)			
Gingival bleeding	歯肉出血	3 (1.4%)	3 (1.4%)			3 (1.4%)			
Reproductive system and breast disorders	生殖系および乳房障害	5 (2.4%)	4 (1.9%)		1 (0.5%)	5 (2.4%)			
Menorrhagia	月経過多	5 (2.4%)	4 (1.9%)		1 (0.5%)	5 (2.4%)			
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	7 (3.4%)	5 (2.4%)	2 (1.0%)		7 (3.4%)			
Epistaxis	鼻出血	7 (3.4%)	5 (2.4%)	2 (1.0%)		7 (3.4%)			
Vascular disorders	血管障害	4 (1.9%)	2 (1.0%)		2 (1.0%)	4 (1.9%)			
Haematoma	血腫	4 (1.9%)	2 (1.0%)		2 (1.0%)	4 (1.9%)			

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:26

表 2.7.4.7-13 全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		201 (100%)	201 (100%)	187 (100%)	183 (100%)	201 (100%)	171 (100%)		
Gastrointestinal disorders	胃腸障害	6 (3.0%)	1 (0.5%)	2 (1.1%)	2 (1.1%)	5 (2.5%)	1 (0.6%)		
Gingival bleeding	歯肉出血	6 (3.0%)	1 (0.5%)	2 (1.1%)	2 (1.1%)	5 (2.5%)	1 (0.6%)		
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	7 (3.5%)	7 (3.5%)			7 (3.5%)			
Contusion	挫傷	7 (3.5%)	7 (3.5%)			7 (3.5%)			
Investigations	臨床検査	5 (2.5%)	5 (2.5%)			5 (2.5%)			
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	5 (2.5%)	5 (2.5%)			5 (2.5%)			
Reproductive system and breast disorders	生殖系および乳房障害	4 (2.0%)	1 (0.5%)		3 (1.6%)	4 (2.0%)			
Menorrhagia	月経過多	4 (2.0%)	1 (0.5%)		3 (1.6%)	4 (2.0%)			
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	6 (3.0%)	2 (1.0%)	1 (0.5%)	2 (1.1%)	5 (2.5%)	1 (0.6%)		
Epistaxis	鼻出血	6 (3.0%)	2 (1.0%)	1 (0.5%)	2 (1.1%)	5 (2.5%)	1 (0.6%)		
Vascular disorders	血管障害	6 (3.0%)	5 (2.5%)	1 (0.5%)		6 (3.0%)			
Haematoma	血腫	6 (3.0%)	5 (2.5%)	1 (0.5%)		6 (3.0%)			

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:26

表 2.7.4.7-13 全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		1074 (100%)	1074 (100%)	1024 (100%)	1007 (100%)	1074 (100%)	996 (100%)	852 (100%)	
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	23 (2.1%)	7 (0.7%)	7 (0.7%)	4 (0.4%)	18 (1.7%)	4 (0.4%)	1 (0.1%)	
Contusion	挫傷	23 (2.1%)	7 (0.7%)	7 (0.7%)	4 (0.4%)	18 (1.7%)	4 (0.4%)	1 (0.1%)	
Reproductive system and breast disorders	生殖系および乳房障害	29 (2.7%)	23 (2.1%)	2 (0.2%)	1 (<0.1%)	26 (2.4%)	3 (0.3%)		
Menorrhagia	月経過多	29 (2.7%)	23 (2.1%)	2 (0.2%)	1 (<0.1%)	26 (2.4%)	3 (0.3%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	38 (3.5%)	18 (1.7%)	8 (0.8%)	3 (0.3%)	29 (2.7%)	9 (0.9%)		
Epistaxis	鼻出血	38 (3.5%)	18 (1.7%)	8 (0.8%)	3 (0.3%)	29 (2.7%)	9 (0.9%)		
Vascular disorders	血管障害	13 (1.2%)	5 (0.5%)	1 (<0.1%)	1 (<0.1%)	7 (0.7%)	6 (0.6%)		
Haematoma	血腫	13 (1.2%)	5 (0.5%)	1 (<0.1%)	1 (<0.1%)	7 (0.7%)	6 (0.6%)		

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:26

表 2.7.4.7-13 全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		1079 (100%)	1079 (100%)	1011 (100%)	984 (100%)	1079 (100%)	968 (100%)	765 (100%)	
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	22 (2.0%)	17 (1.6%)	1 (<0.1%)	1 (0.1%)	19 (1.8%)	3 (0.3%)		
Contusion	挫傷	22 (2.0%)	17 (1.6%)	1 (<0.1%)	1 (0.1%)	19 (1.8%)	3 (0.3%)		
Reproductive system and breast disorders	生殖系および乳房障害	6 (0.6%)	2 (0.2%)		2 (0.2%)	4 (0.4%)	2 (0.2%)		
Menorrhagia	月経過多	6 (0.6%)	2 (0.2%)		2 (0.2%)	4 (0.4%)	2 (0.2%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	33 (3.1%)	13 (1.2%)	6 (0.6%)	1 (0.1%)	20 (1.9%)	13 (1.3%)		
Epistaxis	鼻出血	33 (3.1%)	13 (1.2%)	6 (0.6%)	1 (0.1%)	20 (1.9%)	13 (1.3%)		
Vascular disorders	血管障害	27 (2.5%)	19 (1.8%)		1 (0.1%)	20 (1.9%)	6 (0.6%)	1 (0.1%)	
Haematoma	血腫	27 (2.5%)	19 (1.8%)		1 (0.1%)	20 (1.9%)	6 (0.6%)	1 (0.1%)	

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:26

表 2.7.4.7-13 全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		437 (100%)	437 (100%)	427 (100%)	422 (100%)	437 (100%)	417 (100%)	400 (100%)	328 (100%)
Gastrointestinal disorders	胃腸障害	11 (2.5%)	3 (0.7%)	3 (0.7%)		6 (1.4%)	2 (0.5%)	2 (0.5%)	1 (0.3%)
Gingival bleeding	歯肉出血	11 (2.5%)	3 (0.7%)	3 (0.7%)		6 (1.4%)	2 (0.5%)	2 (0.5%)	1 (0.3%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	5 (1.1%)	3 (0.7%)	2 (0.5%)		5 (1.1%)			
Contusion	挫傷	5 (1.1%)	3 (0.7%)	2 (0.5%)		5 (1.1%)			
Renal and urinary disorders	腎および尿路障害	7 (1.6%)	1 (0.2%)	2 (0.5%)	1 (0.2%)	4 (0.9%)		1 (0.3%)	2 (0.6%)
Haematuria	血尿	7 (1.6%)	1 (0.2%)	2 (0.5%)	1 (0.2%)	4 (0.9%)		1 (0.3%)	2 (0.6%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	22 (5.0%)	9 (2.1%)	3 (0.7%)	2 (0.5%)	14 (3.2%)	3 (0.7%)	2 (0.5%)	3 (0.9%)
Epistaxis	鼻出血	22 (5.0%)	9 (2.1%)	3 (0.7%)	2 (0.5%)	14 (3.2%)	3 (0.7%)	2 (0.5%)	3 (0.9%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:26

表 2.7.4.7-13　全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-DVT、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{13.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		431 (100%)	431 (100%)	410 (100%)	403 (100%)	431 (100%)	399 (100%)	382 (100%)	317 (100%)
Gastrointestinal disorders	胃腸障害	11 (2.6%)	2 (0.5%)	1 (0.2%)	1 (0.2%)	4 (0.9%)	2 (0.5%)	3 (0.8%)	2 (0.6%)
Gingival bleeding	歯肉出血	11 (2.6%)	2 (0.5%)	1 (0.2%)	1 (0.2%)	4 (0.9%)	2 (0.5%)	3 (0.8%)	2 (0.6%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	11 (2.6%)	5 (1.2%)	1 (0.2%)	1 (0.2%)	7 (1.6%)	3 (0.8%)	1 (0.3%)	
Contusion	挫傷	11 (2.6%)	5 (1.2%)	1 (0.2%)	1 (0.2%)	7 (1.6%)	3 (0.8%)	1 (0.3%)	
Investigations	臨床検査	12 (2.8%)	7 (1.6%)			7 (1.6%)	1 (0.3%)	3 (0.8%)	1 (0.3%)
International normalised ratio increased	ＩＮＲ増加	12 (2.8%)	7 (1.6%)			7 (1.6%)	1 (0.3%)	3 (0.8%)	1 (0.3%)
Renal and urinary disorders	腎および尿路障害	12 (2.8%)	2 (0.5%)	1 (0.2%)	2 (0.5%)	5 (1.2%)	1 (0.3%)	3 (0.8%)	3 (0.9%)
Haematuria	血尿	12 (2.8%)	2 (0.5%)	1 (0.2%)	2 (0.5%)	5 (1.2%)	1 (0.3%)	3 (0.8%)	3 (0.9%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	17 (3.9%)	4 (0.9%)	1 (0.2%)	1 (0.2%)	6 (1.4%)	8 (2.0%)	2 (0.5%)	1 (0.3%)
Epistaxis	鼻出血	17 (3.9%)	4 (0.9%)	1 (0.2%)	1 (0.2%)	6 (1.4%)	8 (2.0%)	2 (0.5%)	1 (0.3%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas　erjli　21MAR2013 10:26
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表 2.7.4.7-14　全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		2412 (100%)	2412 (100%)	2289 (100%)	2258 (100%)	2412 (100%)	2241 (100%)	1885 (100%)	712 (100%)
Gastrointestinal disorders	胃腸障害	46 (1.9%)	28 (1.2%)	6 (0.3%)	2 (<0.1%)	36 (1.5%)	6 (0.3%)		4 (0.6%)
Gingival bleeding	歯肉出血	46 (1.9%)	28 (1.2%)	6 (0.3%)	2 (<0.1%)	36 (1.5%)	6 (0.3%)		4 (0.6%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	53 (2.2%)	19 (0.8%)	4 (0.2%)	7 (0.3%)	30 (1.2%)	17 (0.8%)	6 (0.3%)	
Contusion	挫傷	53 (2.2%)	19 (0.8%)	4 (0.2%)	7 (0.3%)	30 (1.2%)	17 (0.8%)	6 (0.3%)	
Investigations	臨床検査	4 (0.2%)	3 (0.1%)			3 (0.1%)	1 (<0.1%)		
International normalised ratio increased	ＩＮＲ増加	4 (0.2%)	3 (0.1%)			3 (0.1%)	1 (<0.1%)		
Renal and urinary disorders	腎および尿路障害	49 (2.0%)	28 (1.2%)	8 (0.3%)	4 (0.2%)	40 (1.7%)	6 (0.3%)		3 (0.4%)
Haematuria	血尿	49 (2.0%)	28 (1.2%)	8 (0.3%)	4 (0.2%)	40 (1.7%)	6 (0.3%)		3 (0.4%)
Reproductive system and breast disorders	生殖系および乳房障害	61 (2.5%)	34 (1.4%)	11 (0.5%)	4 (0.2%)	49 (2.0%)	11 (0.5%)	1 (<0.1%)	
Menorrhagia	月経過多	61 (2.5%)	34 (1.4%)	11 (0.5%)	4 (0.2%)	49 (2.0%)	11 (0.5%)	1 (<0.1%)	
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	224 (9.3%)	121 (5.0%)	23 (1.0%)	15 (0.7%)	158 (6.6%)	41 (1.8%)	14 (0.7%)	16 (2.2%)
Epistaxis	鼻出血	173 (7.2%)	90 (3.7%)	18 (0.8%)	10 (0.4%)	118 (4.9%)	32 (1.4%)	13 (0.7%)	10 (1.4%)
Haemoptysis	喀血	62 (2.6%)	35 (1.5%)	5 (0.2%)	5 (0.2%)	45 (1.9%)	9 (0.4%)	1 (<0.1%)	7 (1.0%)
Vascular disorders	血管障害	37 (1.5%)	8 (0.3%)	4 (0.2%)	6 (0.3%)	18 (0.7%)	12 (0.5%)	3 (0.2%)	4 (0.6%)
Haematoma	血腫	37 (1.5%)	8 (0.3%)	4 (0.2%)	6 (0.3%)	18 (0.7%)	12 (0.5%)	3 (0.2%)	4 (0.6%)

表 2.7.4.7-14　全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas　erjli　21MAR2013 10:40

表 2.7.4.7-14　全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		2405 (100%)	2405 (100%)	2289 (100%)	2244 (100%)	2405 (100%)	2215 (100%)	1798 (100%)	690 (100%)
Gastrointestinal disorders	胃腸障害	64 (2.7%)	31 (1.3%)	11 (0.5%)	7 (0.3%)	49 (2.0%)	10 (0.5%)	3 (0.2%)	2 (0.3%)
Gingival bleeding	歯肉出血	64 (2.7%)	31 (1.3%)	11 (0.5%)	7 (0.3%)	49 (2.0%)	10 (0.5%)	3 (0.2%)	2 (0.3%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	86 (3.6%)	47 (2.0%)	5 (0.2%)	4 (0.2%)	56 (2.3%)	26 (1.2%)	3 (0.2%)	
Contusion	挫傷	86 (3.6%)	47 (2.0%)	5 (0.2%)	4 (0.2%)	56 (2.3%)	26 (1.2%)	3 (0.2%)	
Investigations	臨床検査	76 (3.2%)	51 (2.1%)	2 (<0.1%)	4 (0.2%)	57 (2.4%)	8 (0.4%)	9 (0.5%)	2 (0.3%)
International normalised ratio increased	ＩＮＲ増加	76 (3.2%)	51 (2.1%)	2 (<0.1%)	4 (0.2%)	57 (2.4%)	8 (0.4%)	9 (0.5%)	2 (0.3%)
Renal and urinary disorders	腎および尿路障害	52 (2.2%)	31 (1.3%)	3 (0.1%)	4 (0.2%)	38 (1.6%)	7 (0.3%)	3 (0.2%)	4 (0.6%)
Haematuria	血尿	52 (2.2%)	31 (1.3%)	3 (0.1%)	4 (0.2%)	38 (1.6%)	7 (0.3%)	3 (0.2%)	4 (0.6%)
Reproductive system and breast disorders	生殖系および乳房障害	34 (1.4%)	18 (0.7%)	7 (0.3%)	1 (<0.1%)	26 (1.1%)	7 (0.3%)		1 (0.1%)
Menorrhagia	月経過多	34 (1.4%)	18 (0.7%)	7 (0.3%)	1 (<0.1%)	26 (1.1%)	7 (0.3%)		1 (0.1%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	192 (8.0%)	92 (3.8%)	29 (1.3%)	21 (0.9%)	139 (5.8%)	35 (1.6%)	16 (0.9%)	6 (0.9%)
Epistaxis	鼻出血	159 (6.6%)	67 (2.8%)	27 (1.2%)	16 (0.7%)	110 (4.6%)	31 (1.4%)	13 (0.7%)	5 (0.7%)
Haemoptysis	喀血	45 (1.9%)	28 (1.2%)	3 (0.1%)	5 (0.2%)	36 (1.5%)	5 (0.2%)	3 (0.2%)	1 (0.1%)
Vascular disorders	血管障害	68 (2.8%)	36 (1.5%)	6 (0.3%)	3 (0.1%)	45 (1.9%)	14 (0.6%)	6 (0.3%)	3 (0.4%)
Haematoma	血腫	68 (2.8%)	36 (1.5%)	6 (0.3%)	3 (0.1%)	45 (1.9%)	14 (0.6%)	6 (0.3%)	3 (0.4%)

表 2.7.4.7-14　全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Enoxaparin/VKA

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas　erjli　21MAR2013 10:40

表 2.7.4.7-14 全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		125 (100%)	125 (100%)	113 (100%)	111 (100%)	125 (100%)			
Investigations	臨床検査	1 (0.8%)	1 (0.8%)			1 (0.8%)			
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	1 (0.8%)	1 (0.8%)			1 (0.8%)			
Renal and urinary disorders	腎および尿路障害	4 (3.2%)	3 (2.4%)		1 (0.9%)	4 (3.2%)			
Haematuria	血尿	4 (3.2%)	3 (2.4%)		1 (0.9%)	4 (3.2%)			
Reproductive system and breast disorders	生殖系および乳房障害	2 (1.6%)	1 (0.8%)	1 (0.9%)		2 (1.6%)			
Menorrhagia	月経過多	2 (1.6%)	1 (0.8%)	1 (0.9%)		2 (1.6%)			
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	4 (3.2%)	4 (3.2%)			4 (3.2%)			
Epistaxis	鼻出血	4 (3.2%)	4 (3.2%)			4 (3.2%)			

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:40

表 2.7.4.7-14 全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		122 (100%)	122 (100%)	115 (100%)	110 (100%)	122 (100%)	101 (100%)		
Investigations	臨床検査	3 (2.5%)	3 (2.5%)			3 (2.5%)			
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	3 (2.5%)	3 (2.5%)			3 (2.5%)			
Renal and urinary disorders	腎および尿路障害	3 (2.5%)	2 (1.6%)			2 (1.6%)	1 (1.0%)		
Haematuria	血尿	3 (2.5%)	2 (1.6%)			2 (1.6%)	1 (1.0%)		
Reproductive system and breast disorders	生殖系および乳房障害	4 (3.3%)	3 (2.5%)	1 (0.9%)		4 (3.3%)			
Menorrhagia	月経過多	4 (3.3%)	3 (2.5%)	1 (0.9%)		4 (3.3%)			
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	4 (3.3%)	1 (0.8%)	2 (1.7%)	1 (0.9%)	4 (3.3%)			
Epistaxis	鼻出血	4 (3.3%)	1 (0.8%)	2 (1.7%)	1 (0.9%)	4 (3.3%)			

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:40

表 2.7.4.7-14　全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		1383 (100%)	1383 (100%)	1310 (100%)	1291 (100%)	1383 (100%)	1282 (100%)	1070 (100%)	
Gastrointestinal disorders	胃腸障害	20 (1.4%)	14 (1.0%)	1 (<0.1%)	1 (<0.1%)	16 (1.2%)	4 (0.3%)		
Gingival bleeding	歯肉出血	20 (1.4%)	14 (1.0%)	1 (<0.1%)	1 (<0.1%)	16 (1.2%)	4 (0.3%)		
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	19 (1.4%)	8 (0.6%)	2 (0.2%)		10 (0.7%)	8 (0.6%)	1 (<0.1%)	
Contusion	挫傷	19 (1.4%)	8 (0.6%)	2 (0.2%)		10 (0.7%)	8 (0.6%)	1 (<0.1%)	
Investigations	臨床検査	4 (0.3%)	3 (0.2%)			3 (0.2%)	1 (<0.1%)		
International normalised ratio increased	ＩＮＲ増加	4 (0.3%)	3 (0.2%)			3 (0.2%)	1 (<0.1%)		
Renal and urinary disorders	腎および尿路障害	23 (1.7%)	15 (1.1%)	4 (0.3%)	1 (<0.1%)	20 (1.4%)	3 (0.2%)		
Haematuria	血尿	23 (1.7%)	15 (1.1%)	4 (0.3%)	1 (<0.1%)	20 (1.4%)	3 (0.2%)		
Reproductive system and breast disorders	生殖系および乳房障害	36 (2.6%)	24 (1.7%)	5 (0.4%)		29 (2.1%)	7 (0.5%)		
Menorrhagia	月経過多	36 (2.6%)	24 (1.7%)	5 (0.4%)		29 (2.1%)	7 (0.5%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	115 (8.3%)	64 (4.6%)	16 (1.2%)	10 (0.8%)	90 (6.5%)	24 (1.9%)	2 (0.2%)	
Epistaxis	鼻出血	87 (6.3%)	47 (3.4%)	13 (1.0%)	7 (0.5%)	67 (4.8%)	18 (1.4%)	2 (0.2%)	
Haemoptysis	喀血	31 (2.2%)	19 (1.4%)	3 (0.2%)	3 (0.2%)	25 (1.8%)	6 (0.5%)		
Vascular disorders	血管障害	15 (1.1%)	5 (0.4%)	2 (0.2%)	2 (0.2%)	9 (0.7%)	6 (0.5%)		
Haematoma	血腫	15 (1.1%)	5 (0.4%)	2 (0.2%)	2 (0.2%)	9 (0.7%)	6 (0.5%)		

表 2.7.4.7-14　全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Rivaroxaban

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas　erjli　21MAR2013 10:40

表 2.7.4.7-14　全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		1382 (100%)	1382 (100%)	1315 (100%)	1283 (100%)	1382 (100%)	1273 (100%)	989 (100%)	
Gastrointestinal disorders	胃腸障害	37 (2.7%)	19 (1.4%)	8 (0.6%)	4 (0.3%)	31 (2.2%)	6 (0.5%)		
Gingival bleeding	歯肉出血	37 (2.7%)	19 (1.4%)	8 (0.6%)	4 (0.3%)	31 (2.2%)	6 (0.5%)		
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	49 (3.5%)	30 (2.2%)	2 (0.2%)	2 (0.2%)	34 (2.5%)	13 (1.0%)	1 (0.1%)	
Contusion	挫傷	49 (3.5%)	30 (2.2%)	2 (0.2%)	2 (0.2%)	34 (2.5%)	13 (1.0%)	1 (0.1%)	
Investigations	臨床検査	36 (2.6%)	28 (2.0%)	1 (<0.1%)	1 (<0.1%)	30 (2.2%)	6 (0.5%)		
International normalised ratio increased	ＩＮＲ増加	36 (2.6%)	28 (2.0%)	1 (<0.1%)	1 (<0.1%)	30 (2.2%)	6 (0.5%)		
Renal and urinary disorders	腎および尿路障害	33 (2.4%)	22 (1.6%)	3 (0.2%)	3 (0.2%)	28 (2.0%)	5 (0.4%)		
Haematuria	血尿	33 (2.4%)	22 (1.6%)	3 (0.2%)	3 (0.2%)	28 (2.0%)	5 (0.4%)		
Reproductive system and breast disorders	生殖系および乳房障害	21 (1.5%)	11 (0.8%)	5 (0.4%)	1 (<0.1%)	17 (1.2%)	4 (0.3%)		
Menorrhagia	月経過多	21 (1.5%)	11 (0.8%)	5 (0.4%)	1 (<0.1%)	17 (1.2%)	4 (0.3%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	103 (7.5%)	61 (4.4%)	16 (1.2%)	10 (0.8%)	85 (6.2%)	18 (1.4%)	2 (0.2%)	
Epistaxis	鼻出血	80 (5.8%)	41 (3.0%)	14 (1.1%)	8 (0.6%)	63 (4.6%)	15 (1.2%)	2 (0.2%)	
Haemoptysis	喀血	30 (2.2%)	22 (1.6%)	3 (0.2%)	2 (0.2%)	27 (2.0%)	3 (0.2%)		
Vascular disorders	血管障害	37 (2.7%)	25 (1.8%)	3 (0.2%)	1 (<0.1%)	29 (2.1%)	8 (0.6%)		
Haematoma	血腫	37 (2.7%)	25 (1.8%)	3 (0.2%)	1 (<0.1%)	29 (2.1%)	8 (0.6%)		

表 2.7.4.7-14　全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Enoxaparin/VKA

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas　erjli　21MAR2013 10:40

表 2.7.4.7-14 全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Rivaroxaban

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		904 (100%)	904 (100%)	866 (100%)	856 (100%)	904 (100%)	849 (100%)	815 (100%)	712 (100%)
Gastrointestinal disorders	胃腸障害	25 (2.8%)	14 (1.5%)	4 (0.5%)	1 (0.1%)	19 (2.1%)	2 (0.2%)		4 (0.6%)
Gingival bleeding	歯肉出血	25 (2.8%)	14 (1.5%)	4 (0.5%)	1 (0.1%)	19 (2.1%)	2 (0.2%)		4 (0.6%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	34 (3.8%)	11 (1.2%)	2 (0.2%)	7 (0.8%)	20 (2.2%)	9 (1.1%)	5 (0.6%)	
Contusion	挫傷	34 (3.8%)	11 (1.2%)	2 (0.2%)	7 (0.8%)	20 (2.2%)	9 (1.1%)	5 (0.6%)	
Renal and urinary disorders	腎および尿路障害	22 (2.4%)	10 (1.1%)	4 (0.5%)	2 (0.2%)	16 (1.8%)	3 (0.4%)		3 (0.4%)
Haematuria	血尿	22 (2.4%)	10 (1.1%)	4 (0.5%)	2 (0.2%)	16 (1.8%)	3 (0.4%)		3 (0.4%)
Reproductive system and breast disorders	生殖系および乳房障害	23 (2.5%)	9 (1.0%)	5 (0.6%)	4 (0.5%)	18 (2.0%)	4 (0.5%)	1 (0.1%)	
Menorrhagia	月経過多	23 (2.5%)	9 (1.0%)	5 (0.6%)	4 (0.5%)	18 (2.0%)	4 (0.5%)	1 (0.1%)	
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	103 (11.4%)	51 (5.6%)	7 (0.8%)	5 (0.6%)	62 (6.9%)	17 (2.0%)	12 (1.5%)	16 (2.2%)
Epistaxis	鼻出血	82 (9.1%)	39 (4.3%)	5 (0.6%)	3 (0.4%)	47 (5.2%)	14 (1.6%)	11 (1.3%)	10 (1.4%)
Haemoptysis	喀血	29 (3.2%)	14 (1.5%)	2 (0.2%)	2 (0.2%)	18 (2.0%)	3 (0.4%)	1 (0.1%)	7 (1.0%)
Vascular disorders	血管障害	22 (2.4%)	3 (0.3%)	2 (0.2%)	4 (0.5%)	9 (1.0%)	6 (0.7%)	3 (0.4%)	4 (0.6%)
Haematoma	血腫	22 (2.4%)	3 (0.3%)	2 (0.2%)	4 (0.5%)	9 (1.0%)	6 (0.7%)	3 (0.4%)	4 (0.6%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:40

表 2.7.4.7-14　全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Enoxaparin/VKA

Primary System Organ Class Preferred Term MedDRA version{14.1}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		901 (100%)	901 (100%)	859 (100%)	851 (100%)	901 (100%)	841 (100%)	809 (100%)	690 (100%)
Gastrointestinal disorders	胃腸障害	25 (2.8%)	10 (1.1%)	3 (0.3%)	3 (0.4%)	16 (1.8%)	4 (0.5%)	3 (0.4%)	2 (0.3%)
Gingival bleeding	歯肉出血	25 (2.8%)	10 (1.1%)	3 (0.3%)	3 (0.4%)	16 (1.8%)	4 (0.5%)	3 (0.4%)	2 (0.3%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	35 (3.9%)	16 (1.8%)	2 (0.2%)	2 (0.2%)	20 (2.2%)	13 (1.5%)	2 (0.2%)	
Contusion	挫傷	35 (3.9%)	16 (1.8%)	2 (0.2%)	2 (0.2%)	20 (2.2%)	13 (1.5%)	2 (0.2%)	
Investigations	臨床検査	40 (4.4%)	23 (2.6%)	1 (0.1%)	3 (0.4%)	27 (3.0%)	2 (0.2%)	9 (1.1%)	2 (0.3%)
International normalised ratio increased	ＩＮＲ増加	40 (4.4%)	23 (2.6%)	1 (0.1%)	3 (0.4%)	27 (3.0%)	2 (0.2%)	9 (1.1%)	2 (0.3%)
Renal and urinary disorders	腎および尿路障害	16 (1.8%)	7 (0.8%)		1 (0.1%)	8 (0.9%)	1 (0.1%)	3 (0.4%)	4 (0.6%)
Haematuria	血尿	16 (1.8%)	7 (0.8%)		1 (0.1%)	8 (0.9%)	1 (0.1%)	3 (0.4%)	4 (0.6%)
Reproductive system and breast disorders	生殖系および乳房障害	9 (1.0%)	4 (0.4%)	1 (0.1%)		5 (0.6%)	3 (0.4%)		1 (0.1%)
Menorrhagia	月経過多	9 (1.0%)	4 (0.4%)	1 (0.1%)		5 (0.6%)	3 (0.4%)		1 (0.1%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	84 (9.3%)	29 (3.2%)	11 (1.3%)	10 (1.2%)	49 (5.4%)	17 (2.0%)	14 (1.7%)	6 (0.9%)
Epistaxis	鼻出血	75 (8.3%)	25 (2.8%)	11 (1.3%)	7 (0.8%)	43 (4.8%)	16 (1.9%)	11 (1.4%)	5 (0.7%)
Haemoptysis	喀血	14 (1.6%)	5 (0.6%)		3 (0.4%)	8 (0.9%)	2 (0.2%)	3 (0.4%)	1 (0.1%)
Vascular disorders	血管障害	29 (3.2%)	9 (1.0%)	3 (0.3%)	2 (0.2%)	14 (1.6%)	6 (0.7%)	6 (0.7%)	3 (0.4%)
Haematoma	血腫	29 (3.2%)	9 (1.0%)	3 (0.3%)	2 (0.2%)	14 (1.6%)	6 (0.7%)	6 (0.7%)	3 (0.4%)

表 2.7.4.7-14　全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11702-PE、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Enoxaparin/VKA

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas　erjli　21MAR2013 10:40
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表 2.7.4.7-15 全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）

Intended treatment duration: ALL DURATION
Treatment Group: BAY 59-7939

Primary System Organ Class Preferred Term MedDRA version{12.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		598 (100%)	594 (100%)	572 (100%)	559 (100%)	594 (100%)	551 (100%)	398 (100%)	97 (100%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	17 (2.8%)	4 (0.7%)	4 (0.7%)	1 (0.2%)	9 (1.5%)	5 (0.9%)	2 (0.5%)	1 (1.0%)
Epistaxis	鼻出血	17 (2.8%)	4 (0.7%)	4 (0.7%)	1 (0.2%)	9 (1.5%)	5 (0.9%)	2 (0.5%)	1 (1.0%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:55

表 2.7.4.7-15 全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Placebo

Primary System Organ Class Preferred Term MedDRA version{12.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		590 (100%)	587 (100%)	576 (100%)	555 (100%)	587 (100%)	536 (100%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	9 (1.5%)	3 (0.5%)	3 (0.5%)	2 (0.4%)	8 (1.4%)	1 (0.2%)		
Epistaxis	鼻出血	9 (1.5%)	3 (0.5%)	3 (0.5%)	2 (0.4%)	8 (1.4%)	1 (0.2%)		

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:55

表 2.7.4.7-15 全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: BAY 59-7939

Primary System Organ Class Preferred Term MedDRA version{12.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		359 (100%)	357 (100%)	343 (100%)	339 (100%)	357 (100%)	335 (100%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	9 (2.5%)	2 (0.6%)	1 (0.3%)	1 (0.3%)	4 (1.1%)	5 (1.5%)		
Epistaxis	鼻出血	9 (2.5%)	2 (0.6%)	1 (0.3%)	1 (0.3%)	4 (1.1%)	5 (1.5%)		

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:55

表 2.7.4.7-15 全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS
Treatment Group: Placebo

Primary System Organ Class Preferred Term MedDRA version{12.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		353 (100%)	351 (100%)	346 (100%)	334 (100%)	351 (100%)	321 (100%)		
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	6 (1.7%)	1 (0.3%)	2 (0.6%)	2 (0.6%)	5 (1.4%)	1 (0.3%)		
Epistaxis	鼻出血	6 (1.7%)	1 (0.3%)	2 (0.6%)	2 (0.6%)	5 (1.4%)	1 (0.3%)		

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:55

表 2.7.4.7-15　全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: BAY 59-7939

Primary System Organ Class Preferred Term MedDRA version{12.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		239 (100%)	237 (100%)	229 (100%)	220 (100%)	237 (100%)	216 (100%)	168 (100%)	97 (100%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	7 (2.9%)	3 (1.3%)	1 (0.4%)		4 (1.7%)	3 (1.4%)		
Contusion	挫傷	7 (2.9%)	3 (1.3%)	1 (0.4%)		4 (1.7%)	3 (1.4%)		
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	2 (0.8%)	1 (0.4%)			1 (0.4%)	1 (0.5%)		
Pain in extremity	四肢痛	2 (0.8%)	1 (0.4%)			1 (0.4%)	1 (0.5%)		
Renal and urinary disorders	腎および尿路障害	5 (2.1%)	2 (0.8%)	1 (0.4%)	1 (0.5%)	4 (1.7%)		1 (0.6%)	
Haematuria	血尿	5 (2.1%)	2 (0.8%)	1 (0.4%)	1 (0.5%)	4 (1.7%)		1 (0.6%)	
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	8 (3.3%)	2 (0.8%)	3 (1.3%)		5 (2.1%)		2 (1.2%)	1 (1.0%)
Epistaxis	鼻出血	8 (3.3%)	2 (0.8%)	3 (1.3%)		5 (2.1%)		2 (1.2%)	1 (1.0%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted,and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas　erjli　21MAR2013 10:55
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表 2.7.4.7-15 全期間で合計 2%以上に認められた治験薬との因果関係が否定できない TEAE の時期別発現頻度（30 日ごと）（試験 11899、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS
Treatment Group: Placebo

Primary System Organ Class Preferred Term MedDRA version{12.0}		Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated		237 (100%)	236 (100%)	230 (100%)	221 (100%)	236 (100%)		160 (100%)	96 (100%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	5 (2.1%)	2 (0.8%)		1 (0.5%)	3 (1.3%)		1 (0.6%)	1 (1.0%)
Contusion	挫傷	5 (2.1%)	2 (0.8%)		1 (0.5%)	3 (1.3%)		1 (0.6%)	1 (1.0%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	5 (2.1%)	3 (1.3%)	2 (0.9%)		5 (2.1%)			
Pain in extremity	四肢痛	5 (2.1%)	3 (1.3%)	2 (0.9%)		5 (2.1%)			
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	3 (1.3%)	2 (0.8%)	1 (0.4%)		3 (1.3%)			
Epistaxis	鼻出血	3 (1.3%)	2 (0.8%)	1 (0.4%)		3 (1.3%)			

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query30/pgms/t-p-5-6.sas erjli 21MAR2013 10:55

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	100134015	YES	GERMANY	WHITE	MALE	78	Oesophageal adenocarcinoma	食道腺癌	20 mg	.	SEVERE	YES	YES	106	121	NO	DEATH
Rivaroxaban	100134038	YES	GERMANY	WHITE	MALE	54	Multi-organ failure	多臓器不全	20 mg	.	SEVERE	YES	YES	84	25	NO	DEATH
Rivaroxaban	100134038	YES	GERMANY	WHITE	MALE	54	Subacute endocarditis	亜急性心内膜炎	20 mg	.	MODERATE	NO	YES	84		NO	UNCHANGED
Rivaroxaban	100134038	YES	GERMANY	WHITE	MALE	54	Renal failure	腎不全	20 mg	.	MODERATE	NO	YES	84		NO	UNCHANGED
Rivaroxaban	100134038	YES	GERMANY	WHITE	MALE	54	Oesophagitis	食道炎	20 mg	.	MILD	NO	YES	84		NO	UNCHANGED
Rivaroxaban	100134038	YES	GERMANY	WHITE	MALE	54	Hepatic cirrhosis	肝硬変	20 mg	F	MODERATE	NO	NO	87		NO	UNCHANGED
Rivaroxaban	100134038	YES	GERMANY	WHITE	MALE	54	Bile duct cancer	胆管癌	20 mg	F	SEVERE	YES	NO	87		NO	UNCHANGED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Pain in extremity	四肢痛			MODERATE	NO	NO	0	2	NO	RESOLVED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Anxiety	不安	15 mg	.	MODERATE	NO	YES	2	96	NO	IMPROVED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Insomnia	不眠症	15 mg	.	MODERATE	NO	YES	2		NO	UNCHANGED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Rectal haemorrhage	直腸出血	15 mg	.	MILD	NO	YES	5		YES	UNCHANGED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Vaginal haemorrhage	膣出血	15 mg	.	MILD	NO	YES	8	2	YES	RESOLVED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Vaginal haemorrhage	膣出血	15 mg	.	MILD	NO	YES	10	1	YES	RESOLVED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Vaginal haemorrhage	膣出血	15 mg	.	MILD	NO	YES	13		YES	UNCHANGED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Endometrial cancer	子宮内膜癌	20 mg	.	SEVERE	YES	YES	32	119	NO	DEATH
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Diarrhoea	下痢	20 mg	.	MODERATE	NO	YES	35	1	YES	RESOLVED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Contusion	挫傷	20 mg	.	MILD	NO	YES	46		YES	UNCHANGED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Dizziness	浮動性めまい	20 mg	.	MILD	NO	YES	50	49	NO	WORSENED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Oedema peripheral	末梢性浮腫	20 mg	.	MILD	NO	YES	51	3	NO	WORSENED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Cough	咳嗽	20 mg	.	MILD	NO	YES	51	1	NO	RESOLVED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Oedema peripheral	末梢性浮腫	20 mg	.	MODERATE	NO	YES	53		NO	UNCHANGED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Anaemia	貧血	20 mg	.	SEVERE	YES	YES	53		YES	IMPROVED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Pain in extremity	四肢痛	20 mg	.	MILD	NO	YES	53		NO	UNCHANGED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Pyrexia	発熱	20 mg	.	MILD	NO	YES	98	1	NO	RESOLVED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Dizziness	浮動性めまい	20 mg	.	MODERATE	NO	YES	98	2	NO	RESOLVED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Anxiety	不安	20 mg	.	MILD	NO	YES	98		NO	UNCHANGED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Anaemia	貧血	15 mg	.	MODERATE	NO	YES	1		NO	UNCHANGED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Pain in extremity	四肢痛	15 mg	.	MODERATE	NO	YES	2	5	YES	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Thrombocytopenia	血小板減少症	15 mg	.	MILD	NO	YES	11	6	NO	WORSENED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Thrombocytopenia	血小板減少症	15 mg	.	SEVERE	NO	YES	16		NO	UNCHANGED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Fatigue	疲労	15 mg	.	MODERATE	NO	YES	16		NO	UNCHANGED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Pruritus	そう痒症	15 mg	.	MILD	NO	YES	21		NO	UNCHANGED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Oedema	浮腫			MILD	NO	YES	29		NO	UNCHANGED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Nausea	悪心			MILD	NO	YES	29		NO	UNCHANGED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Bone pain	骨痛			MODERATE	NO	YES	50		NO	UNCHANGED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Contusion	挫傷			MILD	NO	YES	57		NO	UNCHANGED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Contusion	挫傷			MILD	NO	YES	75	9	NO	RESOLVED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Rectal haemorrhage	直腸出血			MILD	NO	YES	80		NO	UNCHANGED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Constipation	便秘			MILD	NO	YES	80		NO	UNCHANGED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Diarrhoea	下痢			MILD	NO	YES	80		NO	UNCHANGED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Epistaxis	鼻出血			MILD	NO	YES	113		NO	UNCHANGED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Hypokalaemia	低カリウム血症			MILD	NO	YES	114	85	NO	RESOLVED
Rivaroxaban	140164005	YES	UNITED	WHITE	MALE	52	Orthopnoea	起坐呼吸			MILD	NO	YES	162		NO	UNCHANGED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
			STATES														
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Oedema peripheral	末梢性浮腫			MILD	NO	YES	176		NO	UNCHANGED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Small cell lung cancer metastatic	転移性小細胞肺癌			SEVERE	YES	YES	183	41	NO	DEATH
Enoxaparin/VKA	140164016	YES	UNITED STATES	WHITE	FEMALE	66	Oedema peripheral	末梢性浮腫			MODERATE	NO	NO	1		NO	UNCHANGED
Enoxaparin/VKA	140164016	YES	UNITED STATES	WHITE	FEMALE	66	Dysphonia	発声障害			MILD	NO	NO	36		NO	UNCHANGED
Enoxaparin/VKA	140164016	YES	UNITED STATES	WHITE	FEMALE	66	Pleural effusion	胸水			MODERATE	NO	NO	36		NO	UNCHANGED
Enoxaparin/VKA	140164016	YES	UNITED STATES	WHITE	FEMALE	66	International normalised ratio increased	ＩＮＲ増加			MODERATE	NO	NO	81	3	NO	RESOLVED
Enoxaparin/VKA	140164016	YES	UNITED STATES	WHITE	FEMALE	66	Decreased appetite	食欲減退			MILD	NO	NO	81		NO	UNCHANGED
Rivaroxaban	140164040	YES	UNITED STATES	HISPANIC	FEMALE	48	Nausea	悪心	20 mg	.	MODERATE	YES	YES	28		NO	UNCHANGED
Rivaroxaban	140164040	YES	UNITED STATES	HISPANIC	FEMALE	48	Vomiting	嘔吐	20 mg	.	MODERATE	YES	YES	28		NO	UNCHANGED
Rivaroxaban	140164040	YES	UNITED STATES	HISPANIC	FEMALE	48	Cervix carcinoma	子宮頚部癌	20 mg	.	SEVERE	YES	YES	28	30	NO	DEATH
Rivaroxaban	140164040	YES	UNITED STATES	HISPANIC	FEMALE	48	Pain	疼痛	20 mg	.	SEVERE	NO	YES	31	27	NO	WORSENED
Rivaroxaban	140164040	YES	UNITED STATES	HISPANIC	FEMALE	48	Anaemia	貧血	20 mg	.	MODERATE	NO	YES	32	10	NO	IMPROVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	Nausea	悪心			MILD	NO	YES	38	50	NO	RESOLVED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	Vomiting	嘔吐			MILD	NO	YES	38	50	NO	RESOLVED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	Vaginal haemorrhage	膣出血			MODERATE	YES	NO	119	8	NO	RESOLVED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	Mental status changes	精神状態変化			MODERATE	NO	NO	119		NO	UNCHANGED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	Haematuria	血尿			MODERATE	YES	NO	120		NO	IMPROVED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	Renal failure acute	急性腎不全			SEVERE	YES	NO	120	47	NO	RESOLVED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	International normalised ratio increased	ＩＮＲ増加			MODERATE	YES	NO	120	5	NO	RESOLVED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	Hydronephrosis	水腎症			MODERATE	YES	NO	120	2	NO	RESOLVED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	Fatigue	疲労			MODERATE	NO	NO	120		NO	UNCHANGED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	Cervix carcinoma	子宮頚部癌			SEVERE	YES	NO	178	8	NO	DEATH
Enoxaparin/VKA	140314012	YES	UNITED STATES	WHITE	MALE	67	Sepsis	敗血症			SEVERE	YES	YES	6	18	NO	DEATH
Enoxaparin/VKA	140314012	YES	UNITED STATES	WHITE	MALE	67	Intestinal ischaemia	腸管虚血			MODERATE	NO	YES	10	8	NO	WORSENED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	140314012	YES	UNITED STATES	WHITE	MALE	67	Gastric ulcer perforation	穿孔性胃潰瘍			MODERATE	YES	YES	10	1	NO	RESOLVED
Enoxaparin/VKA	140314012	YES	UNITED STATES	WHITE	MALE	67	Post procedural haemorrhage	処置後出血			MODERATE	YES	NO	14	2	NO	RESOLVED
Enoxaparin/VKA	140314012	YES	UNITED STATES	WHITE	MALE	67	Thrombocytopenia	血小板減少症			MODERATE	NO	NO	14		NO	IMPROVED
Enoxaparin/VKA	140314012	YES	UNITED STATES	WHITE	MALE	67	Liver function test abnormal	肝機能検査異常			MODERATE	NO	NO	15		NO	UNCHANGED
Enoxaparin/VKA	140314012	YES	UNITED STATES	WHITE	MALE	67	Gastrointestinal necrosis	消化管壊死			SEVERE	YES	NO	17		NO	UNCHANGED
Enoxaparin/VKA	160104015	YES	FRANCE	N.A.	MALE	56	Chest X-ray abnormal	胸部Ｘ線異常			SEVERE	YES	YES	22		NO	UNCHANGED
Enoxaparin/VKA	160104015	YES	FRANCE	N.A.	MALE	56	Eczema	湿疹			SEVERE	NO	YES	80		NO	UNCHANGED
Enoxaparin/VKA	160104015	YES	FRANCE	N.A.	MALE	56	Insomnia	不眠症			MILD	NO	YES	133	152	NO	RESOLVED
Enoxaparin/VKA	160104015	YES	FRANCE	N.A.	MALE	56	Haemoptysis	喀血			MILD	NO	YES	270	7	NO	RESOLVED
Enoxaparin/VKA	160104015	YES	FRANCE	N.A.	MALE	56	Brain injury	脳損傷			MILD	NO	YES	274		NO	RESOLVED
Enoxaparin/VKA	160104015	YES	FRANCE	N.A.	MALE	56	Weight decreased	体重減少			MILD	NO	YES	305		NO	UNCHANGED
Enoxaparin/VKA	160104015	YES	FRANCE	N.A.	MALE	56	Constipation	便秘			MILD	NO	YES	305	24	NO	RESOLVED
Enoxaparin/VKA	160104015	YES	FRANCE	N.A.	MALE	56	Pneumonia bacterial	細菌性肺炎			SEVERE	YES	YES	313	32	NO	DEATH
Enoxaparin/VKA	160104015	YES	FRANCE	N.A.	MALE	56	Liver function test abnormal	肝機能検査異常			SEVERE	YES	YES	313	5	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160104020	YES	FRANCE	N.A.	FEMALE	58	Bronchitis	気管支炎	15 mg	.	MILD	NO	YES	3	8	NO	RESOLVED
Rivaroxaban	160104020	YES	FRANCE	N.A.	FEMALE	58	Rectal haemorrhage	直腸出血	20 mg	.	MILD	NO	YES	27	1	YES	RESOLVED
Rivaroxaban	160104020	YES	FRANCE	N.A.	FEMALE	58	Staphylococcal skin infection	ブドウ球菌皮膚感染	20 mg	.	MILD	NO	YES	150		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	160104020	YES	FRANCE	N.A.	FEMALE	58	Chest pain	胸痛	20 mg	.	MILD	YES	YES	166	11	NO	RESOLVED
Rivaroxaban	160104020	YES	FRANCE	N.A.	FEMALE	58	Abdominal pain	腹痛	20 mg	.	SEVERE	NO	YES	218		NO	UNCHANGED
Rivaroxaban	160104020	YES	FRANCE	N.A.	FEMALE	58	Pleural effusion	胸水	20 mg	.	MILD	YES	YES	219		NO	UNCHANGED
Rivaroxaban	160104020	YES	FRANCE	N.A.	FEMALE	58	Metastases to liver	肝転移	20 mg	.	SEVERE	YES	YES	246	30	NO	DEATH
Enoxaparin/VKA	160184002	YES	FRANCE	N.A.	MALE	57	Dermatitis exfoliative	剥脱性皮膚炎			MODERATE	YES	YES	95	8	NO	RESOLVED
Enoxaparin/VKA	160184002	YES	FRANCE	N.A.	MALE	57	International normalised ratio increased	ＩＮＲ増加			MILD	NO	YES	137	5	NO	RESOLVED
Enoxaparin/VKA	160184002	YES	FRANCE	N.A.	MALE	57	Anaemia	貧血			MILD	YES	YES	158	2	NO	RESOLVED
Enoxaparin/VKA	160184002	YES	FRANCE	N.A.	MALE	57	Fatigue	疲労			SEVERE	NO	YES	160		NO	WORSENED
Enoxaparin/VKA	160184002	YES	FRANCE	N.A.	MALE	57	Asthenia	無力症			SEVERE	NO	YES	160		NO	UNCHANGED
Enoxaparin/VKA	160184002	YES	FRANCE	N.A.	MALE	57	Septic shock	敗血症性ショック			SEVERE	YES	YES	166	2	NO	DEATH
Enoxaparin/VKA	160194013	YES	FRANCE	N.A.	MALE	81	Eczema	湿疹			MILD	NO	YES	2	12	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	160194013	YES	FRANCE	N.A.	MALE	81	Haemorrhage intracranial	頭蓋内出血			SEVERE	YES	YES	98	3	YES	DEATH
Enoxaparin/VKA	160264014	YES	FRANCE	N.A.	FEMALE	97	Insomnia	不眠症			MILD	NO	YES	2	18	NO	RESOLVED
Enoxaparin/VKA	160264014	YES	FRANCE	N.A.	FEMALE	97	Anaemia	貧血			MODERATE	YES	YES	3	3	NO	RESOLVED
Enoxaparin/VKA	160264014	YES	FRANCE	N.A.	FEMALE	97	Epilepsy	てんかん			SEVERE	YES	NO	13	25	NO	RESOLVED
Enoxaparin/VKA	160264014	YES	FRANCE	N.A.	FEMALE	97	General physical health deterioration	全身健康状態低下			SEVERE	YES	NO	14	24	NO	DEATH
Rivaroxaban	160294013	YES	FRANCE	N.A.	MALE	74	Haematoma	血腫	15 mg	.	MILD	NO	YES	2	33	NO	RESOLVED
Rivaroxaban	160294013	YES	FRANCE	N.A.	MALE	74	Haematuria	血尿	15 mg	.	MILD	NO	YES	4	2	NO	RESOLVED
Rivaroxaban	160294013	YES	FRANCE	N.A.	MALE	74	Rectal haemorrhage	直腸出血	15 mg	.	MILD	NO	YES	5	1	NO	RESOLVED
Rivaroxaban	160294013	YES	FRANCE	N.A.	MALE	74	Haematoma	血腫	20 mg	.	MILD	NO	YES	92		NO	RESOLVED
Rivaroxaban	160294013	YES	FRANCE	N.A.	MALE	74	Lung neoplasm	肺新生物	20 mg	F	SEVERE	YES	NO	201	6	NO	DEATH
Enoxaparin/VKA	180194001	YES	POLAND	WHITE	FEMALE	86	Cardiac arrest	心停止			SEVERE	YES	YES	4	1	NO	DEATH
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Respiratory failure	呼吸不全	20 mg	.	SEVERE	YES	YES	54	23	NO	RESOLVED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Constipation	便秘	20 mg	.	MILD	NO	YES	55	2	NO	RESOLVED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Pain	疼痛	20 mg	.	MODERATE	NO	YES	58	2	NO	RESOLVED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Nausea	悪心	20 mg	.	MILD	NO	YES	60	3	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Nausea	悪心	20 mg	.	MODERATE	NO	YES	69	2	NO	RESOLVED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Vomiting	嘔吐	20 mg	.	MODERATE	NO	YES	69	2	NO	RESOLVED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Constipation	便秘	20 mg	.	MILD	NO	YES	73	3	NO	RESOLVED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Fungal infection	真菌感染	20 mg	.	MODERATE	NO	YES	76	21	NO	RESOLVED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Constipation	便秘	20 mg	.	MODERATE	NO	YES	76	19	NO	RESOLVED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Breast cancer	乳癌	20 mg	F	SEVERE	YES	YES	95		NO	UNCHANGED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Respiratory failure	呼吸不全	20 mg	F	SEVERE	YES	YES	95	2	NO	DEATH
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Arrhythmia	不整脈	20 mg	F	SEVERE	YES	YES	95		NO	UNCHANGED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Hyperglycaemia	高血糖	20 mg	F	MODERATE	NO	YES	95	1	NO	RESOLVED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Anxiety	不安	20 mg	F	MODERATE	NO	YES	95	2	NO	RESOLVED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Metastases to lung	肺転移	20 mg	F	SEVERE	YES	YES	95		NO	UNCHANGED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Pain	疼痛	20 mg	F	SEVERE	NO	YES	95	2	NO	RESOLVED
Enoxaparin/VKA	220014021	YES	ITALY	WHITE	FEMALE	77	Interstitial lung disease	間質性肺疾患			SEVERE	YES	YES	89	8	NO	DEATH
Enoxaparin/VKA	220014021	YES	ITALY	WHITE	FEMALE	77	Oral candidiasis	口腔カンジダ症			MILD	NO	YES	89	3	NO	RESOLVED
Enoxaparin/VKA	220014021	YES	ITALY	WHITE	FEMALE	77	Anaemia	貧血			MILD	NO	YES	90	1	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	220014021	YES	ITALY	WHITE	FEMALE	77	Hyperglycaemia	高血糖			MODERATE	NO	YES	91	3	NO	RESOLVED
Enoxaparin/VKA	220014021	YES	ITALY	WHITE	FEMALE	77	Oedema	浮腫			MODERATE	NO	YES	91	5	NO	RESOLVED
Enoxaparin/VKA	220014021	YES	ITALY	WHITE	FEMALE	77	International normalised ratio increased	ＩＮＲ増加			MODERATE	NO	YES	92	3	NO	RESOLVED
Enoxaparin/VKA	220014021	YES	ITALY	WHITE	FEMALE	77	Pain	疼痛			MODERATE	NO	YES	92	4	NO	RESOLVED
Enoxaparin/VKA	220014021	YES	ITALY	WHITE	FEMALE	77	Hyperglycaemia	高血糖			MILD	NO	YES	95	1	NO	RESOLVED
Enoxaparin/VKA	220034002	YES	ITALY	WHITE	MALE	72	Tachycardia	頻脈			MILD	NO	YES	3	6	NO	IMPROVED
Enoxaparin/VKA	220034002	YES	ITALY	WHITE	MALE	72	Chest pain	胸痛			MILD	NO	YES	4	6	NO	RESOLVED
Enoxaparin/VKA	220034002	YES	ITALY	WHITE	MALE	72	Lung adenocarcinoma	肺腺癌			SEVERE	YES	YES	4		NO	UNCHANGED
Enoxaparin/VKA	220034002	YES	ITALY	WHITE	MALE	72	Haemothorax	血胸			SEVERE	YES	YES	8	2	YES	DEATH
Enoxaparin/VKA	220034002	YES	ITALY	WHITE	MALE	72	Tachycardia	頻脈			MILD	NO	YES	9		NO	UNCHANGED
Enoxaparin/VKA	220084048	YES	ITALY	WHITE	MALE	80	Constipation	便秘			MILD	NO	YES	101	1	NO	RESOLVED
Enoxaparin/VKA	220084048	YES	ITALY	WHITE	MALE	80	Renal cyst	腎嚢胞			MILD	NO	YES	101		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	220084048	YES	ITALY	WHITE	MALE	80	Completed suicide	自殺既遂			SEVERE	YES	YES	102	1	NO	DEATH

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	220094002	YES	ITALY	WHITE	MALE	81	Ischaemic stroke	虚血性脳卒中	20 mg	.	SEVERE	YES	YES	95	6	NO	DEATH
Rivaroxaban	220134002	YES	ITALY	WHITE	FEMALE	61	Ischaemic stroke	虚血性脳卒中	20 mg	.	MODERATE	YES	YES	32	8	NO	RESOLVED
Rivaroxaban	220134002	YES	ITALY	WHITE	FEMALE	61	Pyrexia	発熱	20 mg	.	MILD	YES	YES	51	14	NO	RESOLVED
Rivaroxaban	220134002	YES	ITALY	WHITE	FEMALE	61	Acute myocardial infarction	急性心筋梗塞	20 mg	.	SEVERE	YES	YES	57	13	NO	RESOLVED
Rivaroxaban	220134002	YES	ITALY	WHITE	FEMALE	61	Anaemia	貧血	20 mg	.	MODERATE	YES	YES	72	5	NO	RESOLVED
Rivaroxaban	220134002	YES	ITALY	WHITE	FEMALE	61	Renal failure acute	急性腎不全	20 mg	.	SEVERE	YES	YES	93	18	NO	DEATH
Rivaroxaban	220134004	YES	ITALY	WHITE	MALE	71	Haematuria	血尿	15 mg	.	MILD	NO	YES	5	8	YES	RESOLVED
Rivaroxaban	220134004	YES	ITALY	WHITE	MALE	71	Hepatic enzyme increased	肝酵素上昇	20 mg	.	MODERATE	YES	YES	27	22	NO	RESOLVED
Rivaroxaban	220134004	YES	ITALY	WHITE	MALE	71	Blood bilirubin increased	血中ビリルビン増加	20 mg	.	MODERATE	YES	YES	27	22	NO	RESOLVED
Rivaroxaban	220134004	YES	ITALY	WHITE	MALE	71	Bile duct stenosis	胆管狭窄	20 mg	F	SEVERE	NO	NO	41	1	NO	RESOLVED
Rivaroxaban	220134004	YES	ITALY	WHITE	MALE	71	Hepatic enzyme increased	肝酵素上昇	20 mg	F	MILD	NO	NO	49		YES	UNCHANGED
Rivaroxaban	220134004	YES	ITALY	WHITE	MALE	71	Blood bilirubin increased	血中ビリルビン増加	20 mg	F	MILD	NO	NO	49		YES	INSUFFICIENT FOLLOW-UP
Rivaroxaban	220134004	YES	ITALY	WHITE	MALE	71	Death	死亡	20 mg	F	SEVERE	YES	NO	58	1	NO	DEATH

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	220174008	YES	ITALY	WHITE	MALE	67	Colon cancer	結腸癌			MODERATE	NO	YES			NO	UNCHANGED
Rivaroxaban	220174008	YES	ITALY	WHITE	MALE	67	Haematuria	血尿	20 mg	.	MODERATE	NO	YES	48	2	YES	RESOLVED
Enoxaparin/VKA	260054001	YES	CANADA	WHITE	FEMALE	69	Tendon injury	腱損傷			MODERATE	NO	YES			NO	RESOLVED
Enoxaparin/VKA	260054001	YES	CANADA	WHITE	FEMALE	69	Contusion	挫傷			MODERATE	NO	YES	1	43	YES	RESOLVED
Enoxaparin/VKA	260054001	YES	CANADA	WHITE	FEMALE	69	Epistaxis	鼻出血			MILD	NO	YES	125	1	YES	RESOLVED
Enoxaparin/VKA	260054001	YES	CANADA	WHITE	FEMALE	69	Pneumonia	肺炎			MILD	NO	YES	168	14	NO	RESOLVED
Enoxaparin/VKA	260054001	YES	CANADA	WHITE	FEMALE	69	Pneumonia	肺炎			SEVERE	YES	YES	290	5	NO	DEATH
Enoxaparin/VKA	260054001	YES	CANADA	WHITE	FEMALE	69	Hyperkalaemia	高カリウム血症			MODERATE	NO	YES	290	3	NO	RESOLVED
Enoxaparin/VKA	260054001	YES	CANADA	WHITE	FEMALE	69	Cardiac failure congestive	うっ血性心不全			SEVERE	YES	YES	291		NO	UNCHANGED
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Liver function test abnormal	肝機能検査異常			SEVERE	YES	YES	25		NO	UNCHANGED
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Pancreatic carcinoma metastatic	転移性膵癌			SEVERE	YES	NO	27	14	NO	WORSENED
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Nausea	悪心			MILD	NO	NO	28		NO	UNCHANGED
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Hyponatraemia	低ナトリウム血症			MILD	NO	NO	28		NO	UNCHANGED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Tachycardia	頻脈			MILD	NO	NO	28	5	NO	RESOLVED
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Cough	咳嗽			MILD	NO	NO	29		NO	UNCHANGED
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Vomiting	嘔吐			MILD	NO	NO	29		NO	UNCHANGED
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Upper gastrointestinal haemorrhage	上部消化管出血			SEVERE	YES	NO	41	3	NO	RESOLVED
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Pancreatic carcinoma metastatic	転移性膵癌			SEVERE	YES	NO	41	16	NO	DEATH
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Oedema	浮腫			MODERATE	NO	NO	41		NO	UNCHANGED
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Hypokalaemia	低カリウム血症			MILD	NO	NO	44	2	NO	RESOLVED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Epistaxis	鼻出血			MILD	NO	YES	1	43	YES	RESOLVED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Lymphadenopathy mediastinal	縦隔リンパ節腫脹			SEVERE	YES	YES	2	22	NO	WORSENED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪			MODERATE	NO	YES	3	19	NO	RESOLVED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Metastatic squamous cell carcinoma	転移性扁平上皮癌			SEVERE	YES	YES	23		NO	IMPROVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪			MODERATE	NO	YES	47	9	NO	IMPROVED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Epistaxis	鼻出血			MILD	NO	YES	77		YES	RESOLVED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪			SEVERE	YES	YES	86	27	NO	IMPROVED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪			MODERATE	NO	YES	132	15	NO	WORSENED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Radiation pneumonitis	放射線性肺臓炎			SEVERE	YES	NO	147		NO	UNCHANGED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Lung infection	肺感染			SEVERE	YES	NO	147	24	NO	DEATH
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Thrombocytopenia	血小板減少症			SEVERE	YES	NO	151		NO	UNCHANGED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Sepsis	敗血症			SEVERE	YES	NO	155		NO	UNCHANGED
Rivaroxaban	300064024	YES	NETHERLANDS	WHITE	FEMALE	67	Anaemia	貧血			SEVERE	NO	YES			YES	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	300064024	YES	NETHERLANDS	WHITE	FEMALE	67	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	20 mg	.	MILD	NO	YES	66		NO	UNCHANGED
Rivaroxaban	300064024	YES	NETHERLANDS	WHITE	FEMALE	67	Arthralgia	関節痛	20 mg	.	SEVERE	YES	YES	89		NO	UNCHANGED
Rivaroxaban	300064024	YES	NETHERLANDS	WHITE	FEMALE	67	Duodenal ulcer	十二指腸潰瘍	20 mg	.	MILD	NO	YES	89		YES	UNCHANGED
Rivaroxaban	300064024	YES	NETHERLANDS	WHITE	FEMALE	67	Constipation	便秘	20 mg	F	MILD	NO	YES	90	4	NO	RESOLVED
Rivaroxaban	300064024	YES	NETHERLANDS	WHITE	FEMALE	67	Constipation	便秘	20 mg	F	MILD	NO	NO	96	3	NO	RESOLVED
Rivaroxaban	300064024	YES	NETHERLANDS	WHITE	FEMALE	67	Rectal cancer	直腸癌	20 mg	F	SEVERE	NO	NO	103		NO	UNCHANGED
Rivaroxaban	300064024	YES	NETHERLANDS	WHITE	FEMALE	67	Abscess limb	四肢膿瘍	20 mg	F	MODERATE	NO	NO	104	2	NO	RESOLVED
Rivaroxaban	300064024	YES	NETHERLANDS	WHITE	FEMALE	67	Metabolic acidosis	代謝性アシドーシス	20 mg	F	MODERATE	NO	NO	105		NO	UNCHANGED
Rivaroxaban	300064024	YES	NETHERLANDS	WHITE	FEMALE	67	Abdominal sepsis	腹部敗血症	20 mg	F	MODERATE	NO	NO	105		NO	UNCHANGED
Rivaroxaban	300064024	YES	NETHERLANDS	WHITE	FEMALE	67	Respiratory failure	呼吸不全	20 mg	F	MODERATE	NO	NO	105		NO	UNCHANGED
Rivaroxaban	300064024	YES	NETHERLANDS	WHITE	FEMALE	67	Death	死亡	20 mg	F	SEVERE	YES	NO	108	1	NO	DEATH
Enoxaparin/VKA	300074100	YES	NETHERLANDS	WHITE	MALE	81	Lower respiratory tract infection	下気道感染			MODERATE	YES	YES	6	19	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	300074100	YES	NETHERLANDS	WHITE	MALE	81	Blood glucose increased	血中ブドウ糖増加			MILD	NO	YES	6		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	300074100	YES	NETHERLANDS	WHITE	MALE	81	International normalised ratio increased	ＩＮＲ増加			MILD	NO	YES	24	7	YES	RESOLVED
Enoxaparin/VKA	300074100	YES	NETHERLANDS	WHITE	MALE	81	Respiratory tract infection	気道感染			SEVERE	YES	YES	29	3	NO	DEATH
Rivaroxaban	300074111	YES	NETHERLANDS	WHITE	FEMALE	65	Pancreatic carcinoma	膵癌	15 mg	.	SEVERE	YES	YES	20	4	NO	DEATH
Enoxaparin/VKA	300074126	YES	NETHERLANDS	WHITE	FEMALE	79	Pneumonia	肺炎			MILD	NO	YES	14	8	NO	RESOLVED
Enoxaparin/VKA	300074126	YES	NETHERLANDS	WHITE	FEMALE	79	Large cell carcinoma of the respiratory tract stage unspecified	呼吸器大細胞癌、病期不明			SEVERE	YES	YES	20	36	NO	DEATH
Enoxaparin/VKA	300074203	YES	NETHERLANDS	WHITE	FEMALE	91	Cervix carcinoma	子宮頚部癌			SEVERE	YES	YES	10	11	NO	DEATH
Enoxaparin/VKA	300074203	YES	NETHERLANDS	WHITE	FEMALE	91	Dermatitis	皮膚炎			MILD	NO	YES	10	10	NO	RESOLVED
Enoxaparin/VKA	300074223	YES	NETHERLANDS	WHITE	FEMALE	30	Folate deficiency	葉酸欠乏			MODERATE	NO	YES			NO	UNCHANGED
Enoxaparin/VKA	300074223	YES	NETHERLANDS	WHITE	FEMALE	30	Depression	うつ病			MODERATE	NO	YES			NO	UNCHANGED
Enoxaparin/VKA	300074223	YES	NETHERLANDS	WHITE	FEMALE	30	Traumatic haematoma	外傷性血腫			MILD	NO	YES	6		YES	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	300074223	YES	NETHERLANDS	WHITE	FEMALE	30	Cerebral toxoplasmosis	脳トキソプラズマ症			SEVERE	YES	YES	17	132	NO	DEATH
Enoxaparin/VKA	300074223	YES	NETHERLANDS	WHITE	FEMALE	30	Hypokalaemia	低カリウム血症			MODERATE	NO	NO	25	57	NO	RESOLVED
Enoxaparin/VKA	300074223	YES	NETHERLANDS	WHITE	FEMALE	30	Post procedural haemorrhage	処置後出血			MILD	NO	NO	38		YES	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	300074223	YES	NETHERLANDS	WHITE	FEMALE	30	Anxiety	不安			SEVERE	NO	NO	51	31	NO	RESOLVED
Enoxaparin/VKA	300074223	YES	NETHERLANDS	WHITE	FEMALE	30	Anaemia megaloblastic	巨赤芽球性貧血			MODERATE	NO	NO	57		NO	UNCHANGED
Rivaroxaban	370024021	YES	SOUTH AFRICA	BLACK	FEMALE	53	Abdominal pain	腹痛	15 mg	.	MODERATE	NO	YES	6	1	NO	RESOLVED
Rivaroxaban	370024021	YES	SOUTH AFRICA	BLACK	FEMALE	53	Vaginal haemorrhage	膣出血	15 mg	.	MODERATE	NO	YES	19		YES	INSUFFICIENT FOLLOW-UP
Rivaroxaban	370024021	YES	SOUTH AFRICA	BLACK	FEMALE	53	Cervix carcinoma	子宮頚部癌	20 mg	F	SEVERE	YES	YES	24	1	NO	DEATH
Enoxaparin/VKA	370044001	YES	SOUTH AFRICA	WHITE	FEMALE	80	Nausea	悪心			MILD	NO	YES	2	13	NO	RESOLVED
Enoxaparin/VKA	370044001	YES	SOUTH AFRICA	WHITE	FEMALE	80	International normalised ratio increased	ＩＮＲ増加			MODERATE	NO	YES	4	7	NO	RESOLVED
Enoxaparin/VKA	370044001	YES	SOUTH AFRICA	WHITE	FEMALE	80	Lung neoplasm malignant	肺の悪性新生物			MODERATE	YES	YES	8	41	NO	WORSENED
Enoxaparin/VKA	370044001	YES	SOUTH AFRICA	WHITE	FEMALE	80	Insomnia	不眠症			MILD	NO	YES	29	25	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370044001	YES	SOUTH AFRICA	WHITE	FEMALE	80	Lung neoplasm malignant	肺の悪性新生物			SEVERE	YES	YES	49	6	NO	DEATH
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Fistula discharge	瘻孔分泌物			MODERATE	NO	YES			NO	UNCHANGED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Abdominal pain	腹痛	20 mg	.	MILD	YES	YES	37	20	NO	RESOLVED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Haemoglobin decreased	ヘモグロビン減少	20 mg	.	MODERATE	NO	YES	39	5	NO	RESOLVED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Contusion	挫傷	20 mg	.	MILD	NO	YES	41		NO	RESOLVED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Constipation	便秘	20 mg	.	MILD	NO	YES	52	1	NO	RESOLVED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Enterocutaneous fistula	腸管皮膚瘻	20 mg	.	SEVERE	YES	YES	75		NO	UNCHANGED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Wound infection	創傷感染	20 mg	.	MODERATE	NO	YES	88	16	NO	RESOLVED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Haemoglobin decreased	ヘモグロビン減少	20 mg	.	MODERATE	NO	YES	99	6	NO	RESOLVED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Nausea	悪心	20 mg	.	MILD	NO	YES	101	1	NO	RESOLVED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Procedural pain	処置による疼痛	20 mg	.	MODERATE	NO	YES	107	6	NO	RESOLVED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Anxiety	不安	20 mg	.	MILD	NO	YES	107	4	NO	RESOLVED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Mood swings	気分動揺	20 mg	.	MILD	NO	YES	108	3	NO	RESOLVED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Headache	頭痛	20 mg	.	MILD	NO	YES	108	3	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Oral candidiasis	口腔カンジダ症	20 mg	.	MILD	NO	YES	108	5	NO	RESOLVED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Sepsis	敗血症	20 mg	.	SEVERE	YES	YES	110	3	NO	DEATH
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Haemoglobin decreased	ヘモグロビン減少	20 mg	.	MODERATE	NO	YES	110	3	NO	RESOLVED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Multi-organ failure	多臓器不全	20 mg	.	SEVERE	YES	YES	111	2	NO	DEATH
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Hypotension	低血圧	20 mg	.	SEVERE	NO	YES	111		NO	UNCHANGED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Anuria	無尿	20 mg	.	SEVERE	YES	YES	111	1	NO	RESOLVED
Enoxaparin/VKA	370104001	YES	SOUTH AFRICA	WHITE	FEMALE	81	Myocardial infarction	心筋梗塞			SEVERE	YES	YES	43	1	NO	DEATH
Rivaroxaban	380064028	YES	CZECH REPUBLIC	WHITE	FEMALE	82	Cerebral arteriosclerosis	脳動脈硬化症	15 mg	.	MODERATE	YES	YES	14	12	NO	IMPROVED
Rivaroxaban	380064028	YES	CZECH REPUBLIC	WHITE	FEMALE	82	Pleural effusion	胸水	15 mg	.	MILD	NO	YES	17		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	380064028	YES	CZECH REPUBLIC	WHITE	FEMALE	82	Hepatic cancer metastatic	転移性肝癌	15 mg	F	SEVERE	YES	YES	21	13	NO	DEATH
Rivaroxaban	380064028	YES	CZECH REPUBLIC	WHITE	FEMALE	82	Cerebral arteriosclerosis	脳動脈硬化症	15 mg	F	MILD	NO	NO	26		NO	UNCHANGED
Enoxaparin/VKA	380074018	YES	CZECH REPUBLIC	WHITE	FEMALE	84	Hypercoagulation	凝固亢進			MILD	NO	YES	1		NO	UNCHANGED
Enoxaparin/VKA	380074018	YES	CZECH REPUBLIC	WHITE	FEMALE	84	Cholelithiasis	胆石症			MILD	NO	YES	27		NO	UNCHANGED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	380074018	YES	CZECH REPUBLIC	WHITE	FEMALE	84	Renal failure chronic	慢性腎不全			MILD	NO	YES	27		NO	UNCHANGED
Enoxaparin/VKA	380074018	YES	CZECH REPUBLIC	WHITE	FEMALE	84	Sudden death	突然死			SEVERE	YES	YES	103	1	NO	DEATH
Rivaroxaban	380094016	YES	CZECH REPUBLIC	WHITE	MALE	73	Nephrogenic anaemia	腎性貧血	15 mg	.	MILD	NO	YES	2		NO	UNCHANGED
Rivaroxaban	380094016	YES	CZECH REPUBLIC	WHITE	MALE	73	Cardiac failure	心不全	20 mg	.	SEVERE	YES	YES	32	4	NO	DEATH
Rivaroxaban	380094038	YES	CZECH REPUBLIC	WHITE	MALE	73	Enterocolitis bacterial	細菌性腸炎	15 mg	.	MODERATE	NO	YES	3	10	NO	RESOLVED
Rivaroxaban	380094038	YES	CZECH REPUBLIC	WHITE	MALE	73	General physical health deterioration	全身健康状態低下	20 mg	.	MILD	NO	YES	255		NO	UNCHANGED
Rivaroxaban	380094038	YES	CZECH REPUBLIC	WHITE	MALE	73	Bronchopneumonia	気管支肺炎	20 mg	.	SEVERE	YES	YES	311	4	NO	DEATH
Enoxaparin/VKA	390014021	YES	ISRAEL	WHITE	FEMALE	76	Urinary incontinence	尿失禁			MILD	NO	YES	8		NO	IMPROVED
Enoxaparin/VKA	390014021	YES	ISRAEL	WHITE	FEMALE	76	Haematoma	血腫			MILD	NO	YES	46	14	NO	RESOLVED
Enoxaparin/VKA	390014021	YES	ISRAEL	WHITE	FEMALE	76	Pulmonary oedema	肺水腫			MODERATE	NO	YES	128	1	NO	WORSENED
Enoxaparin/VKA	390014021	YES	ISRAEL	WHITE	FEMALE	76	Pulmonary oedema	肺水腫			MODERATE	YES	YES	129	5	NO	RESOLVED
Enoxaparin/VKA	390014021	YES	ISRAEL	WHITE	FEMALE	76	Ischaemic stroke	虚血性脳卒中			SEVERE	YES	NO	201	3	NO	DEATH
Enoxaparin/VKA	390014025	YES	ISRAEL	WHITE	MALE	75	General physical health	全身健康状態低下			MODERATE	NO	YES	104		NO	UNCHANGED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							deterioration										
Enoxaparin/VKA	390014025	YES	ISRAEL	WHITE	MALE	75	Dyspnoea	呼吸困難			MILD	NO	YES	126	8	NO	WORSENED
Enoxaparin/VKA	390014025	YES	ISRAEL	WHITE	MALE	75	Dyspnoea	呼吸困難			MODERATE	YES	YES	134	11	NO	WORSENED
Enoxaparin/VKA	390014025	YES	ISRAEL	WHITE	MALE	75	Post procedural haemorrhage	処置後出血			MODERATE	NO	NO	137	1	YES	RESOLVED
Enoxaparin/VKA	390014025	YES	ISRAEL	WHITE	MALE	75	Dyspnoea	呼吸困難			SEVERE	NO	NO	145		NO	UNCHANGED
Enoxaparin/VKA	390014025	YES	ISRAEL	WHITE	MALE	75	Metastases to lung	肺転移			SEVERE	YES	NO	150	5	NO	DEATH
Enoxaparin/VKA	390014025	YES	ISRAEL	WHITE	MALE	75	Metastases to liver	肝転移			SEVERE	YES	NO	150	5	NO	DEATH
Enoxaparin/VKA	390034009	YES	ISRAEL	WHITE	FEMALE	58	Hypertension	高血圧			MILD	NO	YES	1	7	NO	RESOLVED
Enoxaparin/VKA	390034009	YES	ISRAEL	WHITE	FEMALE	58	Leukocytosis	白血球増加症			MILD	NO	YES	2		NO	UNCHANGED
Enoxaparin/VKA	390034009	YES	ISRAEL	WHITE	FEMALE	58	Pulmonary infarction	肺梗塞			MILD	NO	YES	2		NO	UNCHANGED
Enoxaparin/VKA	390034009	YES	ISRAEL	WHITE	FEMALE	58	Cellulitis	蜂巣炎			MODERATE	NO	YES	3		NO	IMPROVED
Enoxaparin/VKA	390034009	YES	ISRAEL	WHITE	FEMALE	58	Hepatic neoplasm malignant	肝の悪性新生物			SEVERE	YES	YES	7	46	NO	DEATH
Enoxaparin/VKA	390034009	YES	ISRAEL	WHITE	FEMALE	58	Pleural effusion	胸水			MILD	NO	YES	8		NO	UNCHANGED
Enoxaparin/V	390034009	YES	ISRAEL	WHITE	FEMALE	58	Headache	頭痛			MILD	NO	NO	13	1	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA																	
Enoxaparin/VKA	390034009	YES	ISRAEL	WHITE	FEMALE	58	Hypertension	高血圧			MILD	NO	NO	14	1	NO	RESOLVED
Enoxaparin/VKA	390034009	YES	ISRAEL	WHITE	FEMALE	58	Colonic polyp	結腸ポリープ			MILD	NO	NO	14		NO	UNCHANGED
Enoxaparin/VKA	390034009	YES	ISRAEL	WHITE	FEMALE	58	Haemorrhoids	痔核			MILD	NO	NO	14		NO	UNCHANGED
Rivaroxaban	390044001	YES	ISRAEL	WHITE	FEMALE	79	Diarrhoea	下痢	15 mg	.	MILD	NO	YES	4	1	NO	RESOLVED
Rivaroxaban	390044001	YES	ISRAEL	WHITE	FEMALE	79	Cellulitis	蜂巣炎	15 mg	.	MILD	NO	YES	7	4	NO	RESOLVED
Rivaroxaban	390044001	YES	ISRAEL	WHITE	FEMALE	79	Pneumonia	肺炎	15 mg	.	MILD	NO	YES	7	4	NO	RESOLVED
Rivaroxaban	390044001	YES	ISRAEL	WHITE	FEMALE	79	Sudden cardiac death	心突然死	20 mg	.	SEVERE	YES	YES	44	1	NO	DEATH
Enoxaparin/VKA	400034028	YES	AUSTRALIA	WHITE	MALE	62	Dyspnoea	呼吸困難			MODERATE	YES	NO	174	8	NO	RESOLVED
Enoxaparin/VKA	400034028	YES	AUSTRALIA	WHITE	MALE	62	Lung neoplasm malignant	肺の悪性新生物			SEVERE	YES	NO	203	1	NO	DEATH
Rivaroxaban	400034031	YES	AUSTRALIA	WHITE	FEMALE	86	Cholangitis	胆管炎	15 mg	.	MODERATE	YES	YES	7	7	NO	RESOLVED
Rivaroxaban	400034031	YES	AUSTRALIA	WHITE	FEMALE	86	Nausea	悪心	15 mg	.	MODERATE	NO	YES	14		NO	UNCHANGED
Rivaroxaban	400034031	YES	AUSTRALIA	WHITE	FEMALE	86	Vomiting	嘔吐	15 mg	.	MODERATE	NO	YES	14		NO	UNCHANGED
Rivaroxaban	400034031	YES	AUSTRALIA	WHITE	FEMALE	86	Pancreatic carcinoma	膵癌	20 mg	.	SEVERE	YES	YES	27	13	NO	DEATH
Rivaroxaban	400034031	YES	AUSTRALIA	WHITE	FEMALE	86	Gastrooesophageal reflux disease	胃食道逆流性疾患	20 mg	.	MODERATE	NO	YES	33	6	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	400034031	YES	AUSTRALIA	WHITE	FEMALE	86	Oral candidiasis	口腔カンジダ症	20 mg	.	MILD	NO	YES	36	3	NO	RESOLVED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Catheter site infection	カテーテル留置部位感染			MILD	NO	YES	13	7	NO	RESOLVED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Oesophageal carcinoma	食道癌			SEVERE	YES	YES	13		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Gastric ulcer	胃潰瘍			MODERATE	NO	YES	27		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Malnutrition	栄養障害			MILD	NO	YES	27		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加			MILD	NO	YES	27		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Contusion	挫傷			MILD	NO	YES	70		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Dizziness	浮動性めまい			MILD	NO	NO	78	12	NO	RESOLVED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Venous thrombosis limb	四肢静脈血栓症			MODERATE	NO	NO	78		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Hypotension	低血圧			SEVERE	YES	NO	85		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Escherichia sepsis	大腸菌性敗血症			SEVERE	YES	NO	96	3	NO	DEATH
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Lobar pneumonia	大葉性肺炎			SEVERE	YES	NO	96		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Dizziness	浮動性めまい			MODERATE	NO	NO	96		NO	UNCHANGED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Hypovolaemia	血液量減少症			MODERATE	NO	NO	96		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Atrial fibrillation	心房細動			MODERATE	NO	NO	96		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加			MODERATE	NO	NO	96		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MODERATE	NO	NO	96		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Acute hepatic failure	急性肝不全			SEVERE	YES	NO	96		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Pleural effusion	胸水			MODERATE	NO	NO	96		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Blood bilirubin increased	血中ビリルビン増加			MILD	NO	NO	97		NO	UNCHANGED
Enoxaparin/VKA	400094008	YES	AUSTRALIA	ASIAN	FEMALE	66	Ascites	腹水			SEVERE	NO	YES			NO	UNCHANGED
Enoxaparin/VKA	400094008	YES	AUSTRALIA	ASIAN	FEMALE	66	Iron deficiency	鉄欠乏			MODERATE	NO	NO	1		NO	UNCHANGED
Enoxaparin/VKA	400094008	YES	AUSTRALIA	ASIAN	FEMALE	66	Upper respiratory tract infection	上気道感染			MODERATE	NO	YES	8	8	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400094008	YES	AUSTRALIA	ASIAN	FEMALE	66	Pancreatic carcinoma metastatic	転移性膵癌			SEVERE	YES	NO	95	43	NO	DEATH
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Contusion	挫傷			MILD	NO	YES	15		YES	IMPROVED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Rash	発疹			MILD	NO	YES	16	1	NO	RESOLVED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Lung adenocarcinoma	肺腺癌			MODERATE	YES	YES	27		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Atrial fibrillation	心房細動			MODERATE	YES	YES	33	3	NO	RESOLVED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Nausea	悪心			MILD	NO	YES	33		NO	IMPROVED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Vomiting	嘔吐			MILD	NO	YES	33	1	NO	RESOLVED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Ischaemic stroke	虚血性脳卒中			SEVERE	YES	YES	34		NO	UNCHANGED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Headache	頭痛			MODERATE	NO	YES	34	1	NO	RESOLVED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Catheter site haemorrhage	カテーテル留置部位出血			MILD	NO	YES	36	1	NO	RESOLVED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Cardiac valve vegetation	心臓弁疣贅			MODERATE	YES	YES	36		NO	UNCHANGED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Catheter site haemorrhage	カテーテル留置部位出血			MILD	NO	YES	36	1	NO	RESOLVED
Enoxaparin/V	400204011	YES	AUSTRALI	WHITE	MALE	63	Constipation	便秘			MILD	NO	NO	38	1	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA			A														
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Dizziness	浮動性めまい			SEVERE	YES	NO	60		NO	UNCHANGED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Headache	頭痛			MODERATE	NO	NO	60		NO	UNCHANGED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Vomiting	嘔吐			MILD	NO	NO	60	1	NO	RESOLVED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Cardiac arrest	心停止			SEVERE	YES	NO	61	1	NO	DEATH
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Epiglottitis	喉頭蓋炎			MODERATE	NO	YES			NO	RESOLVED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪	15 mg	.	MODERATE	NO	YES	7	15	NO	RESOLVED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Pyrexia	発熱	20 mg	.	SEVERE	YES	YES	53	9	NO	RESOLVED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Oral candidiasis	口腔カンジダ症	20 mg	.	MODERATE	NO	YES	53	8	NO	RESOLVED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Leukopenia	白血球減少症	20 mg	.	SEVERE	NO	YES	53	7	NO	RESOLVED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Basedow's disease	バセドウ病	20 mg	.	MODERATE	YES	YES	182	7	NO	RESOLVED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Diarrhoea	下痢	20 mg	F	MODERATE	NO	NO	196		NO	UNCHANGED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Large	大腸穿孔	20 mg	F	SEVERE	YES	NO	198	3	NO	DEATH

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							intestine perforation										
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Ascites	腹水	20 mg	F	SEVERE	NO	NO	198		NO	UNCHANGED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Pyloric stenosis	幽門狭窄	20 mg	F	SEVERE	NO	NO	198		NO	UNCHANGED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Metastases to peritoneum	腹膜転移	20 mg	F	SEVERE	YES	NO	198		NO	UNCHANGED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Vomiting	嘔吐	20 mg	F	SEVERE	NO	NO	198	1	NO	WORSENED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Abdominal pain	腹痛	20 mg	F	SEVERE	NO	NO	198		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Ovarian cancer	卵巣癌	20 mg	F	SEVERE	YES	NO	198		NO	UNCHANGED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Gastric ulcer haemorrhage	出血性胃潰瘍	20 mg	F	MODERATE	NO	NO	200		NO	UNCHANGED
Enoxaparin/VKA	460094046	YES	HUNGARY	WHITE	FEMALE	65	Peripheral embolism	末梢血管塞栓症			SEVERE	YES	YES	5	14	NO	RESOLVED
Enoxaparin/VKA	460094046	YES	HUNGARY	WHITE	FEMALE	65	Pneumonia	肺炎			SEVERE	YES	YES	41	10	NO	DEATH
Rivaroxaban	460104010	YES	HUNGARY	WHITE	MALE	59	Lung neoplasm malignant	肺の悪性新生物	20 mg	.	SEVERE	YES	YES	23	11	NO	DEATH
Rivaroxaban	460104021	YES	HUNGARY	WHITE	FEMALE	65	Breast cancer metastatic	転移性乳癌	15 mg	.	MODERATE	YES	YES	15		NO	IMPROVED
Rivaroxaban	460104021	YES	HUNGARY	WHITE	FEMALE	65	Haemoptysis	喀血	15 mg	.	MILD	NO	YES	15	6	NO	RESOLVED
Rivaroxaban	460104021	YES	HUNGARY	WHITE	FEMALE	65	Hypoglycaemia	低血糖症	20 mg	.	MODERATE	NO	YES	105	1	NO	RESOLVED
Rivaroxaban	460104021	YES	HUNGARY	WHITE	FEMALE	65	Metastatic neoplasm	転移性新生物	20 mg	.	SEVERE	YES	YES	133	4	NO	DEATH

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	500024008	YES	BRAZIL	WHITE	MALE	56	Pulmonary embolism	肺塞栓症	20 mg	F	SEVERE	YES	YES	44	32	NO	DEATH
Rivaroxaban	500024008	YES	BRAZIL	WHITE	MALE	56	Nausea	悪心	20 mg	F	MILD	NO	NO	74	2	NO	RESOLVED
Rivaroxaban	500024008	YES	BRAZIL	WHITE	MALE	56	Anxiety	不安	20 mg	F	MILD	NO	NO	74	1	NO	RESOLVED
Rivaroxaban	500024008	YES	BRAZIL	WHITE	MALE	56	Pancreatic carcinoma	膵癌	20 mg	F	SEVERE	YES	NO	75		NO	UNCHANGED
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Pyrexia	発熱	15 mg	.	MODERATE	NO	YES	4	1	NO	RESOLVED
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Pneumonia	肺炎	15 mg	.	MODERATE	YES	YES	4		NO	UNCHANGED
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Dermatitis	皮膚炎	15 mg	.	MILD	NO	YES	4		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Pleural effusion	胸水	15 mg	.	MODERATE	NO	YES	5	1	NO	WORSENED
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Breast cancer	乳癌	15 mg	.	SEVERE	YES	YES	5	21	NO	DEATH
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Pleural effusion	胸水	15 mg	.	MODERATE	NO	YES	6		NO	UNCHANGED
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Nausea	悪心	15 mg	.	MILD	NO	YES	9	5	NO	RESOLVED
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Haemoptysis	喀血	15 mg	.	MILD	NO	YES	11	1	NO	RESOLVED
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Pleural effusion	胸水	15 mg	.	MODERATE	NO	YES	11		NO	UNCHANGED
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Tachycardia	頻脈	15 mg	.	MILD	NO	YES	16		NO	UNCHANGED
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Alanine aminotransferase increased	アラニン・アミノトランスフェラ	15 mg	.	MILD	NO	YES	16		NO	UNCHANGED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
								ーゼ増加									
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	15 mg	.	MILD	NO	YES	16		NO	UNCHANGED
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Oral candidiasis	口腔カンジダ症	15 mg	.	MILD	NO	YES	20		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Respiratory failure	呼吸不全	20 mg	F	SEVERE	NO	YES	24		NO	UNCHANGED
Enoxaparin/VKA	500114001	YES	BRAZIL	WHITE	FEMALE	76	Pain in extremity	四肢痛			MILD	NO	YES	4	1	NO	RESOLVED
Enoxaparin/VKA	500114001	YES	BRAZIL	WHITE	FEMALE	76	Hypovitaminosis	ビタミン欠乏症			MILD	NO	YES	9		NO	UNCHANGED
Enoxaparin/VKA	500114001	YES	BRAZIL	WHITE	FEMALE	76	Cough	咳嗽			MILD	NO	YES	9		NO	UNCHANGED
Enoxaparin/VKA	500114001	YES	BRAZIL	WHITE	FEMALE	76	Therapeutic agent toxicity	治療薬毒性			MODERATE	YES	YES	15		YES	UNCHANGED
Enoxaparin/VKA	500114001	YES	BRAZIL	WHITE	FEMALE	76	Pulmonary embolism	肺塞栓症			SEVERE	YES	NO	18	1	NO	DEATH
Enoxaparin/VKA	500114001	YES	BRAZIL	WHITE	FEMALE	76	Gingival bleeding	歯肉出血			MILD	NO	NO	18	1	NO	RESOLVED
Enoxaparin/VKA	540024030	YES	CHINA	ASIAN	FEMALE	87	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加			MODERATE	NO	NO	1		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	540024030	YES	CHINA	ASIAN	FEMALE	87	Abdominal distension	腹部膨満			MILD	NO	YES	2	3	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	540024030	YES	CHINA	ASIAN	FEMALE	87	Prothrombin time prolonged	プロトロンビン時間延長			MODERATE	NO	YES	5	2	YES	RESOLVED
Enoxaparin/VKA	540024030	YES	CHINA	ASIAN	FEMALE	87	Intestinal haemorrhage	腸出血			MODERATE	NO	YES	8		YES	UNCHANGED
Enoxaparin/VKA	540024030	YES	CHINA	ASIAN	FEMALE	87	Metabolic acidosis	代謝性アシドーシス			SEVERE	NO	YES	8	2	NO	RESOLVED
Enoxaparin/VKA	540024030	YES	CHINA	ASIAN	FEMALE	87	Hyperbilirubinaemia	高ビリルビン血症			MODERATE	NO	YES	8		YES	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	540024030	YES	CHINA	ASIAN	FEMALE	87	Hyponatraemia	低ナトリウム血症			SEVERE	NO	YES	8	2	NO	RESOLVED
Enoxaparin/VKA	540024030	YES	CHINA	ASIAN	FEMALE	87	Oliguria	乏尿			MODERATE	NO	NO	10		NO	UNCHANGED
Enoxaparin/VKA	540024030	YES	CHINA	ASIAN	FEMALE	87	Pyrexia	発熱			MILD	NO	NO	11	1	NO	RESOLVED
Enoxaparin/VKA	540024030	YES	CHINA	ASIAN	FEMALE	87	Platelet count decreased	血小板数減少			SEVERE	NO	NO	11		YES	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	540024030	YES	CHINA	ASIAN	FEMALE	87	Hyponatraemia	低ナトリウム血症			SEVERE	NO	NO	11	3	NO	RESOLVED
Enoxaparin/VKA	540024030	YES	CHINA	ASIAN	FEMALE	87	Metabolic acidosis	代謝性アシドーシス			SEVERE	NO	NO	11		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	540024030	YES	CHINA	ASIAN	FEMALE	87	Multi-organ failure	多臓器不全			SEVERE	YES	NO	14	1	YES	DEATH
Enoxaparin/VKA	540024033	YES	CHINA	ASIAN	FEMALE	75	Cholangitis	胆管炎			MODERATE	NO	YES	9	2	NO	RESOLVED
Enoxaparin/V	540024033	YES	CHINA	ASIAN	FEMALE	75	Constipation	便秘			MILD	NO	YES	9	6	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA																	
Enoxaparin/VKA	540024033	YES	CHINA	ASIAN	FEMALE	75	Jaundice cholestatic	胆汁うっ滞性黄疸			SEVERE	YES	YES	19		NO	UNCHANGED
Enoxaparin/VKA	540024033	YES	CHINA	ASIAN	FEMALE	75	Hepatic failure	肝不全			SEVERE	YES	NO	53	2	NO	DEATH
Enoxaparin/VKA	540034007	YES	CHINA	ASIAN	FEMALE	52	Cervix carcinoma	子宮頚部癌			SEVERE	YES	YES	80	1	NO	DEATH
Enoxaparin/VKA	540064016	YES	CHINA	ASIAN	MALE	62	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加			MODERATE	NO	YES	1		NO	UNCHANGED
Enoxaparin/VKA	540064016	YES	CHINA	ASIAN	MALE	62	Cough	咳嗽			MILD	NO	YES	8		NO	UNCHANGED
Enoxaparin/VKA	540064016	YES	CHINA	ASIAN	MALE	62	Tachycardia	頻脈			MODERATE	NO	YES	8		NO	UNCHANGED
Enoxaparin/VKA	540064016	YES	CHINA	ASIAN	MALE	62	Pyrexia	発熱			MILD	NO	YES	11	5	NO	RESOLVED
Enoxaparin/VKA	540064016	YES	CHINA	ASIAN	MALE	62	Petechiae	点状出血			MILD	NO	YES	13		YES	UNCHANGED
Enoxaparin/VKA	540064016	YES	CHINA	ASIAN	MALE	62	Insomnia	不眠症			MILD	NO	YES	15		NO	UNCHANGED
Enoxaparin/VKA	540064016	YES	CHINA	ASIAN	MALE	62	Abdominal distension	腹部膨満			MILD	NO	YES	23		NO	IMPROVED
Enoxaparin/VKA	540064016	YES	CHINA	ASIAN	MALE	62	Malnutrition	栄養障害			MODERATE	NO	YES	23		NO	UNCHANGED
Enoxaparin/VKA	540064016	YES	CHINA	ASIAN	MALE	62	Metastases to liver	肝転移			SEVERE	YES	YES	29	24	NO	DEATH
Rivaroxaban	540074003	YES	CHINA	ASIAN	MALE	46	Rectal cancer recurrent	再発直腸癌	15 mg	.	SEVERE	YES	YES	16	124	NO	DEATH
Rivaroxaban	540074003	YES	CHINA	ASIAN	MALE	46	Haematochezia	血便排泄	20 mg	.	MILD	NO	YES	46	1	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	540074004	YES	CHINA	ASIAN	MALE	74	Rash	発疹			MILD	NO	YES	4	3	YES	RESOLVED
Enoxaparin/VKA	540074004	YES	CHINA	ASIAN	MALE	74	Asthma	喘息			MODERATE	YES	YES	5	4	NO	IMPROVED
Enoxaparin/VKA	540074004	YES	CHINA	ASIAN	MALE	74	Asthma	喘息			MILD	YES	YES	8	6	NO	WORSENED
Enoxaparin/VKA	540074004	YES	CHINA	ASIAN	MALE	74	Cholecystitis acute	急性胆嚢炎			SEVERE	YES	NO	11		NO	WORSENED
Enoxaparin/VKA	540074004	YES	CHINA	ASIAN	MALE	74	Asthma	喘息			SEVERE	YES	NO	13		NO	WORSENED
Enoxaparin/VKA	540074004	YES	CHINA	ASIAN	MALE	74	Respiratory failure	呼吸不全			SEVERE	YES	NO	14	1	NO	DEATH
Enoxaparin/VKA	540074004	YES	CHINA	ASIAN	MALE	74	Septic shock	敗血症性ショック			SEVERE	YES	NO	14	1	NO	DEATH
Enoxaparin/VKA	540074023	YES	CHINA	ASIAN	MALE	56	Hepatic neoplasm malignant	肝の悪性新生物			SEVERE	YES	YES	11	137	NO	DEATH
Enoxaparin/VKA	540114003	YES	CHINA	ASIAN	MALE	53	Retroperitoneal neoplasm	後腹膜新生物			SEVERE	YES	YES	5	106	NO	DEATH
Enoxaparin/VKA	540134019	YES	CHINA	ASIAN	MALE	63	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MILD	NO	YES	10	9	YES	RESOLVED
Enoxaparin/VKA	540134019	YES	CHINA	ASIAN	MALE	63	Cerebral haemorrhage	脳出血			SEVERE	YES	YES	63	1	YES	DEATH
Enoxaparin/VKA	550014012	YES	INDONESIA	ASIAN	FEMALE	28	Haematoma	血腫			MILD	NO	YES	1		YES	INSUFFICIENT FOLLOW-UP

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	550014012	YES	INDONESIA	ASIAN	FEMALE	28	Neutropenia	好中球減少症			MODERATE	YES	NO	1	6	NO	RESOLVED
Enoxaparin/VKA	550014012	YES	INDONESIA	ASIAN	FEMALE	28	Febrile neutropenia	発熱性好中球減少症			MODERATE	NO	YES	2	4	NO	RESOLVED
Enoxaparin/VKA	550014012	YES	INDONESIA	ASIAN	FEMALE	28	Ecchymosis	斑状出血			MILD	NO	YES	3		YES	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	550024001	YES	INDONESIA	ASIAN	FEMALE	42	Haematuria	血尿			SEVERE	YES	NO	87		NO	UNCHANGED
Enoxaparin/VKA	550024001	YES	INDONESIA	ASIAN	FEMALE	42	Anaemia	貧血			SEVERE	YES	NO	177		NO	IMPROVED
Enoxaparin/VKA	550024001	YES	INDONESIA	ASIAN	FEMALE	42	Cervix carcinoma	子宮頚部癌			SEVERE	YES	NO	182	1	NO	DEATH
Rivaroxaban	550034002	YES	INDONESIA	ASIAN	MALE	66	Rhabdomyosarcoma	横紋筋肉腫	15 mg	.	SEVERE	YES	YES	16	1	NO	DEATH
Enoxaparin/VKA	550034003	YES	INDONESIA	ASIAN	FEMALE	72	Haematoma	血腫			MILD	NO	YES	8	1	NO	RESOLVED
Enoxaparin/VKA	550034003	YES	INDONESIA	ASIAN	FEMALE	72	Chest pain	胸痛			SEVERE	NO	YES	27		NO	UNCHANGED
Enoxaparin/VKA	550034003	YES	INDONESIA	ASIAN	FEMALE	72	Dyspnoea	呼吸困難			SEVERE	YES	YES	27		NO	UNCHANGED
Enoxaparin/VKA	550034003	YES	INDONESIA	ASIAN	FEMALE	72	Pulmonary embolism	肺塞栓症			SEVERE	YES	YES	27	1	NO	DEATH
Enoxaparin/VKA	550034003	YES	INDONESIA	ASIAN	FEMALE	72	Tachypnoea	頻呼吸			SEVERE	YES	YES	27		NO	UNCHANGED
Enoxaparin/VKA	550034004	YES	INDONESIA	ASIAN	FEMALE	19	Haematochezia	血便排泄			SEVERE	YES	YES	7	6	YES	RESOLVED
Enoxaparin/VKA	550034004	YES	INDONESIA	ASIAN	FEMALE	19	Anaemia	貧血			MODERATE	NO	YES	8		YES	UNCHANGED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	550034004	YES	INDONESIA	ASIAN	FEMALE	19	Pneumonia	肺炎			MODERATE	NO	YES	25	5	NO	WORSENED
Enoxaparin/VKA	550034004	YES	INDONESIA	ASIAN	FEMALE	19	Haematochezia	血便排泄			MODERATE	YES	YES	26		YES	UNCHANGED
Enoxaparin/VKA	550034004	YES	INDONESIA	ASIAN	FEMALE	19	Pulmonary sepsis	肺敗血症			SEVERE	YES	YES	28		NO	WORSENED
Enoxaparin/VKA	550034004	YES	INDONESIA	ASIAN	FEMALE	19	Septic shock	敗血症性ショック			SEVERE	YES	NO	29	1	NO	DEATH
Enoxaparin/VKA	550034007	YES	INDONESIA	ASIAN	FEMALE	55	Gingival bleeding	歯肉出血			MODERATE	YES	YES	20	3	YES	RESOLVED
Enoxaparin/VKA	550034007	YES	INDONESIA	ASIAN	FEMALE	55	Vaginal haemorrhage	膣出血			MODERATE	YES	YES	20	3	YES	RESOLVED
Enoxaparin/VKA	550034007	YES	INDONESIA	ASIAN	FEMALE	55	Cervix carcinoma	子宮頚部癌			SEVERE	YES	YES	121	1	NO	DEATH
Rivaroxaban	550034008	YES	INDONESIA	ASIAN	FEMALE	48	Hepatic neoplasm malignant	肝の悪性新生物	15 mg	.	SEVERE	YES	YES	11	51	NO	DEATH
Rivaroxaban	550034008	YES	INDONESIA	ASIAN	FEMALE	48	Ascites	腹水	15 mg	.	MODERATE	NO	YES	11		NO	UNCHANGED
Rivaroxaban	550034008	YES	INDONESIA	ASIAN	FEMALE	48	Nausea	悪心	15 mg	.	MILD	NO	YES	13		YES	IMPROVED
Rivaroxaban	550034008	YES	INDONESIA	ASIAN	FEMALE	48	Hypocalcaemia	低カルシウム血症	15 mg	F	MILD	NO	YES	20		NO	IMPROVED
Rivaroxaban	550034008	YES	INDONESIA	ASIAN	FEMALE	48	Haematuria	血尿	15 mg	F	MODERATE	NO	YES	21	2	NO	RESOLVED
Rivaroxaban	550034008	YES	INDONESIA	ASIAN	FEMALE	48	Pneumonia	肺炎	15 mg	F	MODERATE	NO	NO	27	18	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	550034008	YES	INDONESIA	ASIAN	FEMALE	48	Decubitus ulcer	褥瘡性潰瘍	15 mg	F	MILD	NO	NO	45		NO	UNCHANGED
Rivaroxaban	550034011	YES	INDONESIA	ASIAN	MALE	45	Urticaria	蕁麻疹	15 mg	.	MODERATE	NO	YES	14	4	NO	RESOLVED
Rivaroxaban	550034011	YES	INDONESIA	ASIAN	MALE	45	Anaemia	貧血	15 mg	.	MODERATE	NO	YES	17	5	NO	RESOLVED
Rivaroxaban	550034011	YES	INDONESIA	ASIAN	MALE	45	Cough	咳嗽	20 mg	.	MODERATE	NO	YES	24	2	NO	WORSENED
Rivaroxaban	550034011	YES	INDONESIA	ASIAN	MALE	45	Pneumonia	肺炎	20 mg	.	MILD	NO	YES	26	7	NO	RESOLVED
Rivaroxaban	550034011	YES	INDONESIA	ASIAN	MALE	45	Hypoglycaemic coma	低血糖昏睡	20 mg	.	SEVERE	YES	YES	34	1	NO	DEATH
Enoxaparin/VKA	550034012	YES	INDONESIA	ASIAN	FEMALE	49	Ear haemorrhage	耳出血			MILD	NO	YES	5	1	YES	RESOLVED
Enoxaparin/VKA	550034012	YES	INDONESIA	ASIAN	FEMALE	49	Haematochezia	血便排泄			MILD	NO	YES	6	1	YES	RESOLVED
Enoxaparin/VKA	550034012	YES	INDONESIA	ASIAN	FEMALE	49	Pleural effusion	胸水			MODERATE	YES	YES	57		NO	IMPROVED
Enoxaparin/VKA	550034012	YES	INDONESIA	ASIAN	FEMALE	49	Death	死亡			SEVERE	YES	YES	155	1	NO	DEATH
Rivaroxaban	550034013	YES	INDONESIA	ASIAN	MALE	69	Vomiting	嘔吐	15 mg	.	MILD	NO	YES	2	3	NO	RESOLVED
Rivaroxaban	550034013	YES	INDONESIA	ASIAN	MALE	69	Pneumonia	肺炎	15 mg	F	SEVERE	YES	YES	10	1	NO	DEATH
Enoxaparin/VKA	550034015	YES	INDONESIA	ASIAN	FEMALE	60	Conjunctival haemorrhage	結膜出血			MILD	NO	YES	24	3	YES	RESOLVED
Enoxaparin/VKA	550034015	YES	INDONESIA	ASIAN	FEMALE	60	Ischaemic stroke	虚血性脳卒中			SEVERE	YES	YES	50		NO	UNCHANGED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	550034015	YES	INDONESIA	ASIAN	FEMALE	60	Sepsis	敗血症			SEVERE	YES	YES	50	3	NO	DEATH
Enoxaparin/VKA	550034015	YES	INDONESIA	ASIAN	FEMALE	60	Bronchopneumonia	気管支肺炎			SEVERE	YES	YES	50		NO	UNCHANGED
Enoxaparin/VKA	550034015	YES	INDONESIA	ASIAN	FEMALE	60	Haematemesis	吐血			MODERATE	NO	YES	51		YES	UNCHANGED
Rivaroxaban	550034018	YES	INDONESIA	ASIAN	FEMALE	33	Urinary tract infection	尿路感染	15 mg	.	MILD	NO	YES	1	14	NO	RESOLVED
Rivaroxaban	550034018	YES	INDONESIA	ASIAN	FEMALE	33	Hypochloraemia	低クロール血症	15 mg	.	MILD	NO	YES	2	6	NO	RESOLVED
Rivaroxaban	550034018	YES	INDONESIA	ASIAN	FEMALE	33	Hypokalaemia	低カリウム血症	15 mg	.	MILD	NO	YES	18	22	NO	RESOLVED
Rivaroxaban	550034018	YES	INDONESIA	ASIAN	FEMALE	33	Renal failure	腎不全	20 mg	.	SEVERE	YES	YES	146	21	NO	DEATH
Rivaroxaban	550034018	YES	INDONESIA	ASIAN	FEMALE	33	Hypertension	高血圧	20 mg	F	MILD	NO	YES	152		NO	UNCHANGED
Rivaroxaban	550034018	YES	INDONESIA	ASIAN	FEMALE	33	Metastases to liver	肝転移	20 mg	F	MODERATE	YES	YES	152		NO	UNCHANGED
Rivaroxaban	550034018	YES	INDONESIA	ASIAN	FEMALE	33	Metastases to lymph nodes	リンパ節転移	20 mg	F	MODERATE	YES	YES	152		NO	UNCHANGED
Rivaroxaban	550034019	YES	INDONESIA	ASIAN	FEMALE	63	Colorectal cancer	結腸直腸癌	20 mg	.	SEVERE	YES	YES	32	20	NO	DEATH
Rivaroxaban	550034021	YES	INDONESIA	ASIAN	MALE	58	Back pain	背部痛	20 mg	.	SEVERE	YES	YES	59		NO	UNCHANGED
Rivaroxaban	550034021	YES	INDONESIA	ASIAN	MALE	58	Hypercalcaemia	高カルシウム血症	20 mg	.	MILD	NO	YES	59		NO	UNCHANGED
Rivaroxaban	550034021	YES	INDONESIA	ASIAN	MALE	58	Hiccups	しゃっくり	20 mg	.	MILD	NO	YES	63	1	NO	RESOLVED
Rivaroxaban	550034021	YES	INDONESI	ASIAN	MALE	58	Haematemesis	吐血	20 mg	.	SEVERE	YES	YES	66	1	YES	DEATH

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
			A														
Rivaroxaban	550034022	YES	INDONESIA	ASIAN	FEMALE	41	Cervix carcinoma stage III	子宮頚部癌第３期	20 mg	.	SEVERE	YES	YES	111	32	NO	DEATH
Enoxaparin/VKA	550034026	YES	INDONESIA	ASIAN	FEMALE	56	Ascites	腹水			MILD	NO	YES	1		NO	UNCHANGED
Enoxaparin/VKA	550034026	YES	INDONESIA	ASIAN	FEMALE	56	Hydronephrosis	水腎症			MILD	NO	YES	1		NO	UNCHANGED
Enoxaparin/VKA	550034026	YES	INDONESIA	ASIAN	FEMALE	56	Hypokalaemia	低カリウム血症			MILD	NO	YES	8		NO	UNCHANGED
Enoxaparin/VKA	550034026	YES	INDONESIA	ASIAN	FEMALE	56	Pyrexia	発熱			MILD	NO	YES	8	3	NO	RESOLVED
Enoxaparin/VKA	550034026	YES	INDONESIA	ASIAN	FEMALE	56	Haematemesis	吐血			SEVERE	YES	YES	10	1	YES	DEATH
Rivaroxaban	550034027	YES	INDONESIA	ASIAN	FEMALE	47	Ascites	腹水	20 mg	.	MODERATE	NO	YES	100		NO	UNCHANGED
Rivaroxaban	550034027	YES	INDONESIA	ASIAN	FEMALE	47	Ovarian cyst	卵巣嚢胞	20 mg	.	MODERATE	YES	YES	101		NO	UNCHANGED
Rivaroxaban	550034027	YES	INDONESIA	ASIAN	FEMALE	47	Hypoalbuminaemia	低アルブミン血症	20 mg	.	MILD	NO	YES	109		NO	IMPROVED
Rivaroxaban	550034027	YES	INDONESIA	ASIAN	FEMALE	47	Urinary tract infection	尿路感染	20 mg	.	MILD	NO	YES	112	8	NO	RESOLVED
Rivaroxaban	550034027	YES	INDONESIA	ASIAN	FEMALE	47	Pleural effusion	胸水	20 mg	.	MILD	NO	YES	163		NO	UNCHANGED
Rivaroxaban	550034027	YES	INDONESIA	ASIAN	FEMALE	47	Melaena	メレナ	20 mg	.	MILD	NO	YES	172	6	YES	RESOLVED
Rivaroxaban	550034027	YES	INDONESIA	ASIAN	FEMALE	47	Melaena	メレナ	20 mg	F	MILD	NO	NO	185		NO	INSUFFICIENT FOLLOW-UP

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	550034027	YES	INDONESIA	ASIAN	FEMALE	47	Hypokalaemia	低カリウム血症	20 mg	F	SEVERE	YES	NO	189		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	550034027	YES	INDONESIA	ASIAN	FEMALE	47	Systemic inflammatory response syndrome	全身性炎症反応症候群	20 mg	F	SEVERE	YES	NO	190	1	NO	DEATH
Enoxaparin/VKA	550034028	YES	INDONESIA	ASIAN	FEMALE	77	Haematuria	血尿			MILD	NO	YES	4	1	YES	RESOLVED
Enoxaparin/VKA	550034028	YES	INDONESIA	ASIAN	FEMALE	77	Haematoma	血腫			MILD	NO	YES	4	2	YES	RESOLVED
Enoxaparin/VKA	550034028	YES	INDONESIA	ASIAN	FEMALE	77	Septic shock	敗血症性ショック			SEVERE	YES	NO	9	2	NO	DEATH
Enoxaparin/VKA	550044014	YES	INDONESIA	ASIAN	FEMALE	69	Bronchitis	気管支炎			MODERATE	NO	YES	5	23	NO	RESOLVED
Enoxaparin/VKA	550044014	YES	INDONESIA	ASIAN	FEMALE	69	Asthma	喘息			SEVERE	YES	YES	7	21	NO	RESOLVED
Enoxaparin/VKA	550044014	YES	INDONESIA	ASIAN	FEMALE	69	Anaemia	貧血			MODERATE	NO	YES	12		NO	IMPROVED
Enoxaparin/VKA	550044014	YES	INDONESIA	ASIAN	FEMALE	69	Shock	ショック			SEVERE	YES	NO	99	2	NO	DEATH
Enoxaparin/VKA	550044014	YES	INDONESIA	ASIAN	FEMALE	69	Subileus	亜イレウス			MODERATE	NO	NO	99		NO	UNCHANGED
Enoxaparin/VKA	550044014	YES	INDONESIA	ASIAN	FEMALE	69	Flatulence	鼓腸			MILD	NO	NO	99		NO	UNCHANGED
Enoxaparin/VKA	550044014	YES	INDONESIA	ASIAN	FEMALE	69	Stress ulcer	ストレス潰瘍			MODERATE	NO	NO	99		NO	UNCHANGED
Enoxaparin/VKA	550044016	YES	INDONESIA	ASIAN	FEMALE	66	Sepsis	敗血症			SEVERE	YES	YES	2		NO	UNCHANGED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	550044016	YES	INDONESIA	ASIAN	FEMALE	66	Multi-organ failure	多臓器不全			SEVERE	YES	YES	4	1	NO	DEATH
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Enterocutaneous fistula	腸管皮膚瘻	15 mg	.	MODERATE	YES	YES	9	26	NO	RESOLVED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Cough	咳嗽	15 mg	.	MILD	NO	YES	11	5	NO	RESOLVED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	International normalised ratio increased	ＩＮＲ増加	15 mg	.	MODERATE	NO	YES	11	2	NO	RESOLVED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Respiratory tract infection	気道感染	20 mg	.	MODERATE	YES	YES	67	32	NO	RESOLVED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Incision site abscess	切開部位膿瘍	20 mg	.	MODERATE	YES	YES	67	32	NO	RESOLVED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Hypoproteinaemia	低蛋白血症	20 mg	.	MODERATE	YES	YES	67		NO	UNCHANGED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Enterocutaneous fistula	腸管皮膚瘻	20 mg	.	MODERATE	YES	YES	93	8	NO	WORSENED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Metabolic encephalopathy	代謝性脳症	20 mg	F	SEVERE	YES	YES	101	5	NO	DEATH
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Sepsis	敗血症	20 mg	F	SEVERE	YES	YES	101	5	NO	DEATH
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Enterocutaneous fistula	腸管皮膚瘻	20 mg	F	SEVERE	YES	YES	101		NO	UNCHANGED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Multi-organ failure	多臓器不全	20 mg	F	SEVERE	YES	YES	101	5	NO	DEATH
Rivaroxaban	660014010	YES	MALAYSIA	ASIAN	FEMALE	77	Cervix cancer metastatic	転移性子宮頚部癌	20 mg	.	MODERATE	YES	YES	71	107	NO	DEATH

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	660014010	YES	MALAYSIA	ASIAN	FEMALE	77	Anaemia	貧血	20 mg	.	MODERATE	YES	YES	71	2	NO	IMPROVED
Rivaroxaban	660014010	YES	MALAYSIA	ASIAN	FEMALE	77	Anaemia	貧血	20 mg	.	MODERATE	YES	YES	149	1	NO	IMPROVED
Enoxaparin/VKA	670014018	YES	PHILIPPINES	ASIAN	FEMALE	75	Atrial fibrillation	心房細動			MILD	YES	YES	4		NO	UNCHANGED
Enoxaparin/VKA	670014018	YES	PHILIPPINES	ASIAN	FEMALE	75	Ischaemic stroke	虚血性脳卒中			SEVERE	YES	YES	33		YES	UNCHANGED
Enoxaparin/VKA	670014018	YES	PHILIPPINES	ASIAN	FEMALE	75	Sepsis	敗血症			SEVERE	YES	NO	42		NO	UNCHANGED
Enoxaparin/VKA	670014018	YES	PHILIPPINES	ASIAN	FEMALE	75	Cardiac arrest	心停止			SEVERE	YES	NO	42	1	NO	DEATH
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Gastrointestinal haemorrhage	胃腸出血	15 mg	.	MODERATE	YES	YES	3	40	YES	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Haemorrhoids	痔核	15 mg	.	MILD	NO	YES	3		NO	UNCHANGED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Constipation	便秘	15 mg	.	MILD	NO	YES	3	4	NO	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Haematoma	血腫	15 mg	.	MILD	NO	YES	4	7	NO	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Melaena	メレナ	15 mg	I	MILD	NO	YES	7	1	YES	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Lymphoma	リンパ腫	15 mg	I	MODERATE	YES	YES	8	73	NO	WORSENED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Aortic arteriosclerosis	大動脈硬化症	15 mg	I	MODERATE	NO	YES	8		NO	UNCHANGED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Scoliosis	側弯症	15 mg	I	MODERATE	NO	YES	8		NO	UNCHANGED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Spinal cord compression	脊髄圧迫	15 mg	I	MODERATE	NO	YES	8		NO	UNCHANGED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Oesophagogastroduodenoscopy	食道胃十二指腸内視鏡検査	15 mg	I	MILD	NO	YES	9	1	NO	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Osteoarthropathy	骨関節障害	15 mg	I	MILD	NO	YES	14		NO	IMPROVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Pyrexia	発熱	15 mg	I	MILD	NO	YES	14	3	NO	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Urinary tract infection	尿路感染	15 mg	I	MILD	NO	YES	14	84	NO	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Cough	咳嗽	15 mg	I	MILD	NO	YES	27	6	NO	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Melaena	メレナ	20 mg	.	MILD	NO	YES	67	1	NO	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Gastrointestinal haemorrhage	胃腸出血	20 mg	.	MODERATE	YES	YES	76	10	YES	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Lymphoma	リンパ腫	20 mg	F	SEVERE	YES	NO	81		NO	UNCHANGED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Hypokalaemia	低カリウム血症	20 mg	F	MILD	NO	NO	95	4	NO	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Blood bilirubin increased	血中ビリルビン増加	20 mg	F	MILD	NO	NO	96		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Constipation	便秘	20 mg	F	MILD	NO	NO	99	1	NO	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPI	ASIAN	FEMALE	92	Hyperkalaemia	高カリウム	20 mg	F	MILD	NO	NO	99	1	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
			NES					血症									
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Pneumonia	肺炎	20 mg	F	MODERATE	NO	NO	101		NO	UNCHANGED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Respiratory tract infection	気道感染	20 mg	F	MILD	NO	NO	101	40	NO	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Gastrointestinal haemorrhage	胃腸出血	20 mg	F	SEVERE	YES	NO	106	6	NO	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Anaemia	貧血	20 mg	F	MODERATE	NO	NO	118	5	NO	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Anaemia	貧血	20 mg	F	SEVERE	NO	NO	125	3	NO	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Anaemia	貧血	20 mg	F	SEVERE	NO	NO	137		NO	UNCHANGED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Cardio-respiratory arrest	心肺停止	20 mg	F	SEVERE	YES	NO	159	1	NO	DEATH
Enoxaparin/VKA	670024008	YES	PHILIPPINES	ASIAN	FEMALE	38	Vaginal haemorrhage	膣出血			MODERATE	NO	YES	11	10	YES	RESOLVED
Enoxaparin/VKA	670024008	YES	PHILIPPINES	ASIAN	FEMALE	38	Pain in extremity	四肢痛			MILD	NO	YES	20	1	NO	RESOLVED
Enoxaparin/VKA	670024008	YES	PHILIPPINES	ASIAN	FEMALE	38	Upper respiratory tract infection	上気道感染			MILD	NO	YES	25	8	NO	RESOLVED
Enoxaparin/VKA	670024008	YES	PHILIPPINES	ASIAN	FEMALE	38	Vaginal haemorrhage	膣出血			MILD	NO	YES	34	1	NO	RESOLVED

表 2.7.4.7-16 死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	670024008	YES	PHILIPPINES	ASIAN	FEMALE	38	Vaginal haemorrhage	膣出血			MODERATE	NO	YES	35	8	NO	RESOLVED
Enoxaparin/VKA	670024008	YES	PHILIPPINES	ASIAN	FEMALE	38	Vaginal haemorrhage	膣出血			MILD	NO	YES	59	2	NO	RESOLVED
Enoxaparin/VKA	670024008	YES	PHILIPPINES	ASIAN	FEMALE	38	Back pain	背部痛			MILD	NO	YES	71		NO	UNCHANGED
Enoxaparin/VKA	670024008	YES	PHILIPPINES	ASIAN	FEMALE	38	Fatigue	疲労			MILD	NO	YES	73		NO	UNCHANGED
Enoxaparin/VKA	670024008	YES	PHILIPPINES	ASIAN	FEMALE	38	Urinary tract infection	尿路感染			MILD	NO	YES	73		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	670024008	YES	PHILIPPINES	ASIAN	FEMALE	38	Cervix carcinoma	子宮頚部癌			MODERATE	YES	YES	74	94	NO	WORSENED
Enoxaparin/VKA	670024008	YES	PHILIPPINES	ASIAN	FEMALE	38	Cervix carcinoma	子宮頚部癌			SEVERE	YES	NO	168	4	NO	DEATH
Rivaroxaban	680024008	YES	SINGAPORE	ASIAN	MALE	77	Insomnia	不眠症			MILD	NO	YES			NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	680024008	YES	SINGAPORE	ASIAN	MALE	77	Exercise tolerance decreased	運動耐性低下			MILD	NO	YES			NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	680024008	YES	SINGAPORE	ASIAN	MALE	77	Pneumonia	肺炎	20 mg	.	SEVERE	YES	YES	57	2	NO	DEATH
Rivaroxaban	680024008	YES	SINGAPORE	ASIAN	MALE	77	Blood creatinine increased	血中クレアチニン増加	20 mg	F	MILD	NO	YES	58		NO	UNCHANGED
Rivaroxaban	710024002	YES	THAILAND	ASIAN	MALE	25	Cough	咳嗽	20 mg	.	MILD	NO	YES	106	7	NO	RESOLVED
Rivaroxaban	710024002	YES	THAILAND	ASIAN	MALE	25	Diarrhoea	下痢	20 mg	.	MODERATE	NO	YES	111		NO	UNCHANGED

表 2.7.4.7-16　死亡例一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	710024002	YES	THAILAND	ASIAN	MALE	25	Septic shock	敗血症性ショック	20 mg	F	SEVERE	YES	YES	113	1	NO	DEATH

All AEs for death patients adjudicated by CIAC are presented.
Relative day is calculated from the first day of study drug administration: The formula for this calculation is (onset day of death minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase, F will be listed.

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	100093010	YES	GERMANY	WHITE	MALE	80	Urinary tract infection	尿路感染	20 mg	.	MILD	NO	YES	28	9	NO	RESOLVED
Rivaroxaban	100093010	YES	GERMANY	WHITE	MALE	80	Lumbar vertebral fracture	腰椎骨折	20 mg	F	MODERATE	YES	YES	36	7	NO	RESOLVED
Rivaroxaban	100093010	YES	GERMANY	WHITE	MALE	80	Cholecystitis infective	感染性胆嚢炎	20 mg	F	SEVERE	YES	NO	46		NO	UNCHANGED
Rivaroxaban	100093010	YES	GERMANY	WHITE	MALE	80	Infectious peritonitis	感染性腹膜炎	20 mg	F	SEVERE	YES	NO	47		NO	UNCHANGED
Rivaroxaban	100093010	YES	GERMANY	WHITE	MALE	80	Sepsis	敗血症	20 mg	F	SEVERE	YES	NO	49	28	NO	DEATH
Enoxaparin/VKA	100093025	YES	GERMANY	WHITE	MALE	72	Tumour haemorrhage	腫瘍出血			SEVERE	YES	YES	133		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	100093025	YES	GERMANY	WHITE	MALE	72	Gastric neoplasm	胃新生物			SEVERE	YES	YES	133		NO	DEATH
Enoxaparin/VKA	100093025	YES	GERMANY	WHITE	MALE	72	Metastatic gastric cancer	転移性胃癌			SEVERE	YES	YES	133		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	100093025	YES	GERMANY	WHITE	MALE	72	Haemorrhoids	痔核			MILD	NO	YES	133		NO	UNCHANGED
Enoxaparin/VKA	100093025	YES	GERMANY	WHITE	MALE	72	Colonic polyp	結腸ポリープ			MILD	NO	YES	133		NO	UNCHANGED
Enoxaparin/VKA	100223005	YES	GERMANY	WHITE	FEMALE	85	Tachyarrhythmia	頻脈性不整脈			MODERATE	NO	YES	1	1	NO	RESOLVED
Enoxaparin/VKA	100223005	YES	GERMANY	WHITE	FEMALE	85	Pulmonary oedema	肺水腫			MODERATE	NO	YES	2		NO	IMPROVED
Enoxaparin/VKA	100223005	YES	GERMANY	WHITE	FEMALE	85	Chronic obstructive pulmonary	慢性閉塞性肺疾患			MILD	NO	YES	2	1	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							disease										
Enoxaparin/VKA	100223005	YES	GERMANY	WHITE	FEMALE	85	Pneumonia	肺炎			SEVERE	YES	YES	3	3	NO	DEATH
Enoxaparin/VKA	100343017	YES	GERMANY	WHITE	FEMALE	61	Metastases to liver	肝転移			SEVERE	YES	YES	1		NO	UNCHANGED
Enoxaparin/VKA	100343017	YES	GERMANY	WHITE	FEMALE	61	Gastroenteritis norovirus	ノロウイルス性胃腸炎			MILD	NO	YES	2	10	NO	RESOLVED
Enoxaparin/VKA	100343017	YES	GERMANY	WHITE	FEMALE	61	Lung adenocarcinoma	肺腺癌			SEVERE	YES	YES	9	27	NO	DEATH
Enoxaparin/VKA	100343017	YES	GERMANY	WHITE	FEMALE	61	Metastases to pleura	胸膜転移			SEVERE	YES	YES	9		NO	UNCHANGED
Enoxaparin/VKA	100343017	YES	GERMANY	WHITE	FEMALE	61	Cerebral infarction	脳梗塞			MILD	YES	YES	9	9	NO	RESOLVED
Enoxaparin/VKA	100343021	YES	GERMANY	WHITE	MALE	77	Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪			SEVERE	YES	YES	18	5	NO	DEATH
Enoxaparin/VKA	100343021	YES	GERMANY	WHITE	MALE	77	Hypercapnia	高炭酸ガス血症			SEVERE	NO	YES	21		NO	UNCHANGED
Enoxaparin/VKA	100393044	YES	GERMANY	WHITE	MALE	71	Cough	咳嗽			MILD	NO	YES			NO	UNCHANGED
Enoxaparin/VKA	100393044	YES	GERMANY	WHITE	MALE	71	Conjunctival haemorrhage	結膜出血			MILD	NO	YES	11	12	NO	RESOLVED
Enoxaparin/VKA	100393044	YES	GERMANY	WHITE	MALE	71	Oedema peripheral	末梢性浮腫			MILD	NO	YES	98		NO	IMPROVED

表 2.7.4.7-17　死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	100393044	YES	GERMANY	WHITE	MALE	71	International normalised ratio increased	ＩＮＲ増加			MODERATE	YES	YES	144	2	YES	RESOLVED
Enoxaparin/VKA	100393044	YES	GERMANY	WHITE	MALE	71	Conjunctival haemorrhage	結膜出血			MILD	NO	YES	144		YES	RESOLVED
Enoxaparin/VKA	100393044	YES	GERMANY	WHITE	MALE	71	Neoplasm malignant	悪性新生物			SEVERE	YES	YES	201	1	NO	DEATH
Enoxaparin/VKA	100393044	YES	GERMANY	WHITE	MALE	71	International normalised ratio increased	ＩＮＲ増加			MODERATE	NO	YES	201		YES	UNCHANGED
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Ileus paralytic	麻痺性イレウス			SEVERE	NO	YES			NO	UNCHANGED
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Abdominal pain	腹痛			SEVERE	NO	YES			NO	UNCHANGED
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Metastases to pleura	胸膜転移			MODERATE	YES	YES			NO	DEATH
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Oedema peripheral	末梢性浮腫			MILD	NO	YES	10		NO	UNCHANGED
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Pneumonia	肺炎			SEVERE	YES	YES	49	11	NO	RESOLVED
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Pleural effusion	胸水			MODERATE	NO	YES	51	7	NO	RESOLVED
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Dysphonia	発声障害			MILD	NO	YES	59		NO	UNCHANGED
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Conjunctival haemorrhage	結膜出血			MILD	NO	YES	78	20	YES	RESOLVED

表 2.7.4.7-17　死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	International normalised ratio increased	ＩＮＲ増加			MODERATE	NO	YES	196	7	YES	RESOLVED
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	International normalised ratio increased	ＩＮＲ増加			MODERATE	NO	YES	223	1	YES	RESOLVED
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Pleural effusion	胸水			MODERATE	YES	YES	328	3	NO	RESOLVED
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Pleural effusion	胸水			MODERATE	YES	YES	337	38	NO	DEATH
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	C-reactive protein increased	Ｃ－反応性蛋白増加			SEVERE	NO	NO	362		NO	UNCHANGED
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Oedema	浮腫			MODERATE	NO	NO	363		NO	UNCHANGED
Rivaroxaban	100433006	YES	GERMANY	WHITE	MALE	73	Cachexia	悪液質			MODERATE	NO	YES			NO	UNCHANGED
Rivaroxaban	100433006	YES	GERMANY	WHITE	MALE	73	Rectal cancer	直腸癌			SEVERE	YES	YES			NO	DEATH
Rivaroxaban	100433006	YES	GERMANY	WHITE	MALE	73	Constipation	便秘	15 mg	.	MILD	NO	YES	1		NO	RESOLVED
Rivaroxaban	100433006	YES	GERMANY	WHITE	MALE	73	Sleep disorder	睡眠障害	15 mg	.	MILD	NO	YES	1		NO	RESOLVED
Rivaroxaban	100433006	YES	GERMANY	WHITE	MALE	73	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	MODERATE	NO	YES	172		NO	IMPROVED
Rivaroxaban	100433006	YES	GERMANY	WHITE	MALE	73	Anaemia	貧血	20 mg	.	SEVERE	NO	YES	179		NO	IMPROVED

表 2.7.4.7-17　死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	100433006	YES	GERMANY	WHITE	MALE	73	Hepatic pain	肝臓痛	20 mg	.	MODERATE	YES	YES	179		NO	IMPROVED
Rivaroxaban	100433006	YES	GERMANY	WHITE	MALE	73	Depressed mood	抑うつ気分	20 mg	.	MILD	NO	YES	179		NO	IMPROVED
Rivaroxaban	100433006	YES	GERMANY	WHITE	MALE	73	Oedema peripheral	末梢性浮腫	20 mg	F	MODERATE	NO	NO	184		NO	IMPROVED
Rivaroxaban	100433006	YES	GERMANY	WHITE	MALE	73	Candidiasis	カンジダ症	20 mg	F	MODERATE	NO	NO	199		NO	UNCHANGED
Rivaroxaban	100433006	YES	GERMANY	WHITE	MALE	73	Cardiac arrest	心停止	20 mg	F	SEVERE	YES	NO	203	1	NO	DEATH
Enoxaparin/VKA	120033003	YES	UNITED KINGDOM	WHITE	FEMALE	65	International normalised ratio increased	ＩＮＲ増加			MODERATE	NO	YES	8	3	YES	RESOLVED
Enoxaparin/VKA	120033003	YES	UNITED KINGDOM	WHITE	FEMALE	65	International normalised ratio increased	ＩＮＲ増加			MILD	NO	YES	14	9	YES	RESOLVED
Enoxaparin/VKA	120033003	YES	UNITED KINGDOM	WHITE	FEMALE	65	Depression	うつ病			MILD	NO	YES	22		NO	UNCHANGED
Enoxaparin/VKA	120033003	YES	UNITED KINGDOM	WHITE	FEMALE	65	Fatigue	疲労			MODERATE	NO	YES	22		NO	UNCHANGED
Enoxaparin/VKA	120033003	YES	UNITED KINGDOM	WHITE	FEMALE	65	Dyspnoea	呼吸困難			MILD	NO	YES	25		NO	UNCHANGED
Enoxaparin/VKA	120033003	YES	UNITED KINGDOM	WHITE	FEMALE	65	Oedema	浮腫			MODERATE	NO	YES	25		NO	UNCHANGED
Enoxaparin/VKA	120033003	YES	UNITED KINGDOM	WHITE	FEMALE	65	International normalised	ＩＮＲ増加			MODERATE	NO	YES	39		YES	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							ratio increased										
Enoxaparin/VKA	120033003	YES	UNITED KINGDOM	WHITE	FEMALE	65	Cervix carcinoma	子宮頚部癌			MODERATE	YES	NO	63	16	NO	DEATH
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Anxiety	不安			MODERATE	NO	YES	1		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Bladder spasm	膀胱痙縮			MODERATE	NO	YES	2		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Hyponatraemia	低ナトリウム血症			MODERATE	NO	YES	3		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Inappropriate antidiuretic hormone secretion	抗利尿ホルモン不適合分泌			MODERATE	NO	YES	3		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Adrenal insufficiency	副腎機能不全			MODERATE	NO	YES	3		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Hypocoagulable state	凝固低下状態			SEVERE	NO	YES	4	2	YES	RESOLVED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Bladder pain	膀胱痛			MODERATE	NO	YES	4		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	International normalised ratio increased	ＩＮＲ増加			SEVERE	NO	YES	4	2	NO	RESOLVED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Intra-abdominal haemorrhage	腹腔内出血			SEVERE	YES	YES	5	1	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Malignant ascites	悪性腹水			SEVERE	YES	YES	5	9	NO	DEATH
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Anaemia	貧血			MODERATE	NO	YES	5		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Lactic acidosis	乳酸アシドーシス			MODERATE	NO	YES	5		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Metabolic acidosis	代謝性アシドーシス			MODERATE	NO	YES	5		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Renal failure acute	急性腎不全			MODERATE	YES	YES	5		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	White blood cell count increased	白血球数増加			MODERATE	NO	YES	5		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Blood creatinine increased	血中クレアチニン増加			MODERATE	NO	YES	5		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Hypotension	低血圧			MODERATE	NO	YES	5		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Hyperkalaemia	高カリウム血症			MODERATE	NO	YES	5	1	NO	RESOLVED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Blood glucose decreased	血中ブドウ糖減少			MODERATE	NO	YES	5	1	NO	RESOLVED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Skin irritation	皮膚刺激			MILD	NO	NO	8		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Abdominal pain	腹痛			MODERATE	NO	NO	9		NO	UNCHANGED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Pain in extremity	四肢痛			MILD	NO	NO	10		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Pruritus	そう痒症			MILD	NO	NO	10		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Sedation	鎮静			MODERATE	NO	NO	10		NO	UNCHANGED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Decreased appetite	食欲減退			MILD	NO	NO	11		NO	UNCHANGED
Enoxaparin/VKA	140313014	YES	UNITED STATES	WHITE	FEMALE	68	Pleural effusion	胸水			MODERATE	NO	YES			NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	140313014	YES	UNITED STATES	WHITE	FEMALE	68	Lung cancer metastatic	転移性肺癌			SEVERE	YES	YES	4	74	NO	DEATH
Enoxaparin/VKA	140313051	YES	UNITED STATES	BLACK	FEMALE	78	Failure to thrive	成長障害			SEVERE	YES	YES	3	24	NO	DEATH
Enoxaparin/VKA	140313051	YES	UNITED STATES	BLACK	FEMALE	78	Depression	うつ病			SEVERE	NO	YES	3		NO	UNCHANGED
Rivaroxaban	140323054	YES	UNITED STATES	WHITE	FEMALE	68	Dehydration	脱水	20 mg	.	MODERATE	NO	YES	33		NO	UNCHANGED
Rivaroxaban	140323054	YES	UNITED STATES	WHITE	FEMALE	68	Cellulitis	蜂巣炎	20 mg	.	MODERATE	NO	YES	33		NO	UNCHANGED
Rivaroxaban	140323054	YES	UNITED STATES	WHITE	FEMALE	68	Sepsis	敗血症	20 mg	.	SEVERE	YES	YES	33		NO	UNCHANGED
Rivaroxaban	140323054	YES	UNITED STATES	WHITE	FEMALE	68	Renal failure acute	急性腎不全	20 mg	.	MODERATE	NO	YES	33		NO	UNCHANGED

表 2.7.4.7-17　死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	140323054	YES	UNITED STATES	WHITE	FEMALE	68	White blood cell count increased	白血球数増加	20 mg	.	MILD	NO	YES	33		NO	UNCHANGED
Rivaroxaban	140323054	YES	UNITED STATES	WHITE	FEMALE	68	International normalised ratio increased	ＩＮＲ増加	20 mg	.	MILD	NO	YES	33		NO	UNCHANGED
Rivaroxaban	140323054	YES	UNITED STATES	WHITE	FEMALE	68	Hepatic failure	肝不全	20 mg	F	SEVERE	YES	YES	41		NO	UNCHANGED
Rivaroxaban	140323054	YES	UNITED STATES	WHITE	FEMALE	68	Breast cancer metastatic	転移性乳癌	20 mg	F	SEVERE	YES	YES	41	1	NO	DEATH
Rivaroxaban	140323054	YES	UNITED STATES	WHITE	FEMALE	68	Metastases to liver	肝転移	20 mg	F	SEVERE	YES	YES	41	1	NO	DEATH
Enoxaparin/VKA	140373051	YES	UNITED STATES	WHITE	MALE	62	Respiratory arrest	呼吸停止			SEVERE	YES	YES	3	1	NO	DEATH
Enoxaparin/VKA	160013092	YES	FRANCE	N.A.	MALE	87	Dizziness	浮動性めまい			MODERATE	NO	YES	2	1	NO	RESOLVED
Enoxaparin/VKA	160013092	YES	FRANCE	N.A.	MALE	87	Atrioventricular block	房室ブロック			SEVERE	YES	YES	6	2	NO	DEATH
Rivaroxaban	160013107	YES	FRANCE	N.A.	FEMALE	82	Lung infection	肺感染	15 mg	.	MILD	NO	YES	6	14	NO	RESOLVED
Rivaroxaban	160013107	YES	FRANCE	N.A.	FEMALE	82	Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	20 mg	.	MODERATE	NO	YES	34		YES	UNCHANGED
Rivaroxaban	160013107	YES	FRANCE	N.A.	FEMALE	82	Pulmonary embolism	肺塞栓症	20 mg	.	SEVERE	YES	YES	36	1	YES	DEATH

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160053009	YES	FRANCE	N.A.	MALE	70	Pruritus	そう痒症	15 mg	.	MILD	NO	YES	15	4	NO	RESOLVED
Rivaroxaban	160053009	YES	FRANCE	N.A.	MALE	70	Anaemia	貧血	20 mg	.	MODERATE	NO	YES	62		NO	UNCHANGED
Rivaroxaban	160053009	YES	FRANCE	N.A.	MALE	70	Lung adenocarcinoma	肺腺癌	20 mg	.	SEVERE	YES	YES	62	114	NO	DEATH
Rivaroxaban	160053009	YES	FRANCE	N.A.	MALE	70	Nausea	悪心	20 mg	.	MILD	NO	YES	70	1	NO	RESOLVED
Rivaroxaban	160053009	YES	FRANCE	N.A.	MALE	70	Oedema peripheral	末梢性浮腫	20 mg	.	MILD	NO	YES	84		NO	RESOLVED
Rivaroxaban	160053009	YES	FRANCE	N.A.	MALE	70	Pulmonary hypertension	肺高血圧症	20 mg	.	MILD	NO	YES	88		NO	UNCHANGED
Rivaroxaban	160053009	YES	FRANCE	N.A.	MALE	70	Hiatus hernia	裂孔ヘルニア	20 mg	.	MILD	NO	YES	88		NO	UNCHANGED
Rivaroxaban	160053009	YES	FRANCE	N.A.	MALE	70	Oesophagitis	食道炎	20 mg	.	MILD	NO	YES	88		NO	UNCHANGED
Rivaroxaban	160053009	YES	FRANCE	N.A.	MALE	70	Bronchial haemorrhage	気管支出血	20 mg	I	MODERATE	NO	YES	90	1	NO	RESOLVED
Rivaroxaban	160053009	YES	FRANCE	N.A.	MALE	70	Cerebellar tumour	小脳腫瘍	20 mg	.	MILD	NO	YES	103		NO	UNCHANGED
Rivaroxaban	160053009	YES	FRANCE	N.A.	MALE	70	Central nervous system lesion	中枢神経系病変	20 mg	.	MODERATE	NO	YES	103		NO	UNCHANGED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Depression	うつ病			MODERATE	NO	YES			NO	UNCHANGED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Ischaemic stroke	虚血性脳卒中	15 mg	.	MODERATE	YES	YES	11		NO	RESOLVED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Metastases to spine	脊椎転移	20 mg	.	SEVERE	YES	YES	45	127	NO	WORSENED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Lung cancer	転移性肺癌	20 mg	.	SEVERE	YES	YES	45		NO	UNCHANGED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							metastatic										
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Abdominal pain upper	上腹部痛	20 mg	.	MODERATE	NO	YES	68	132	NO	RESOLVED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Metastases to spine	脊椎転移	20 mg	.	SEVERE	YES	YES	171		NO	WORSENED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Pneumonia	肺炎	20 mg	F	SEVERE	YES	NO	191		NO	UNCHANGED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Cardiac failure acute	急性心不全	20 mg	F	SEVERE	YES	NO	191		NO	UNCHANGED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Coma	昏睡	20 mg	F	SEVERE	YES	NO	197	3	NO	DEATH
Rivaroxaban	160083010	YES	FRANCE	N.A.	MALE	81	Epilepsy	てんかん	15 mg	.	MILD	YES	YES	14	3	NO	RESOLVED
Rivaroxaban	160083010	YES	FRANCE	N.A.	MALE	81	Cerebral haemorrhage traumatic	外傷性脳出血	20 mg	.	SEVERE	YES	YES	110	6	YES	DEATH
Enoxaparin/VKA	160083030	YES	FRANCE	N.A.	FEMALE	87	Anaemia	貧血			MILD	NO	YES	3	115	NO	RESOLVED
Enoxaparin/VKA	160083030	YES	FRANCE	N.A.	FEMALE	87	Blood blister	血性水疱			MILD	NO	YES	3	73	NO	RESOLVED
Enoxaparin/VKA	160083030	YES	FRANCE	N.A.	FEMALE	87	Gastroenteritis	胃腸炎			MILD	NO	YES	54	22	NO	RESOLVED
Enoxaparin/VKA	160083030	YES	FRANCE	N.A.	FEMALE	87	Death	死亡			SEVERE	YES	YES	117	1	YES	DEATH
Enoxaparin/VKA	160083040	YES	FRANCE	N.A.	FEMALE	75	Blood creatinine increased	血中クレアチニン増加			MILD	NO	YES	1	56	NO	RESOLVED
Enoxaparin/VKA	160083040	YES	FRANCE	N.A.	FEMALE	75	Respiratory failure	呼吸不全			SEVERE	YES	YES	56	2	NO	DEATH
Enoxaparin/VKA	160083043	YES	FRANCE	N.A.	MALE	76	Tachycardia	頻脈			MILD	NO	YES	2	4	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	160083043	YES	FRANCE	N.A.	MALE	76	Respiratory failure	呼吸不全			SEVERE	YES	YES	4	3	NO	DEATH
Enoxaparin/VKA	160083043	YES	FRANCE	N.A.	MALE	76	Constipation	便秘			MILD	NO	YES	4	1	NO	RESOLVED
Enoxaparin/VKA	160083043	YES	FRANCE	N.A.	MALE	76	Anxiety	不安			MILD	NO	YES	5	1	NO	RESOLVED
Enoxaparin/VKA	160083125	YES	FRANCE	N.A.	FEMALE	78	Abdominal pain	腹痛			MILD	NO	YES	1	10	NO	RESOLVED
Enoxaparin/VKA	160083125	YES	FRANCE	N.A.	FEMALE	78	Lung infection	肺感染			MILD	NO	YES	1	10	NO	RESOLVED
Enoxaparin/VKA	160083125	YES	FRANCE	N.A.	FEMALE	78	Pulmonary arterial hypertension	肺動脈高血圧症			MODERATE	NO	YES	2	8	NO	RESOLVED
Enoxaparin/VKA	160083125	YES	FRANCE	N.A.	FEMALE	78	Anaemia	貧血			MILD	YES	YES	3	14	NO	RESOLVED
Enoxaparin/VKA	160083125	YES	FRANCE	N.A.	FEMALE	78	Myelodysplastic syndrome	骨髄異形成症候群			SEVERE	YES	YES	13	6	NO	DEATH
Enoxaparin/VKA	160083125	YES	FRANCE	N.A.	FEMALE	78	Hypertension	高血圧			MILD	NO	YES	14	2	NO	RESOLVED
Rivaroxaban	160103012	YES	FRANCE	N.A.	MALE	70	Brain neoplasm	脳新生物	15 mg	.	SEVERE	YES	YES	2	20	NO	DEATH
Rivaroxaban	160103012	YES	FRANCE	N.A.	MALE	70	Hypertension	高血圧	15 mg	.	MILD	NO	YES	2	14	NO	RESOLVED
Rivaroxaban	160103012	YES	FRANCE	N.A.	MALE	70	Tumour haemorrhage	腫瘍出血	15 mg	F	SEVERE	YES	NO	16	6	NO	DEATH
Rivaroxaban	160123003	YES	FRANCE	N.A.	MALE	78	Dyspnoea	呼吸困難	20 mg	.	MODERATE	NO	YES	41	11	NO	RESOLVED
Rivaroxaban	160123003	YES	FRANCE	N.A.	MALE	78	Lung infection	肺感染	20 mg	.	SEVERE	NO	YES	41		NO	RESOLVED
Rivaroxaban	160123003	YES	FRANCE	N.A.	MALE	78	Cardiac failure	心不全	20 mg	.	SEVERE	YES	YES	41	11	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160123003	YES	FRANCE	N.A.	MALE	78	Melaena	メレナ	20 mg	I	MODERATE	YES	YES	44	1	YES	RESOLVED
Rivaroxaban	160123003	YES	FRANCE	N.A.	MALE	78	Gastrointestinal dysplasia	胃腸異形成	20 mg	.	MODERATE	YES	YES	64	3	NO	IMPROVED
Rivaroxaban	160123003	YES	FRANCE	N.A.	MALE	78	Gastrointestinal dysplasia	胃腸異形成	20 mg	.	MODERATE	NO	YES	67		NO	UNCHANGED
Rivaroxaban	160123003	YES	FRANCE	N.A.	MALE	78	Cardiac failure	心不全	20 mg	.	MODERATE	YES	YES	80	7	NO	RESOLVED
Rivaroxaban	160123003	YES	FRANCE	N.A.	MALE	78	Cardiac failure	心不全	20 mg	F	SEVERE	YES	NO	196	1	NO	DEATH
Rivaroxaban	160123010	YES	FRANCE	N.A.	MALE	82	Adenocarcinoma	腺癌	15 mg	.	SEVERE	YES	YES	6		NO	UNCHANGED
Rivaroxaban	160123010	YES	FRANCE	N.A.	MALE	82	Ischaemic stroke	虚血性脳卒中	15 mg	.	SEVERE	YES	YES	11	41	NO	DEATH
Rivaroxaban	160123010	YES	FRANCE	N.A.	MALE	82	Hypercalcaemia	高カルシウム血症	15 mg	F	MODERATE	NO	YES	12	1	NO	RESOLVED
Rivaroxaban	160123010	YES	FRANCE	N.A.	MALE	82	Diarrhoea	下痢	15 mg	F	MODERATE	NO	NO	20	18	NO	RESOLVED
Rivaroxaban	160123010	YES	FRANCE	N.A.	MALE	82	Overdose	過量投与	15 mg	F	.	NO	NO	37	1	NO	RESOLVED
Rivaroxaban	160123010	YES	FRANCE	N.A.	MALE	82	Haematoma	血腫	15 mg	F	MODERATE	NO	NO	49		NO	UNCHANGED
Rivaroxaban	160133002	YES	FRANCE	N.A.	MALE	74	Hypertension	高血圧	15 mg	.	MODERATE	NO	YES	12		NO	UNCHANGED
Rivaroxaban	160133002	YES	FRANCE	N.A.	MALE	74	Prostate cancer	前立腺癌	15 mg	I	MODERATE	YES	YES	24		NO	UNCHANGED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160133002	YES	FRANCE	N.A.	MALE	74	Type 2 diabetes mellitus	２型糖尿病	20 mg	.	MODERATE	NO	YES	184		NO	UNCHANGED
Rivaroxaban	160133002	YES	FRANCE	N.A.	MALE	74	Atrial fibrillation	心房細動	20 mg	.	MODERATE	NO	YES	184		NO	UNCHANGED
Rivaroxaban	160133002	YES	FRANCE	N.A.	MALE	74	Sudden death	突然死	20 mg	.	SEVERE	YES	YES	260	1	YES	DEATH
Rivaroxaban	160133002	YES	FRANCE	N.A.	MALE	74	Haematemesis	吐血	20 mg	.	SEVERE	YES	YES	260	1	NO	RESOLVED
Rivaroxaban	160143039	YES	FRANCE	N.A.	MALE	77	Ecchymosis	斑状出血	15 mg	.	MILD	NO	YES	1		YES	UNCHANGED
Rivaroxaban	160143039	YES	FRANCE	N.A.	MALE	77	Diabetes mellitus	糖尿病	15 mg	.	MODERATE	NO	YES	3		NO	UNCHANGED
Rivaroxaban	160143039	YES	FRANCE	N.A.	MALE	77	Bronchitis	気管支炎	20 mg	.	MODERATE	NO	YES	45	34	NO	RESOLVED
Rivaroxaban	160143039	YES	FRANCE	N.A.	MALE	77	Epistaxis	鼻出血	20 mg	.	MILD	NO	YES	64	1	YES	RESOLVED
Rivaroxaban	160143039	YES	FRANCE	N.A.	MALE	77	Sudden death	突然死	20 mg	.	SEVERE	YES	YES	120	1	NO	DEATH
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	Nausea	悪心			MILD	NO	YES	3	13	NO	RESOLVED
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	International normalised ratio increased	ＩＮＲ増加			MODERATE	NO	YES	8	3	YES	RESOLVED
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	Constipation	便秘			MILD	NO	YES	11	3	NO	RESOLVED
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患			SEVERE	YES	YES	15	24	NO	DEATH

表 2.7.4.7-17　死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	International normalised ratio increased	ＩＮＲ増加			MODERATE	NO	YES	15	4	YES	RESOLVED
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	Haemoglobin decreased	ヘモグロビン減少			MODERATE	NO	YES	15	24	NO	RESOLVED
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	Melaena	メレナ			MODERATE	YES	YES	17	2	YES	RESOLVED
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	Diabetes mellitus	糖尿病			MILD	NO	NO	22		NO	UNCHANGED
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	Oedema	浮腫			MILD	NO	NO	25	3	NO	RESOLVED
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	Septic shock	敗血症性ショック			MODERATE	NO	NO	29	3	NO	RESOLVED
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	Rash	発疹			MILD	NO	NO	33	1	NO	RESOLVED
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	Constipation	便秘			MILD	NO	NO	33	1	NO	RESOLVED
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	Bradycardia	徐脈			MODERATE	NO	NO	37	1	NO	RESOLVED
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	Hypokalaemia	低カリウム血症			MILD	NO	NO	38	1	NO	RESOLVED
Rivaroxaban	160153030	YES	FRANCE	N.A.	FEMALE	80	Mitral valve incompetence	僧帽弁閉鎖不全症	20 mg	.	MODERATE	NO	YES	127	230	NO	WORSENED
Rivaroxaban	160153030	YES	FRANCE	N.A.	FEMALE	80	Epistaxis	鼻出血	20 mg	.	MILD	NO	YES	264	4	YES	RESOLVED
Rivaroxaban	160153030	YES	FRANCE	N.A.	FEMALE	80	Mitral valve incompetence	僧帽弁閉鎖不全症	20 mg	F	MODERATE	YES	YES	357		NO	UNCHANGED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160153030	YES	FRANCE	N.A.	FEMALE	80	Pericardial haemorrhage	心嚢内出血	20 mg	F	SEVERE	YES	NO	358		NO	UNCHANGED
Rivaroxaban	160153030	YES	FRANCE	N.A.	FEMALE	80	Cardiogenic shock	心原性ショック	20 mg	F	SEVERE	YES	NO	358	1	NO	DEATH
Rivaroxaban	160183005	YES	FRANCE	N.A.	FEMALE	63	Depression	うつ病	15 mg	.	MILD	NO	YES	9		NO	IMPROVED
Rivaroxaban	160183005	YES	FRANCE	N.A.	FEMALE	63	Asthma	喘息	15 mg	.	MODERATE	NO	YES	16	3	NO	RESOLVED
Rivaroxaban	160183005	YES	FRANCE	N.A.	FEMALE	63	Hepatitis acute	急性肝炎	15 mg	.	SEVERE	YES	YES	18		YES	WORSENED
Rivaroxaban	160183005	YES	FRANCE	N.A.	FEMALE	63	Cardiac failure	心不全	15 mg	F	SEVERE	YES	NO	21	6	NO	DEATH
Enoxaparin/VKA	160233075	YES	FRANCE	N.A.	MALE	62	Constipation	便秘			MILD	NO	YES	3	1	NO	RESOLVED
Enoxaparin/VKA	160233075	YES	FRANCE	N.A.	MALE	62	Asthenia	無力症			MILD	NO	YES	4	6	NO	RESOLVED
Enoxaparin/VKA	160233075	YES	FRANCE	N.A.	MALE	62	Chest pain	胸痛			MODERATE	NO	YES	32		NO	UNCHANGED
Enoxaparin/VKA	160233075	YES	FRANCE	N.A.	MALE	62	Hypertension	高血圧			MILD	NO	YES	77		NO	UNCHANGED
Enoxaparin/VKA	160233075	YES	FRANCE	N.A.	MALE	62	Headache	頭痛			MODERATE	NO	YES	95		NO	UNCHANGED
Enoxaparin/VKA	160233075	YES	FRANCE	N.A.	MALE	62	Neck pain	頚部痛			MODERATE	NO	YES	95		NO	UNCHANGED
Enoxaparin/VKA	160233075	YES	FRANCE	N.A.	MALE	62	Back pain	背部痛			MODERATE	NO	YES	95		NO	UNCHANGED
Enoxaparin/VKA	160233075	YES	FRANCE	N.A.	MALE	62	Asthenia	無力症			MODERATE	NO	YES	95		NO	UNCHANGED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	160233075	YES	FRANCE	N.A.	MALE	62	Amyotrophic lateral sclerosis	筋萎縮性側索硬化症			SEVERE	YES	NO	106	76	NO	DEATH
Rivaroxaban	160243028	YES	FRANCE	N.A.	FEMALE	87	Haemoglobin decreased	ヘモグロビン減少	15 mg	.	MILD	NO	YES	1		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	160243028	YES	FRANCE	N.A.	FEMALE	87	Death	死亡	20 mg	.	SEVERE	YES	YES	136	1	YES	DEATH
Enoxaparin/VKA	160243029	YES	FRANCE	N.A.	MALE	84	Dementia Alzheimer's type	アルツハイマー型認知症			SEVERE	YES	YES	142		NO	UNCHANGED
Enoxaparin/VKA	160243029	YES	FRANCE	N.A.	MALE	84	Confusional state	錯乱状態			MILD	NO	YES	146	1	NO	RESOLVED
Enoxaparin/VKA	160243029	YES	FRANCE	N.A.	MALE	84	Pneumothorax	気胸			MODERATE	YES	YES	148	2	NO	RESOLVED
Enoxaparin/VKA	160243029	YES	FRANCE	N.A.	MALE	84	Rib fracture	肋骨骨折			MODERATE	NO	YES	148		NO	IMPROVED
Enoxaparin/VKA	160243029	YES	FRANCE	N.A.	MALE	84	Fall	転倒			MILD	NO	YES	148	1	NO	RESOLVED
Enoxaparin/VKA	160243029	YES	FRANCE	N.A.	MALE	84	Fall	転倒			MILD	NO	YES	156	1	NO	RESOLVED
Enoxaparin/VKA	160243029	YES	FRANCE	N.A.	MALE	84	Fall	転倒			MILD	NO	YES	157	1	NO	RESOLVED
Enoxaparin/VKA	160243029	YES	FRANCE	N.A.	MALE	84	Hypertension	高血圧			MILD	NO	YES	158	2	NO	RESOLVED
Enoxaparin/VKA	160243029	YES	FRANCE	N.A.	MALE	84	Haemorrhage intracranial	頭蓋内出血			SEVERE	YES	YES	166	4	YES	DEATH
Rivaroxaban	160243030	YES	FRANCE	N.A.	MALE	54	Cardiac failure acute	急性心不全	20 mg	.	MODERATE	YES	YES	53	75	NO	DEATH

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160243030	YES	FRANCE	N.A.	MALE	54	Dyspnoea	呼吸困難	20 mg	.	MODERATE	NO	YES	66	61	NO	RESOLVED
Rivaroxaban	160243030	YES	FRANCE	N.A.	MALE	54	Chest pain	胸痛	20 mg	.	MODERATE	NO	YES	70	26	NO	RESOLVED
Rivaroxaban	160243030	YES	FRANCE	N.A.	MALE	54	Cough	咳嗽	20 mg	.	MILD	NO	YES	70	57	NO	RESOLVED
Rivaroxaban	160243030	YES	FRANCE	N.A.	MALE	54	Chills	悪寒	20 mg	.	MILD	NO	YES	70	57	NO	RESOLVED
Rivaroxaban	160243030	YES	FRANCE	N.A.	MALE	54	Oedema peripheral	末梢性浮腫	20 mg	.	MODERATE	NO	YES	70	57	NO	RESOLVED
Rivaroxaban	160243030	YES	FRANCE	N.A.	MALE	54	Abdominal pain	腹痛	20 mg	.	MODERATE	NO	YES	74	22	NO	RESOLVED
Rivaroxaban	160243030	YES	FRANCE	N.A.	MALE	54	Pleural effusion	胸水	20 mg	.	MODERATE	NO	YES	75	3	NO	RESOLVED
Rivaroxaban	160243030	YES	FRANCE	N.A.	MALE	54	Cardiac failure	心不全	20 mg	F	SEVERE	YES	YES	127	1	NO	DEATH
Rivaroxaban	160263007	YES	FRANCE	N.A.	MALE	39	Constipation	便秘			MILD	NO	YES			NO	UNCHANGED
Rivaroxaban	160263007	YES	FRANCE	N.A.	MALE	39	Urinary tract infection	尿路感染	20 mg	.	MILD	NO	YES	27	3	NO	RESOLVED
Rivaroxaban	160263007	YES	FRANCE	N.A.	MALE	39	Anaemia	貧血	20 mg	.	SEVERE	YES	YES	32	4	NO	RESOLVED
Rivaroxaban	160263007	YES	FRANCE	N.A.	MALE	39	Insomnia	不眠症	20 mg	.	MILD	NO	YES	33		NO	UNCHANGED
Rivaroxaban	160263007	YES	FRANCE	N.A.	MALE	39	Melaena	メレナ	20 mg	.	MODERATE	NO	YES	34		YES	UNCHANGED
Rivaroxaban	160263007	YES	FRANCE	N.A.	MALE	39	Anxiety	不安	20 mg	.	MILD	NO	YES	34		NO	UNCHANGED
Rivaroxaban	160263007	YES	FRANCE	N.A.	MALE	39	Skin haemorrhage	皮膚出血	20 mg	.	MILD	NO	YES	38	1	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160263007	YES	FRANCE	N.A.	MALE	39	Acute respiratory distress syndrome	急性呼吸窮迫症候群	20 mg	.	SEVERE	YES	YES	40	1	NO	DEATH
Enoxaparin/VKA	160273041	YES	FRANCE	N.A.	MALE	70	Depression	うつ病			MILD	NO	YES			NO	UNCHANGED
Enoxaparin/VKA	160273041	YES	FRANCE	N.A.	MALE	70	Anxiety	不安			MILD	NO	YES			NO	UNCHANGED
Enoxaparin/VKA	160273041	YES	FRANCE	N.A.	MALE	70	Skin disorder	皮膚障害			MILD	NO	YES			NO	UNCHANGED
Enoxaparin/VKA	160273041	YES	FRANCE	N.A.	MALE	70	Abdominal pain upper	上腹部痛			MILD	NO	YES	2		NO	UNCHANGED
Enoxaparin/VKA	160273041	YES	FRANCE	N.A.	MALE	70	Spinal cord compression	脊髄圧迫			SEVERE	YES	YES	51		NO	UNCHANGED
Enoxaparin/VKA	160273041	YES	FRANCE	N.A.	MALE	70	Metastatic neoplasm	転移性新生物			SEVERE	YES	YES	51	52	NO	DEATH
Enoxaparin/VKA	160273041	YES	FRANCE	N.A.	MALE	70	Infection	感染			MILD	NO	NO	57	8	NO	RESOLVED
Enoxaparin/VKA	160273041	YES	FRANCE	N.A.	MALE	70	Pyrexia	発熱			MILD	NO	NO	84	13	NO	RESOLVED
Enoxaparin/VKA	160273041	YES	FRANCE	N.A.	MALE	70	Nausea	悪心			MODERATE	NO	NO	85		NO	UNCHANGED
Enoxaparin/VKA	160273041	YES	FRANCE	N.A.	MALE	70	Diarrhoea	下痢			MILD	NO	NO	88	5	NO	RESOLVED
Enoxaparin/VKA	160273041	YES	FRANCE	N.A.	MALE	70	Infection	感染			MILD	NO	NO	91	5	NO	RESOLVED
Enoxaparin/VKA	160273041	YES	FRANCE	N.A.	MALE	70	Oral fungal infection	口腔真菌感染			MILD	NO	NO	100		NO	UNCHANGED
Enoxaparin/VKA	160293078	YES	FRANCE	N.A.	MALE	87	Cerebral haemorrhage	脳出血			SEVERE	YES	YES	135	1	YES	DEATH

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160293080	YES	FRANCE	N.A.	FEMALE	51	Vomiting	嘔吐	15 mg	.	MILD	NO	YES	1	2	NO	RESOLVED
Rivaroxaban	160293080	YES	FRANCE	N.A.	FEMALE	51	Ischaemic stroke	虚血性脳卒中	15 mg	.	SEVERE	YES	YES	7		NO	UNCHANGED
Rivaroxaban	160293080	YES	FRANCE	N.A.	FEMALE	51	Endocarditis	心内膜炎	15 mg	.	MODERATE	YES	YES	7	11	NO	DEATH
Rivaroxaban	160293080	YES	FRANCE	N.A.	FEMALE	51	Respiratory failure	呼吸不全	15 mg	.	MODERATE	NO	YES	7		NO	UNCHANGED
Rivaroxaban	160293080	YES	FRANCE	N.A.	FEMALE	51	Tachycardia	頻脈	15 mg	.	MODERATE	NO	YES	7		NO	UNCHANGED
Rivaroxaban	160293080	YES	FRANCE	N.A.	FEMALE	51	Sepsis	敗血症	15 mg	.	SEVERE	YES	YES	7	11	NO	DEATH
Rivaroxaban	160293080	YES	FRANCE	N.A.	FEMALE	51	Platelet count decreased	血小板数減少	15 mg	F	MODERATE	NO	YES	11		NO	UNCHANGED
Rivaroxaban	160293080	YES	FRANCE	N.A.	FEMALE	51	Lung disorder	肺障害	15 mg	F	MODERATE	NO	NO	14		NO	UNCHANGED
Rivaroxaban	160293080	YES	FRANCE	N.A.	FEMALE	51	Pleural effusion	胸水	15 mg	F	MODERATE	NO	NO	14		NO	UNCHANGED
Rivaroxaban	160293103	YES	FRANCE	N.A.	FEMALE	80	Lung infection	肺感染			MILD	NO	YES			NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	160293103	YES	FRANCE	N.A.	FEMALE	80	Haematemesis	吐血	15 mg	.	MILD	NO	YES	6		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	160293103	YES	FRANCE	N.A.	FEMALE	80	Acute myocardial infarction	急性心筋梗塞	15 mg	.	SEVERE	YES	YES	17	6	NO	DEATH
Rivaroxaban	160293103	YES	FRANCE	N.A.	FEMALE	80	Hyperglycaemia	高血糖	15 mg	.	MILD	NO	YES	17		NO	IMPROVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160303027	YES	FRANCE	N.A.	MALE	59	Tinea pedis	足部白癬	15 mg	.	MILD	NO	YES	20	3	NO	RESOLVED
Rivaroxaban	160303027	YES	FRANCE	N.A.	MALE	59	Bronchopulmonary aspergillosis	気管支肺アスペルギルス症	20 mg	.	SEVERE	YES	YES	44	55	NO	DEATH
Rivaroxaban	160303027	YES	FRANCE	N.A.	MALE	59	Bronchitis	気管支炎	20 mg	.	MODERATE	NO	YES	44		NO	UNCHANGED
Rivaroxaban	160303027	YES	FRANCE	N.A.	MALE	59	Pulmonary haemorrhage	肺出血	20 mg	.	SEVERE	YES	YES	76	23	NO	DEATH
Rivaroxaban	160303027	YES	FRANCE	N.A.	MALE	59	Diabetes mellitus	糖尿病	20 mg	F	MODERATE	NO	NO	90		NO	UNCHANGED
Rivaroxaban	160333004	YES	FRANCE	N.A.	FEMALE	85	Dysphagia	嚥下障害	15 mg	.	MODERATE	NO	YES	2		NO	UNCHANGED
Rivaroxaban	160333004	YES	FRANCE	N.A.	FEMALE	85	Nausea	悪心	15 mg	.	MODERATE	NO	YES	8	18	NO	WORSENED
Rivaroxaban	160333004	YES	FRANCE	N.A.	FEMALE	85	Hyponatraemia	低ナトリウム血症	15 mg	.	MODERATE	NO	YES	11	15	NO	WORSENED
Rivaroxaban	160333004	YES	FRANCE	N.A.	FEMALE	85	Small intestinal haemorrhage	小腸出血	15 mg	F	MILD	NO	NO	16	4	NO	RESOLVED
Rivaroxaban	160333004	YES	FRANCE	N.A.	FEMALE	85	Vomiting	嘔吐	15 mg	F	MODERATE	NO	NO	24	2	NO	WORSENED
Rivaroxaban	160333004	YES	FRANCE	N.A.	FEMALE	85	Acute respiratory distress syndrome	急性呼吸窮迫症候群	15 mg	F	SEVERE	YES	NO	25	1	NO	DEATH
Rivaroxaban	160333004	YES	FRANCE	N.A.	FEMALE	85	Pneumonia	肺炎	15 mg	F	MILD	NO	NO	25	1	NO	WORSENED
Enoxaparin/V	160333009	YES	FRANCE	N.A.	MALE	74	Epistaxis	鼻出血			MILD	NO	YES	14	1	YES	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA																	
Enoxaparin/VKA	160333009	YES	FRANCE	N.A.	MALE	74	Epistaxis	鼻出血			SEVERE	NO	YES	19	1	YES	RESOLVED
Enoxaparin/VKA	160333009	YES	FRANCE	N.A.	MALE	74	Haemoptysis	喀血			MILD	NO	YES	37	1	NO	RESOLVED
Enoxaparin/VKA	160333009	YES	FRANCE	N.A.	MALE	74	Pleurisy	胸膜炎			MODERATE	YES	YES	104	9	NO	DEATH
Enoxaparin/VKA	160333035	YES	FRANCE	N.A.	MALE	65	Asthenia	無力症			MILD	NO	YES	10	17	NO	RESOLVED
Enoxaparin/VKA	160333035	YES	FRANCE	N.A.	MALE	65	Nausea	悪心			MILD	NO	YES	10	17	NO	RESOLVED
Enoxaparin/VKA	160333035	YES	FRANCE	N.A.	MALE	65	Diarrhoea	下痢			MILD	NO	YES	10	17	NO	RESOLVED
Enoxaparin/VKA	160333035	YES	FRANCE	N.A.	MALE	65	Mental disorder	精神障害			MILD	YES	YES	42	5	NO	IMPROVED
Enoxaparin/VKA	160333035	YES	FRANCE	N.A.	MALE	65	Dehydration	脱水			MODERATE	NO	YES	42	5	NO	RESOLVED
Enoxaparin/VKA	160333035	YES	FRANCE	N.A.	MALE	65	Mental disorder	精神障害			MILD	NO	YES	47		NO	IMPROVED
Enoxaparin/VKA	160333035	YES	FRANCE	N.A.	MALE	65	Asthenia	無力症			MILD	NO	YES	74	22	NO	RESOLVED
Enoxaparin/VKA	160333035	YES	FRANCE	N.A.	MALE	65	Bronchitis	気管支炎			MILD	NO	YES	123		NO	RESOLVED
Enoxaparin/VKA	160333035	YES	FRANCE	N.A.	MALE	65	Back pain	背部痛			SEVERE	YES	YES	151		NO	UNCHANGED
Enoxaparin/VKA	160333035	YES	FRANCE	N.A.	MALE	65	Acute respiratory failure	急性呼吸不全			SEVERE	YES	NO	155	1	NO	DEATH
Enoxaparin/V	160333068	YES	FRANCE	N.A.	MALE	77	Pain in	四肢痛			MILD	NO	YES	15	1	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA							extremity										
Enoxaparin/VKA	160333068	YES	FRANCE	N.A.	MALE	77	Multiple injuries	多発性外傷			SEVERE	YES	YES	19	1	NO	DEATH
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Pyrexia	発熱			MODERATE	NO	YES	2	39	NO	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Aortic calcification	大動脈石灰化			MILD	NO	YES	2		NO	UNCHANGED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Abdominal pain upper	上腹部痛			MODERATE	NO	YES	3	2	NO	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Mitral valve incompetence	僧帽弁閉鎖不全症			MILD	NO	YES	3		NO	UNCHANGED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Chest pain	胸痛			MODERATE	NO	YES	4	1	NO	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Gastritis	胃炎			MODERATE	NO	YES	6	38	NO	IMPROVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Back pain	背部痛			MODERATE	NO	YES	7	1	NO	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Pain in extremity	四肢痛			MODERATE	NO	YES	7	7	NO	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Hiatus hernia	裂孔ヘルニア			MILD	NO	YES	8		NO	UNCHANGED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Pelvic neoplasm	骨盤新生物			SEVERE	YES	YES	9	90	NO	DEATH
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Hepatic cyst	肝嚢胞			MILD	NO	YES	9		NO	UNCHANGED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Chest pain	胸痛			MODERATE	NO	YES	12	32	NO	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Vomiting	嘔吐			MODERATE	NO	YES	14	1	NO	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Hiccups	しゃっくり			MODERATE	NO	YES	14	7	NO	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Pneumonia	肺炎			MODERATE	NO	YES	14	8	NO	WORSENED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Pleural effusion	胸水			MODERATE	NO	YES	14	51	NO	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Depression	うつ病			MODERATE	NO	YES	16		NO	UNCHANGED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Anaemia	貧血			SEVERE	YES	YES	19	3	YES	IMPROVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Hyperthyroidism	甲状腺機能亢進症			MILD	NO	YES	20	23	NO	WORSENED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Pneumonia	肺炎			SEVERE	YES	YES	21	23	NO	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Hyperthyroidism	甲状腺機能亢進症			MODERATE	NO	YES	42		NO	UNCHANGED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Gastritis	胃炎			MILD	NO	YES	44		NO	UNCHANGED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Back pain	背部痛			MODERATE	NO	YES	56	1	NO	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Epistaxis	鼻出血			MILD	NO	YES	58	2	YES	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Anaemia	貧血			MILD	NO	YES	58		YES	UNCHANGED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Extremity necrosis	四肢壊死			MODERATE	NO	YES	58		NO	UNCHANGED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Coagulopathy	凝血異常			SEVERE	YES	YES	59	11	YES	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Pain in extremity	四肢痛			MODERATE	NO	YES	59		NO	UNCHANGED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Constipation	便秘			MODERATE	NO	YES	60	6	NO	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Nausea	悪心			MODERATE	NO	YES	62	1	NO	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Ischaemic stroke	虚血性脳卒中			SEVERE	YES	NO	80	6	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Hypokalaemia	低カリウム血症	15 mg	.	MODERATE	NO	YES	3	3	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Dyspnoea	呼吸困難	15 mg	.	MODERATE	NO	YES	4	5	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Cardiac aneurysm	心臓瘤	15 mg	.	MILD	NO	YES	5		NO	UNCHANGED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Mitral valve incompetence	僧帽弁閉鎖不全症	15 mg	.	MILD	NO	YES	5		NO	UNCHANGED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Aortic valve incompetence	大動脈弁閉鎖不全症	15 mg	.	MILD	NO	YES	5		NO	UNCHANGED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Pleural effusion	胸水	15 mg	.	MILD	NO	YES	8	226	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Pleural adhesion	胸膜癒着	15 mg	.	MILD	NO	YES	8	226	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Asthenia	無力症	15 mg	.	MODERATE	NO	YES	8	1	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Nausea	悪心	15 mg	.	MODERATE	NO	YES	9	5	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Cough	咳嗽	15 mg	.	MODERATE	NO	YES	14	3	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Dyspnoea	呼吸困難	20 mg	.	MODERATE	NO	YES	26	11	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Respiratory tract infection	気道感染	20 mg	.	SEVERE	YES	YES	30	7	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Glucose tolerance impaired	耐糖能障害	20 mg	.	MODERATE	NO	YES	30		NO	UNCHANGED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Pleural fibrosis	胸膜線維症	20 mg	.	MILD	NO	YES	30		NO	UNCHANGED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Chest pain	胸痛	20 mg	.	MODERATE	NO	YES	49	20	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Circulatory collapse	循環虚脱	20 mg	.	MODERATE	NO	YES	58	11	NO	WORSENED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Dermatitis	皮膚炎	20 mg	.	MODERATE	NO	YES	58	20	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Circulatory collapse	循環虚脱	20 mg	.	SEVERE	YES	YES	68	11	NO	IMPROVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Contusion	挫傷	20 mg	.	MODERATE	NO	YES	69	46	YES	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Neuropathy peripheral	末梢性ニューロパチー	20 mg	.	MODERATE	NO	YES	70		NO	UNCHANGED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Cervicobrachial syndrome	頚腕症候群	20 mg	.	MODERATE	NO	YES	70		NO	UNCHANGED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Ventricular hypertrophy	心室肥大	20 mg	.	MILD	NO	YES	72		NO	UNCHANGED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Renal cyst	腎嚢胞	20 mg	.	MILD	NO	YES	72	6	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Pancreatic atrophy	膵萎縮	20 mg	F	MILD	NO	YES	76	163	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Hepatic cirrhosis	肝硬変	20 mg	F	MILD	NO	YES	76	163	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Circulatory collapse	循環虚脱	20 mg	F	MILD	NO	NO	78	11	NO	WORSENED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Circulatory collapse	循環虚脱	20 mg	F	MODERATE	NO	NO	89	67	NO	IMPROVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Circulatory collapse	循環虚脱	20 mg	F	MILD	NO	NO	156	122	NO	WORSENED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Erysipelas	丹毒	20 mg	F	MODERATE	NO	NO	209	16	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Cerebrovascular insufficiency	脳血管不全	20 mg	F	SEVERE	YES	NO	231	9	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Chronic sinusitis	慢性副鼻腔炎	20 mg	F	MODERATE	NO	NO	233		NO	UNCHANGED

表 2.7.4.7-17　死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	International normalised ratio increased	ＩＮＲ増加	20 mg	F	MODERATE	NO	NO	233	3	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Emphysema	肺気腫	20 mg	F	MILD	NO	NO	233		NO	UNCHANGED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Cerebral atrophy	大脳萎縮	20 mg	F	MILD	NO	NO	233		NO	UNCHANGED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Circulatory collapse	循環虚脱	20 mg	F	MODERATE	NO	NO	278	5	NO	WORSENED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Circulatory collapse	循環虚脱	20 mg	F	SEVERE	YES	NO	282	3	NO	DEATH
Rivaroxaban	220013020	YES	ITALY	WHITE	FEMALE	76	Hypertension	高血圧	15 mg	.	MILD	NO	YES	7	1	NO	RESOLVED
Rivaroxaban	220013020	YES	ITALY	WHITE	FEMALE	76	Anxiety	不安	15 mg	.	MILD	NO	YES	10	5	NO	RESOLVED
Rivaroxaban	220013020	YES	ITALY	WHITE	FEMALE	76	Ascites	腹水	15 mg	.	MODERATE	NO	YES	20		NO	UNCHANGED
Rivaroxaban	220013020	YES	ITALY	WHITE	FEMALE	76	Ovarian cancer	卵巣癌	20 mg	.	SEVERE	YES	YES	31	1	NO	DEATH
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Hyperglycaemia	高血糖			MODERATE	NO	YES	2	10	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Cardiac failure	心不全			MODERATE	YES	YES	2	6	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Hypotension	低血圧			MILD	NO	YES	2	2	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Cerebral haemorrhage	脳出血			SEVERE	YES	YES	3	10	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Oliguria	乏尿			MILD	NO	YES	3	1	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Hypophosphataemia	低リン酸血症			MODERATE	NO	NO	5	3	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Candidiasis	カンジダ症			MILD	NO	NO	11	30	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Hypertension	高血圧			MODERATE	NO	NO	11	2	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Respiratory failure	呼吸不全			SEVERE	YES	NO	27	47	NO	DEATH
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Convulsion	痙攣			MILD	NO	NO	29	45	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Urinary tract infection	尿路感染			MILD	NO	NO	47	10	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Flatulence	鼓腸			MILD	NO	NO	55	16	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Hypoalbuminaemia	低アルブミン血症			MODERATE	NO	NO	56	14	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Diarrhoea	下痢			MODERATE	NO	NO	64	1	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Enterocolitis	腸炎			MODERATE	NO	NO	64	10	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Depression	うつ病			MODERATE	NO	NO	70	2	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Anuria	無尿			MODERATE	NO	NO	71	3	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Hypotension	低血圧			SEVERE	NO	NO	73	1	NO	RESOLVED
Rivaroxaban	220093011	YES	ITALY	WHITE	FEMALE	77	Sudden death	突然死	15 mg	F	SEVERE	YES	YES	13	1	YES	DEATH

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	240073041	YES	SPAIN	WHITE	FEMALE	80	Constipation	便秘	15 mg	.	MILD	NO	YES	2	4	NO	RESOLVED
Rivaroxaban	240073041	YES	SPAIN	WHITE	FEMALE	80	Insomnia	不眠症	15 mg	.	MILD	NO	YES	2	1	NO	RESOLVED
Rivaroxaban	240073041	YES	SPAIN	WHITE	FEMALE	80	Supraventricular tachycardia	上室性頻脈	15 mg	.	MODERATE	NO	YES	5	2	NO	RESOLVED
Rivaroxaban	240073041	YES	SPAIN	WHITE	FEMALE	80	Pulmonary embolism	肺塞栓症	15 mg	.	SEVERE	YES	YES	5	2	NO	DEATH
Enoxaparin/VKA	260053127	YES	CANADA	WHITE	FEMALE	80	Death	死亡			SEVERE	YES	YES	21	1	YES	DEATH
Enoxaparin/VKA	280013045	YES	BELGIUM	WHITE	FEMALE	88	Haemorrhoidal haemorrhage	痔出血			MILD	NO	YES	3		YES	UNCHANGED
Enoxaparin/VKA	280013045	YES	BELGIUM	WHITE	FEMALE	88	Xanthoma	黄色腫			MILD	NO	YES	33		NO	UNCHANGED
Enoxaparin/VKA	280013045	YES	BELGIUM	WHITE	FEMALE	88	Pruritus generalised	全身性そう痒症			MILD	NO	YES	42	9	NO	RESOLVED
Enoxaparin/VKA	280013045	YES	BELGIUM	WHITE	FEMALE	88	Epilepsy	てんかん			MILD	YES	YES	52	2	NO	IMPROVED
Enoxaparin/VKA	280013045	YES	BELGIUM	WHITE	FEMALE	88	Epilepsy	てんかん			MILD	NO	YES	54	80	NO	WORSENED
Enoxaparin/VKA	280013045	YES	BELGIUM	WHITE	FEMALE	88	Epilepsy	てんかん			MODERATE	YES	YES	134		NO	UNCHANGED
Enoxaparin/VKA	280013045	YES	BELGIUM	WHITE	FEMALE	88	General physical health deterioration	全身健康状態低下			SEVERE	YES	YES	134	11	NO	DEATH
Rivaroxaban	280033002	YES	BELGIUM	WHITE	MALE	82	Neoplasm prostate	前立腺新生物	20 mg	.	MODERATE	NO	YES	72	51	NO	WORSENED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	280033002	YES	BELGIUM	WHITE	MALE	82	Fatigue	疲労	20 mg	.	MODERATE	NO	YES	112		NO	UNCHANGED
Rivaroxaban	280033002	YES	BELGIUM	WHITE	MALE	82	Productive cough	湿性咳嗽	20 mg	.	MILD	NO	YES	113		NO	UNCHANGED
Rivaroxaban	280033002	YES	BELGIUM	WHITE	MALE	82	Neoplasm prostate	前立腺新生物	20 mg	.	SEVERE	YES	YES	123	18	NO	DEATH
Rivaroxaban	280033002	YES	BELGIUM	WHITE	MALE	82	Decreased appetite	食欲減退	20 mg	.	SEVERE	YES	YES	123		NO	UNCHANGED
Rivaroxaban	280033002	YES	BELGIUM	WHITE	MALE	82	Pneumonia	肺炎	20 mg	.	SEVERE	YES	YES	123		NO	UNCHANGED
Rivaroxaban	280033002	YES	BELGIUM	WHITE	MALE	82	Haemoptysis	喀血	20 mg	.	MILD	NO	YES	128	1	NO	RESOLVED
Rivaroxaban	280033002	YES	BELGIUM	WHITE	MALE	82	Platelet count decreased	血小板数減少	20 mg	F	MODERATE	NO	NO	132		NO	UNCHANGED
Enoxaparin/VKA	280083018	YES	BELGIUM	WHITE	FEMALE	83	Sudden death	突然死			SEVERE	YES	YES	3	1	NO	DEATH
Rivaroxaban	280083032	YES	BELGIUM	WHITE	FEMALE	73	Subdural haematoma	硬膜下血腫	15 mg	.	SEVERE	YES	YES	3	61	YES	DEATH
Rivaroxaban	280083032	YES	BELGIUM	WHITE	FEMALE	73	Confusional state	錯乱状態	15 mg	.	MODERATE	NO	YES	3		NO	UNCHANGED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Biliary tract infection bacterial	細菌性胆道感染			MODERATE	NO	YES			NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Depression	うつ病			MODERATE	NO	YES			NO	UNCHANGED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Haemorrhoids	痔核			MILD	NO	YES			NO	UNCHANGED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Epistaxis	鼻出血	15 mg	.	MILD	NO	YES	3	1	YES	RESOLVED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Metrorrhagia	不正子宮出血	15 mg	.	SEVERE	YES	YES	6	3	YES	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Hypokalaemia	低カリウム血症	15 mg	.	MODERATE	NO	YES	9		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Dizziness	浮動性めまい	15 mg	.	MODERATE	YES	YES	10	11	NO	RESOLVED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Haematuria	血尿	15 mg	.	MODERATE	NO	YES	10		YES	RESOLVED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Hepatic enzyme increased	肝酵素上昇	15 mg	.	SEVERE	NO	YES	10		NO	IMPROVED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Pruritus	そう痒症	15 mg	.	MODERATE	NO	YES	17		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Mitral valve incompetence	僧帽弁閉鎖不全症	15 mg	.	MILD	NO	YES	17		NO	UNCHANGED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Aortic valve incompetence	大動脈弁閉鎖不全症	15 mg	.	MODERATE	NO	YES	17		NO	UNCHANGED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Hypomagnesaemia	低マグネシウム血症	15 mg	.	MODERATE	NO	YES	17	2	NO	RESOLVED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Cellulitis	蜂巣炎	20 mg	.	MODERATE	NO	YES	22		NO	UNCHANGED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Nausea	悪心	20 mg	.	MODERATE	NO	YES	29		NO	UNCHANGED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Vomiting	嘔吐	20 mg	.	MILD	NO	YES	50	1	NO	RESOLVED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Abdominal pain	腹痛	20 mg	.	SEVERE	NO	YES	51		NO	UNCHANGED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Hyperuricaemia	高尿酸血症	20 mg	.	MILD	NO	YES	56		NO	INSUFFICIENT FOLLOW-

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

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																	UP
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Gallbladder cancer	胆嚢癌	20 mg	I	SEVERE	YES	YES	57	68	NO	DEATH
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Cholelithiasis	胆石症	20 mg	I	SEVERE	YES	YES	57	7	NO	RESOLVED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Subcutaneous haematoma	皮下血腫	20 mg	.	MODERATE	NO	YES	64		YES	INSUFFICIENT FOLLOW-UP
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Pain in extremity	四肢痛	20 mg	.	MILD	NO	YES	64		NO	RESOLVED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Diarrhoea	下痢	20 mg	.	MILD	NO	YES	72	1	NO	RESOLVED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Rectal haemorrhage	直腸出血	20 mg	.	MODERATE	NO	YES	104		YES	INSUFFICIENT FOLLOW-UP
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Fall	転倒	20 mg	.	MILD	NO	YES	104	1	NO	RESOLVED
Enoxaparin/VKA	280173001	YES	BELGIUM	WHITE	FEMALE	71	Vomiting	嘔吐			MILD	NO	YES	6	1	NO	RESOLVED
Enoxaparin/VKA	280173001	YES	BELGIUM	WHITE	FEMALE	71	Urinary tract infection	尿路感染			MILD	NO	YES	10		NO	UNCHANGED
Enoxaparin/VKA	280173001	YES	BELGIUM	WHITE	FEMALE	71	Respiratory failure	呼吸不全			SEVERE	YES	YES	12	1	NO	DEATH
Rivaroxaban	280173002	YES	BELGIUM	WHITE	MALE	79	Interstitial lung disease	間質性肺疾患	15 mg	.	SEVERE	YES	YES	1	30	NO	DEATH
Rivaroxaban	280173002	YES	BELGIUM	WHITE	MALE	79	Constipation	便秘	15 mg	.	MILD	NO	YES	10		NO	UNCHANGED
Rivaroxaban	280173002	YES	BELGIUM	WHITE	MALE	79	Tachycardia	頻脈	15 mg	F	MILD	NO	YES	11		NO	UNCHANGED
Rivaroxaban	280173002	YES	BELGIUM	WHITE	MALE	79	General physical health	全身健康状態低下	15 mg	F	MODERATE	NO	YES	11		NO	UNCHANGED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							deterioration										
Rivaroxaban	280173002	YES	BELGIUM	WHITE	MALE	79	Catheter site haemorrhage	カテーテル留置部位出血	15 mg	F	MILD	NO	NO	14	1	NO	RESOLVED
Rivaroxaban	280173002	YES	BELGIUM	WHITE	MALE	79	Proteus test positive	プロテウス検査陽性	15 mg	F	MILD	NO	NO	14		NO	UNCHANGED
Rivaroxaban	280173002	YES	BELGIUM	WHITE	MALE	79	Moraxella test positive	モラクセラ検査陽性	15 mg	F	MILD	NO	NO	14		NO	UNCHANGED
Rivaroxaban	280173002	YES	BELGIUM	WHITE	MALE	79	Atrial fibrillation	心房細動	15 mg	F	MILD	NO	NO	16	1	NO	RESOLVED
Rivaroxaban	280173002	YES	BELGIUM	WHITE	MALE	79	Aspergillus test positive	アスペルギルス検査陽性	15 mg	F	MODERATE	NO	NO	20		NO	UNCHANGED
Rivaroxaban	280173002	YES	BELGIUM	WHITE	MALE	79	Pneumothorax	気胸	15 mg	F	MODERATE	NO	NO	23		NO	UNCHANGED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Dermatitis	皮膚炎			MODERATE	NO	YES			NO	UNCHANGED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Decubitus ulcer	褥瘡性潰瘍	15 mg	.	MILD	NO	YES	2	7	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Nausea	悪心	15 mg	.	MODERATE	NO	YES	12	23	YES	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Lung infection	肺感染	20 mg	.	MODERATE	NO	YES	23	9	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Abdominal pain	腹痛	20 mg	.	MODERATE	NO	YES	55	6	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Vomiting	嘔吐	20 mg	.	MILD	NO	YES	55	1	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Cardiac failure	心不全	20 mg	.	SEVERE	YES	YES	55	7	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Blood bilirubin increased	血中ビリルビン増加	20 mg	.	MILD	NO	YES	55	44	YES	WORSENED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Flatulence	鼓腸	20 mg	.	MODERATE	NO	YES	94	8	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Oedema peripheral	末梢性浮腫	20 mg	.	SEVERE	NO	YES	96	9	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Cardiac failure	心不全	20 mg	.	SEVERE	YES	YES	98	7	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Blood bilirubin increased	血中ビリルビン増加	20 mg	.	MODERATE	NO	YES	98	30	YES	IMPROVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Abdominal pain	腹痛	20 mg	.	MODERATE	NO	YES	99	1	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Abdominal distension	腹部膨満	20 mg	.	MODERATE	NO	YES	100	29	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Blood bilirubin increased	血中ビリルビン増加	20 mg	.	MILD	NO	YES	127	27	YES	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Blood bilirubin increased	血中ビリルビン増加	20 mg	.	MILD	NO	YES	183	57	YES	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Abdominal pain	腹痛	20 mg	.	MODERATE	NO	YES	205	5	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Musculoskeletal pain	筋骨格痛	20 mg	.	MODERATE	NO	YES	207	4	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Blood bilirubin increased	血中ビリルビン増加	20 mg	.	MILD	NO	YES	295		YES	UNCHANGED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Bronchopneumonia	気管支肺炎	20 mg	.	MODERATE	YES	YES	330	15	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Haemoptysis	喀血	20 mg	.	MILD	NO	YES	332	5	YES	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Haematuria	血尿	20 mg	I	MILD	NO	YES	333	1	YES	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Vomiting	嘔吐	20 mg	I	MILD	NO	YES	333	1	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Insomnia	不眠症	20 mg	.	MODERATE	NO	YES	336		NO	UNCHANGED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Abdominal pain upper	上腹部痛	20 mg	.	MILD	NO	YES	343	1	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Lung infection	肺感染	20 mg	.	MODERATE	NO	YES	350	10	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Arrhythmia	不整脈	20 mg	F	SEVERE	YES	NO	364	1	NO	DEATH
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Anxiety	不安	20 mg	F	SEVERE	NO	NO	364		NO	UNCHANGED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Chest pain	胸痛	20 mg	F	MODERATE	NO	NO	364		NO	UNCHANGED
Rivaroxaban	300073051	YES	NETHERLANDS	WHITE	MALE	79	Death	死亡	15 mg	.	SEVERE	YES	YES	3	1	NO	DEATH
Enoxaparin/VKA	300073113	YES	NETHERLANDS	WHITE	MALE	57	International normalised ratio increased	ＩＮＲ増加			MILD	NO	YES	12	3	YES	RESOLVED
Enoxaparin/VKA	300073113	YES	NETHERLANDS	WHITE	MALE	57	International normalised	ＩＮＲ増加			MILD	NO	YES	29	3	YES	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							ratio increased										
Enoxaparin/VKA	300073113	YES	NETHERLANDS	WHITE	MALE	57	Acute myocardial infarction	急性心筋梗塞			SEVERE	YES	YES	88	14	NO	DEATH
Enoxaparin/VKA	300073113	YES	NETHERLANDS	WHITE	MALE	57	Pneumonia	肺炎			MODERATE	NO	YES	88		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	300073113	YES	NETHERLANDS	WHITE	MALE	57	Thrombocytopenia	血小板減少症			MODERATE	NO	YES	88	8	NO	RESOLVED
Enoxaparin/VKA	300073113	YES	NETHERLANDS	WHITE	MALE	57	Renal tubular necrosis	腎尿細管壊死			SEVERE	NO	YES	89		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	300073125	YES	NETHERLANDS	WHITE	FEMALE	31	Death	死亡	20 mg	.	SEVERE	YES	YES	165	1	NO	DEATH
Enoxaparin/VKA	300073213	YES	NETHERLANDS	WHITE	MALE	57	International normalised ratio increased	ＩＮＲ増加			MILD	NO	YES	5	4	YES	RESOLVED
Enoxaparin/VKA	300073213	YES	NETHERLANDS	WHITE	MALE	57	Rectal cancer metastatic	転移性直腸癌			SEVERE	YES	YES	36	93	NO	DEATH
Enoxaparin/VKA	300073213	YES	NETHERLANDS	WHITE	MALE	57	Dyspnoea	呼吸困難			MODERATE	NO	YES	87		NO	UNCHANGED
Enoxaparin/VKA	300073213	YES	NETHERLANDS	WHITE	MALE	57	Cough	咳嗽			MILD	NO	YES	90	6	NO	RESOLVED
Enoxaparin/VKA	300073213	YES	NETHERLANDS	WHITE	MALE	57	Subcutaneous haematoma	皮下血腫			MILD	NO	YES	94		YES	INSUFFICIENT FOLLOW-UP

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	300073282	YES	NETHERLANDS	WHITE	FEMALE	44	Pulmonary embolism	肺塞栓症	15 mg	.	SEVERE	YES	YES	1	2	NO	DEATH
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Abdominal pain	腹痛	15 mg	.	MODERATE	NO	YES	1	19	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Hypertension	高血圧	15 mg	.	MILD	NO	YES	1	3	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Dyspepsia	消化不良	15 mg	.	MILD	NO	YES	2	1	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Vomiting	嘔吐	15 mg	.	MILD	NO	YES	3	3	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Nausea	悪心	15 mg	.	MILD	NO	YES	3	13	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Diarrhoea	下痢	15 mg	.	MODERATE	NO	YES	4	5	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Pyrexia	発熱	15 mg	.	MILD	NO	YES	7	1	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Abdominal distension	腹部膨満	15 mg	.	MODERATE	NO	YES	9	11	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Large intestinal obstruction	大腸閉塞	15 mg	.	SEVERE	YES	YES	10		NO	UNCHANGED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Urine output decreased	尿量減少	15 mg	F	MODERATE	NO	YES	11	9	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Scrotal oedema	陰嚢浮腫	15 mg	F	MILD	NO	NO	13	7	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Pyrexia	発熱	15 mg	F	MILD	NO	NO	13	2	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Abdominal abscess	腹部膿瘍	15 mg	F	MODERATE	NO	NO	13	5	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Tachycardia	頻脈	15 mg	F	MODERATE	NO	NO	13	7	NO	WORSENED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Confusional state	錯乱状態	15 mg	F	MILD	NO	NO	14	2	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Haemoglobin decreased	ヘモグロビン減少	15 mg	F	MODERATE	NO	NO	14	6	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Tachypnoea	頻呼吸	15 mg	F	MILD	NO	NO	14	2	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Hypotension	低血圧	15 mg	F	MILD	NO	NO	14	3	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Acidosis	アシドーシス	15 mg	F	MILD	NO	NO	15	5	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Pyrexia	発熱	15 mg	F	MILD	NO	NO	16	2	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Renal failure	腎不全	15 mg	F	MODERATE	NO	NO	16	4	NO	RESOLVED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Atrial fibrillation	心房細動	15 mg	F	MODERATE	NO	NO	16	4	NO	WORSENED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Ventricular fibrillation	心室細動	15 mg	F	SEVERE	YES	NO	19	1	NO	DEATH

表 2.7.4.7-17　死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370023029	YES	SOUTH AFRICA	WHITE	FEMALE	74	International normalised ratio increased	ＩＮＲ増加			MODERATE	NO	YES	6	4	YES	RESOLVED
Enoxaparin/VKA	370023029	YES	SOUTH AFRICA	WHITE	FEMALE	74	Abdominal wall haematoma	腹壁血腫			SEVERE	YES	YES	23	1	YES	DEATH
Enoxaparin/VKA	370023029	YES	SOUTH AFRICA	WHITE	FEMALE	74	Haematemesis	吐血			MILD	NO	YES	23	1	NO	RESOLVED
Enoxaparin/VKA	370023031	YES	SOUTH AFRICA	WHITE	FEMALE	75	Operative haemorrhage	術中出血			MODERATE	NO	YES	1	1	NO	RESOLVED
Enoxaparin/VKA	370023031	YES	SOUTH AFRICA	WHITE	FEMALE	75	Hyperglycaemia	高血糖			MODERATE	NO	YES	2	8	NO	RESOLVED
Enoxaparin/VKA	370023031	YES	SOUTH AFRICA	WHITE	FEMALE	75	Haemorrhagic anaemia	出血性貧血			MODERATE	YES	YES	3		YES	UNCHANGED
Enoxaparin/VKA	370023031	YES	SOUTH AFRICA	WHITE	FEMALE	75	Coagulopathy	凝血異常			SEVERE	YES	YES	4		YES	UNCHANGED
Enoxaparin/VKA	370023031	YES	SOUTH AFRICA	WHITE	FEMALE	75	Hypovolaemia	血液量減少症			MODERATE	NO	YES	4	1	NO	RESOLVED
Enoxaparin/VKA	370023031	YES	SOUTH AFRICA	WHITE	FEMALE	75	Constipation	便秘			MODERATE	NO	YES	5	1	NO	RESOLVED
Enoxaparin/VKA	370023031	YES	SOUTH AFRICA	WHITE	FEMALE	75	Diarrhoea	下痢			MODERATE	NO	YES	7	3	NO	RESOLVED
Enoxaparin/VKA	370023031	YES	SOUTH AFRICA	WHITE	FEMALE	75	Respiratory failure	呼吸不全			SEVERE	YES	NO	10	1	NO	DEATH

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370023031	YES	SOUTH AFRICA	WHITE	FEMALE	75	Epistaxis	鼻出血			MODERATE	NO	NO	10	1	YES	RESOLVED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Haemoptysis	喀血	15 mg	.	MILD	YES	YES	3	1	NO	RESOLVED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	T-cell lymphoma	Ｔ細胞性リンパ腫	15 mg	.	SEVERE	YES	YES	15		NO	UNCHANGED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Spinal compression fracture	脊椎圧迫骨折	15 mg	.	SEVERE	YES	YES	16	10	NO	RESOLVED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Nausea	悪心	15 mg	.	MILD	NO	YES	17	9	NO	RESOLVED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Osteoporosis	骨粗鬆症	20 mg	.	MILD	NO	YES	30		NO	UNCHANGED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Tachycardia	頻脈	20 mg	.	MILD	NO	YES	70	32	NO	RESOLVED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Oedema	浮腫	20 mg	.	MILD	NO	YES	70	57	NO	RESOLVED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Histiocytosis haematophagic	貪食細胞性組織球症	20 mg	.	SEVERE	YES	YES	83		NO	UNCHANGED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Anaemia	貧血	20 mg	.	MODERATE	NO	YES	121	64	NO	RESOLVED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Guillain-Barre syndrome	ギラン・バレー症候群	20 mg	.	SEVERE	YES	YES	121		NO	UNCHANGED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Multi-organ failure	多臓器不全	20 mg	F	SEVERE	YES	NO	184	1	NO	DEATH

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Neutropenic sepsis	好中球減少性敗血症	20 mg	F	SEVERE	YES	NO	184		NO	UNCHANGED
Rivaroxaban	370053046	YES	SOUTH AFRICA	WHITE	FEMALE	65	Urinary tract infection	尿路感染	15 mg	.	MILD	NO	YES	7	10	NO	RESOLVED
Rivaroxaban	370053046	YES	SOUTH AFRICA	WHITE	FEMALE	65	Confusional state	錯乱状態	15 mg	.	MILD	NO	YES	16	20	YES	RESOLVED
Rivaroxaban	370053046	YES	SOUTH AFRICA	WHITE	FEMALE	65	Death	死亡	20 mg	.	SEVERE	YES	YES	56	1	NO	DEATH
Enoxaparin/VKA	370053073	YES	SOUTH AFRICA	WHITE	MALE	97	International normalised ratio increased	ＩＮＲ増加			MODERATE	NO	YES	5	5	YES	RESOLVED
Enoxaparin/VKA	370053073	YES	SOUTH AFRICA	WHITE	MALE	97	Gout	痛風			MILD	NO	YES	15		NO	UNCHANGED
Enoxaparin/VKA	370053073	YES	SOUTH AFRICA	WHITE	MALE	97	Hypothyroidism	甲状腺機能低下症			MILD	NO	YES	16		NO	UNCHANGED
Enoxaparin/VKA	370053073	YES	SOUTH AFRICA	WHITE	MALE	97	Pneumonia	肺炎			SEVERE	YES	YES	17		NO	UNCHANGED
Enoxaparin/VKA	370053073	YES	SOUTH AFRICA	WHITE	MALE	97	Acute respiratory distress syndrome	急性呼吸窮迫症候群			SEVERE	YES	YES	33	1	NO	DEATH
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Arthralgia	関節痛	15 mg	.	MODERATE	YES	YES	18	23	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Hypertensive heart disease	高血圧性心疾患	20 mg	.	MILD	NO	YES	29	92	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Left ventricular hypertrophy	左室肥大	20 mg	.	MILD	NO	YES	29	92	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Diastolic dysfunction	拡張機能障害	20 mg	.	MILD	NO	YES	29	92	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Diarrhoea	下痢	20 mg	.	MILD	YES	YES	35	2	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Convulsion	痙攣	20 mg	.	MILD	NO	YES	36	1	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Supraventricular tachycardia	上室性頻脈	20 mg	.	MODERATE	YES	YES	37	2	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Fluid overload	水分過負荷	20 mg	.	MILD	NO	YES	38	83	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Arthralgia	関節痛	20 mg	.	MILD	NO	YES	41	80	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Diarrhoea	下痢	20 mg	.	SEVERE	YES	YES	81	11	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Vomiting	嘔吐	20 mg	.	SEVERE	YES	YES	81	11	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Hiatus hernia	裂孔ヘルニア	20 mg	.	SEVERE	YES	YES	89		NO	UNCHANGED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Gastrooesophageal reflux disease	胃食道逆流性疾患	20 mg	.	SEVERE	YES	YES	89		NO	UNCHANGED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Thrombocytopenia	血小板減少症	20 mg	.	SEVERE	YES	YES	111		NO	UNCHANGED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Gastroenteritis	胃腸炎	20 mg	.	SEVERE	YES	YES	111		NO	UNCHANGED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Anxiety	不安	20 mg	.	MILD	NO	YES	111	5	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Contusion	挫傷	20 mg	.	MILD	NO	YES	113	8	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Infectious peritonitis	感染性腹膜炎	20 mg	.	MODERATE	YES	YES	116		NO	UNCHANGED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Acidosis	アシドーシス	20 mg	F	MODERATE	YES	YES	117		NO	UNCHANGED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Intestinal infarction	腸梗塞	20 mg	F	SEVERE	YES	YES	118	3	NO	DEATH
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Sepsis	敗血症	20 mg	F	SEVERE	YES	NO	120	1	NO	DEATH
Rivaroxaban	370053132	YES	SOUTH AFRICA	WHITE	MALE	42	Abdominal pain	腹痛	15 mg	.	MODERATE	NO	YES	6		NO	UNCHANGED
Rivaroxaban	370053132	YES	SOUTH AFRICA	WHITE	MALE	42	Agitation	激越	15 mg	.	MILD	NO	YES	6	15	NO	UNCHANGED
Rivaroxaban	370053132	YES	SOUTH AFRICA	WHITE	MALE	42	Vomiting	嘔吐	15 mg	.	MILD	NO	YES	6		NO	UNCHANGED
Rivaroxaban	370053132	YES	SOUTH AFRICA	WHITE	MALE	42	Constipation	便秘	15 mg	.	MILD	NO	YES	7		NO	UNCHANGED
Rivaroxaban	370053132	YES	SOUTH AFRICA	WHITE	MALE	42	Gastritis	胃炎	15 mg	.	MILD	NO	YES	8		NO	UNCHANGED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	370053132	YES	SOUTH AFRICA	WHITE	MALE	42	Respiratory distress	呼吸窮迫	15 mg	.	MODERATE	NO	YES	14	7	NO	UNCHANGED
Rivaroxaban	370053132	YES	SOUTH AFRICA	WHITE	MALE	42	Anxiety	不安	15 mg	.	MODERATE	NO	YES	14		NO	UNCHANGED
Rivaroxaban	370053132	YES	SOUTH AFRICA	WHITE	MALE	42	Hypertension	高血圧	15 mg	.	MILD	NO	YES	14	6	NO	RESOLVED
Rivaroxaban	370053132	YES	SOUTH AFRICA	WHITE	MALE	42	Gastric cancer	胃癌	15 mg	.	SEVERE	YES	YES	14	7	NO	DEATH
Rivaroxaban	370053132	YES	SOUTH AFRICA	WHITE	MALE	42	Chest pain	胸痛	15 mg	.	MODERATE	NO	YES	19		NO	UNCHANGED
Rivaroxaban	370053132	YES	SOUTH AFRICA	WHITE	MALE	42	Tachycardia	頻脈	15 mg	.	MODERATE	NO	YES	19	2	NO	UNCHANGED
Rivaroxaban	370053132	YES	SOUTH AFRICA	WHITE	MALE	42	Hypotension	低血圧	15 mg	.	MODERATE	NO	YES	20	1	NO	UNCHANGED
Rivaroxaban	370053132	YES	SOUTH AFRICA	WHITE	MALE	42	Sepsis	敗血症	15 mg	.	MODERATE	NO	YES	20	1	NO	UNCHANGED
Rivaroxaban	370063018	YES	SOUTH AFRICA	BLACK	FEMALE	45	Pulmonary oedema	肺水腫	20 mg	.	MODERATE	YES	YES	43		NO	IMPROVED
Rivaroxaban	370063018	YES	SOUTH AFRICA	BLACK	FEMALE	45	Cardiac failure	心不全	20 mg	.	MODERATE	YES	YES	43		NO	IMPROVED
Rivaroxaban	370063018	YES	SOUTH AFRICA	BLACK	FEMALE	45	Lower respiratory tract infection	下気道感染	20 mg	.	MODERATE	YES	YES	43	5	NO	IMPROVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

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Rivaroxaban	370063018	YES	SOUTH AFRICA	BLACK	FEMALE	45	Liver function test abnormal	肝機能検査異常	20 mg	.	MILD	NO	YES	96		NO	UNCHANGED
Rivaroxaban	370063018	YES	SOUTH AFRICA	BLACK	FEMALE	45	Congestive cardiomyopathy	うっ血性心筋症	20 mg	.	SEVERE	YES	YES	118	2	YES	DEATH
Rivaroxaban	370063018	YES	SOUTH AFRICA	BLACK	FEMALE	45	Cardiac failure congestive	うっ血性心不全	20 mg	.	SEVERE	YES	YES	118	2	YES	DEATH
Rivaroxaban	370073015	YES	SOUTH AFRICA	WHITE	MALE	71	Laceration	裂傷	20 mg	.	MODERATE	NO	YES	24	1	NO	RESOLVED
Rivaroxaban	370073015	YES	SOUTH AFRICA	WHITE	MALE	71	Sepsis	敗血症	20 mg	F	SEVERE	YES	NO	112	6	NO	DEATH
Rivaroxaban	370093017	YES	SOUTH AFRICA	WHITE	FEMALE	78	Influenza	インフルエンザ	20 mg	.	MODERATE	NO	YES	137	7	NO	RESOLVED
Rivaroxaban	370093017	YES	SOUTH AFRICA	WHITE	FEMALE	78	Diarrhoea	下痢	20 mg	.	MODERATE	NO	YES	171	17	NO	RESOLVED
Rivaroxaban	370093017	YES	SOUTH AFRICA	WHITE	FEMALE	78	Urinary tract infection	尿路感染	20 mg	.	MODERATE	NO	YES	210	7	NO	RESOLVED
Rivaroxaban	370093017	YES	SOUTH AFRICA	WHITE	FEMALE	78	Anaemia	貧血	20 mg	.	SEVERE	YES	YES	217	4	NO	RESOLVED
Rivaroxaban	370093017	YES	SOUTH AFRICA	WHITE	FEMALE	78	Cystitis	膀胱炎	20 mg	.	MODERATE	NO	YES	225	6	NO	RESOLVED
Rivaroxaban	370093017	YES	SOUTH AFRICA	WHITE	FEMALE	78	Diarrhoea	下痢	20 mg	F	MODERATE	NO	NO	372		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	370093017	YES	SOUTH AFRICA	WHITE	FEMALE	78	Colon cancer	結腸癌	20 mg	F	SEVERE	YES	NO	373	1	NO	DEATH

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	370113028	YES	SOUTH AFRICA	WHITE	FEMALE	86	Pneumonia	肺炎	20 mg	.	SEVERE	YES	YES	42	2	NO	DEATH
Rivaroxaban	370113028	YES	SOUTH AFRICA	WHITE	FEMALE	86	Dehydration	脱水	20 mg	.	SEVERE	NO	YES	42		NO	UNCHANGED
Rivaroxaban	370113028	YES	SOUTH AFRICA	WHITE	FEMALE	86	Renal failure	腎不全	20 mg	.	SEVERE	NO	YES	42		NO	UNCHANGED
Rivaroxaban	370113028	YES	SOUTH AFRICA	WHITE	FEMALE	86	Cardiac failure acute	急性心不全	20 mg	.	SEVERE	NO	YES	42		NO	UNCHANGED
Rivaroxaban	370113028	YES	SOUTH AFRICA	WHITE	FEMALE	86	Hypokalaemia	低カリウム血症	20 mg	.	SEVERE	NO	YES	42		NO	UNCHANGED
Rivaroxaban	370113028	YES	SOUTH AFRICA	WHITE	FEMALE	86	Oedema peripheral	末梢性浮腫	20 mg	.	SEVERE	NO	YES	42		NO	UNCHANGED
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Epistaxis	鼻出血			SEVERE	YES	YES	83	1	YES	RESOLVED
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Rectal haemorrhage	直腸出血			SEVERE	YES	YES	83	2	YES	RESOLVED
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Sepsis	敗血症			SEVERE	NO	YES	83		NO	UNCHANGED
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加			MODERATE	NO	YES	83		NO	UNCHANGED
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加			MODERATE	NO	YES	83		NO	UNCHANGED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加			MODERATE	NO	YES	83		NO	UNCHANGED
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Blood urea increased	血中尿素増加			MODERATE	NO	YES	83		NO	UNCHANGED
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Blood creatinine increased	血中クレアチニン増加			MODERATE	NO	YES	83		NO	UNCHANGED
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Pericardial effusion	心嚢液貯留			MODERATE	NO	NO	87		NO	UNCHANGED
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Lymphadenopathy	リンパ節症			MODERATE	NO	NO	87		NO	UNCHANGED
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Hepatic encephalopathy	肝性脳症			MODERATE	NO	NO	87		NO	UNCHANGED
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	International normalised ratio increased	ＩＮＲ増加			MODERATE	NO	NO	90	6	YES	RESOLVED
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Lobar pneumonia	大葉性肺炎			SEVERE	YES	NO	91	11	NO	DEATH
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Tuberculosis	結核			SEVERE	NO	NO	92		NO	UNCHANGED
Rivaroxaban	380093046	YES	CZECH REPUBLIC	WHITE	MALE	80	Pulmonary embolism	肺塞栓症	15 mg	F	SEVERE	YES	NO	29	1	NO	DEATH
Rivaroxaban	390013031	YES	ISRAEL	WHITE	FEMALE	90	Cerebellar	小脳出血	20 mg	F	SEVERE	YES	YES	284	1	YES	DEATH

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

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							haemorrhage										
Rivaroxaban	390013031	YES	ISRAEL	WHITE	FEMALE	90	Hypokalaemia	低カリウム血症	20 mg	F	MILD	NO	YES	284		NO	UNCHANGED
Rivaroxaban	390043009	YES	ISRAEL	WHITE	FEMALE	85	Ischaemic hepatitis	虚血性肝炎	15 mg	.	SEVERE	YES	YES	4	5	NO	DEATH
Rivaroxaban	390043009	YES	ISRAEL	WHITE	FEMALE	85	Brucella test positive	ブルセラ検査陽性	15 mg	F	MODERATE	NO	NO	7		NO	UNCHANGED
Rivaroxaban	400013010	YES	AUSTRALIA	WHITE	MALE	66	Gingival bleeding	歯肉出血	15 mg	.	MILD	NO	YES	1		YES	INSUFFICIENT FOLLOW-UP
Rivaroxaban	400013010	YES	AUSTRALIA	WHITE	MALE	66	Gingival bleeding	歯肉出血	15 mg	.	MILD	NO	YES	8	2	YES	RESOLVED
Rivaroxaban	400013010	YES	AUSTRALIA	WHITE	MALE	66	Contusion	挫傷	20 mg	.	MILD	NO	YES	29	1	NO	RESOLVED
Rivaroxaban	400013010	YES	AUSTRALIA	WHITE	MALE	66	Ischaemic stroke	虚血性脳卒中	20 mg	.	SEVERE	YES	YES	40	21	NO	DEATH
Rivaroxaban	400033012	YES	AUSTRALIA	WHITE	MALE	94	Acute myocardial infarction	急性心筋梗塞	20 mg	.	SEVERE	YES	YES	98	2	NO	RESOLVED
Rivaroxaban	400033012	YES	AUSTRALIA	WHITE	MALE	94	Acute pulmonary oedema	急性肺水腫	20 mg	.	SEVERE	YES	YES	98	6	NO	DEATH
Rivaroxaban	400033012	YES	AUSTRALIA	WHITE	MALE	94	Cardiac failure congestive	うっ血性心不全	20 mg	.	SEVERE	YES	YES	98		NO	UNCHANGED
Rivaroxaban	400033012	YES	AUSTRALIA	WHITE	MALE	94	Bradycardia	徐脈	20 mg	.	MODERATE	NO	YES	98	1	NO	RESOLVED
Rivaroxaban	400033012	YES	AUSTRALIA	WHITE	MALE	94	Agitation	激越	20 mg	.	MODERATE	NO	YES	99	4	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	400033012	YES	AUSTRALIA	WHITE	MALE	94	Hypertension	高血圧	20 mg	.	MODERATE	NO	YES	99	4	NO	RESOLVED
Rivaroxaban	400033043	YES	AUSTRALIA	WHITE	MALE	73	Cardiac failure	心不全	15 mg	.	MODERATE	NO	YES	3		NO	UNCHANGED
Rivaroxaban	400033043	YES	AUSTRALIA	WHITE	MALE	73	Cough	咳嗽	15 mg	.	MODERATE	NO	YES	3	8	NO	RESOLVED
Rivaroxaban	400033043	YES	AUSTRALIA	WHITE	MALE	73	Bladder spasm	膀胱痙縮	15 mg	.	MODERATE	NO	YES	8	1	NO	RESOLVED
Rivaroxaban	400033043	YES	AUSTRALIA	WHITE	MALE	73	Dyspnoea	呼吸困難	15 mg	.	SEVERE	YES	YES	15	2	NO	DEATH
Rivaroxaban	400033052	YES	AUSTRALIA	WHITE	MALE	58	Back pain	背部痛	15 mg	.	MILD	NO	YES	7		NO	RESOLVED
Rivaroxaban	400033052	YES	AUSTRALIA	WHITE	MALE	58	Non-small cell lung cancer	非小細胞肺癌	20 mg	.	MODERATE	NO	YES	36		NO	UNCHANGED
Rivaroxaban	400033052	YES	AUSTRALIA	WHITE	MALE	58	Ischaemic stroke	虚血性脳卒中	20 mg	.	SEVERE	YES	YES	39	4	NO	WORSENED
Rivaroxaban	400033052	YES	AUSTRALIA	WHITE	MALE	58	Haemorrhagic transformation stroke	卒中の出血性変化	20 mg	F	SEVERE	YES	YES	42	21	NO	DEATH
Rivaroxaban	400033052	YES	AUSTRALIA	WHITE	MALE	58	Cough	咳嗽	20 mg	F	MILD	NO	NO	51	6	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Urinary tract infection	尿路感染			MILD	NO	YES			NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Haematuria	血尿	15 mg	.	MILD	NO	YES	20	76	YES	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Urosepsis	尿路性敗血症	20 mg	.	MODERATE	YES	YES	95	10	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Dermatitis	皮膚炎	20 mg	.	MODERATE	NO	YES	95		NO	UNCHANGED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Hypotension	低血圧	20 mg	.	MODERATE	NO	YES	95	4	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Oedema peripheral	末梢性浮腫	20 mg	.	MODERATE	NO	YES	100	47	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Contusion	挫傷	20 mg	.	MILD	NO	YES	106		YES	UNCHANGED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Urinary tract infection	尿路感染	20 mg	.	MODERATE	YES	YES	133	9	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Urinary tract infection	尿路感染	20 mg	.	MILD	YES	YES	151	12	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Dysuria	排尿困難	20 mg	.	MILD	YES	YES	196	6	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Oedema	浮腫	20 mg	.	MILD	NO	YES	209	36	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Dermatitis exfoliative	剥脱性皮膚炎	20 mg	.	MODERATE	YES	YES	214	14	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Dermatitis exfoliative	剥脱性皮膚炎	20 mg	.	MODERATE	NO	YES	228		NO	UNCHANGED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Localised infection	限局性感染	20 mg	.	MILD	NO	YES	234	7	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Back pain	背部痛	20 mg	.	MILD	NO	YES	256		NO	IMPROVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Urosepsis	尿路性敗血症	20 mg	I	MILD	YES	YES	269	5	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Herpes simplex	単純ヘルペス	20 mg	F	MODERATE	YES	NO	279	20	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Gastrointestinal haemorrhage	胃腸出血	20 mg	F	SEVERE	YES	NO	298	10	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Sepsis	敗血症	20 mg	F	MODERATE	NO	NO	300	6	NO	WORSENED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Hypotension	低血圧	20 mg	F	SEVERE	NO	NO	304		NO	UNCHANGED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Urinary tract infection	尿路感染	20 mg	F	SEVERE	NO	NO	306		NO	UNCHANGED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Sepsis	敗血症	20 mg	F	SEVERE	YES	NO	306	3	NO	DEATH
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Febrile neutropenia	発熱性好中球減少症	20 mg	F	SEVERE	NO	NO	306		NO	UNCHANGED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Ischaemic stroke	虚血性脳卒中	20 mg	.	SEVERE	YES	YES	25	6	NO	WORSENED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Hypercholesterolaemia	高コレステロール血症	20 mg	I	MODERATE	NO	YES	26		NO	UNCHANGED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Lung infiltration	肺浸潤	20 mg	I	MILD	NO	YES	26	27	NO	RESOLVED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Lacunar infarction	ラクナ梗塞	20 mg	I	MILD	NO	YES	26		NO	UNCHANGED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Lacunar infarction	ラクナ梗塞	20 mg	I	MILD	NO	YES	26		NO	UNCHANGED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Platelet count decreased	血小板数減少	20 mg	I	MODERATE	NO	YES	26		NO	UNCHANGED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Constipation	便秘	20 mg	.	MODERATE	NO	YES	28	4	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Depression	うつ病	20 mg	.	MODERATE	NO	YES	28		NO	UNCHANGED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Ischaemic stroke	虚血性脳卒中	20 mg	.	SEVERE	YES	YES	30		NO	UNCHANGED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Nausea	悪心	20 mg	.	MODERATE	NO	YES	49	4	NO	RESOLVED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Vomiting	嘔吐	20 mg	.	MODERATE	NO	YES	49	4	NO	RESOLVED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Ischaemic stroke	虚血性脳卒中	20 mg	.	SEVERE	YES	YES	52		NO	UNCHANGED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Epistaxis	鼻出血	20 mg	F	MILD	NO	NO	94	1	NO	RESOLVED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Anaemia	貧血	20 mg	F	MODERATE	NO	NO	94		NO	UNCHANGED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Mouth haemorrhage	口腔内出血	20 mg	F	MILD	NO	NO	96	1	NO	RESOLVED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Disseminated intravascular coagulation	播種性血管内凝固	20 mg	F	SEVERE	YES	NO	97		NO	UNCHANGED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Pancreatic carcinoma metastatic	転移性膵癌	20 mg	F	SEVERE	YES	NO	103	9	NO	DEATH
Enoxaparin/VKA	400123029	YES	AUSTRALIA	WHITE	FEMALE	76	Contusion	挫傷			MILD	NO	YES	1	44	NO	RESOLVED
Enoxaparin/VKA	400123029	YES	AUSTRALIA	WHITE	FEMALE	76	Cellulitis	蜂巣炎			MILD	NO	YES	1	29	NO	RESOLVED
Enoxaparin/VKA	400123029	YES	AUSTRALIA	WHITE	FEMALE	76	Contusion	挫傷			MILD	NO	YES	7	38	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400123029	YES	AUSTRALIA	WHITE	FEMALE	76	Pain in extremity	四肢痛			MILD	NO	YES	10	5	NO	RESOLVED
Enoxaparin/VKA	400123029	YES	AUSTRALIA	WHITE	FEMALE	76	Dyspnoea	呼吸困難			MILD	NO	YES	11	34	NO	RESOLVED
Enoxaparin/VKA	400123029	YES	AUSTRALIA	WHITE	FEMALE	76	Tachypnoea	頻呼吸			MILD	NO	YES	11	34	NO	RESOLVED
Enoxaparin/VKA	400123029	YES	AUSTRALIA	WHITE	FEMALE	76	Pain in extremity	四肢痛			MILD	NO	YES	13	5	NO	RESOLVED
Enoxaparin/VKA	400123029	YES	AUSTRALIA	WHITE	FEMALE	76	Cellulitis	蜂巣炎			MODERATE	NO	YES	21		NO	RESOLVED
Enoxaparin/VKA	400123029	YES	AUSTRALIA	WHITE	FEMALE	76	Lung neoplasm malignant	肺の悪性新生物			MODERATE	NO	YES	21	3	NO	WORSENED
Enoxaparin/VKA	400123029	YES	AUSTRALIA	WHITE	FEMALE	76	Cellulitis	蜂巣炎			MILD	NO	YES	23	22	NO	RESOLVED
Enoxaparin/VKA	400123029	YES	AUSTRALIA	WHITE	FEMALE	76	Lung neoplasm malignant	肺の悪性新生物			SEVERE	YES	NO	24	96	NO	DEATH
Enoxaparin/VKA	400123029	YES	AUSTRALIA	WHITE	FEMALE	76	Pneumonia	肺炎			MODERATE	NO	NO	24		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	400123029	YES	AUSTRALIA	WHITE	FEMALE	76	Venous thrombosis limb	四肢静脈血栓症			MODERATE	NO	NO	28		NO	IMPROVED
Enoxaparin/VKA	400213003	YES	AUSTRALIA	WHITE	MALE	85	Basal cell carcinoma	基底細胞癌			MILD	NO	YES	1	55	NO	RESOLVED
Enoxaparin/VKA	400213003	YES	AUSTRALIA	WHITE	MALE	85	Rash	発疹			MILD	NO	YES	5	11	NO	RESOLVED
Enoxaparin/VKA	400213003	YES	AUSTRALIA	WHITE	MALE	85	Basal cell carcinoma	基底細胞癌			MILD	NO	YES	13	29	NO	RESOLVED
Enoxaparin/V	400213003	YES	AUSTRALI	WHITE	MALE	85	Basal cell	基底細胞癌			MILD	NO	YES	13	29	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA			A				carcinoma										
Enoxaparin/VKA	400213003	YES	AUSTRALIA	WHITE	MALE	85	Metastases to central nervous system	中枢神経系転移			SEVERE	YES	YES	83	58	NO	DEATH
Enoxaparin/VKA	400213003	YES	AUSTRALIA	WHITE	MALE	85	Meningioma	髄膜腫			MODERATE	NO	YES	83		NO	UNCHANGED
Enoxaparin/VKA	400213003	YES	AUSTRALIA	WHITE	MALE	85	Melaena	メレナ			MODERATE	YES	NO	118	6	NO	RESOLVED
Enoxaparin/VKA	400213028	YES	AUSTRALIA	WHITE	FEMALE	66	Contusion	挫傷			MILD	NO	YES	3		NO	UNCHANGED
Enoxaparin/VKA	400213028	YES	AUSTRALIA	WHITE	FEMALE	66	Acute lymphocytic leukaemia	急性リンパ性白血病			SEVERE	YES	YES	8		NO	UNCHANGED
Enoxaparin/VKA	400213028	YES	AUSTRALIA	WHITE	FEMALE	66	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MODERATE	YES	YES	8		NO	UNCHANGED
Enoxaparin/VKA	400213028	YES	AUSTRALIA	WHITE	FEMALE	66	Hyperuricaemia	高尿酸血症			MILD	NO	NO	11		NO	UNCHANGED
Enoxaparin/VKA	400213028	YES	AUSTRALIA	WHITE	FEMALE	66	Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加			MODERATE	YES	NO	18		NO	UNCHANGED
Enoxaparin/VKA	400213028	YES	AUSTRALIA	WHITE	FEMALE	66	Acute abdomen	急性腹症			SEVERE	YES	NO	29	3	NO	DEATH
Enoxaparin/VKA	400213028	YES	AUSTRALIA	WHITE	FEMALE	66	Nausea	悪心			MODERATE	NO	NO	29		NO	UNCHANGED
Enoxaparin/VKA	400213028	YES	AUSTRALIA	WHITE	FEMALE	66	Dizziness	浮動性めまい			MILD	NO	NO	29	1	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400213028	YES	AUSTRALIA	WHITE	FEMALE	66	Mouth ulceration	口腔内潰瘍形成			MILD	NO	NO	29		NO	UNCHANGED
Enoxaparin/VKA	400213028	YES	AUSTRALIA	WHITE	FEMALE	66	Epistaxis	鼻出血			MILD	NO	NO	30	1	NO	RESOLVED
Enoxaparin/VKA	400213071	YES	AUSTRALIA	WHITE	MALE	76	Contusion	挫傷			MILD	NO	YES	1	30	NO	RESOLVED
Enoxaparin/VKA	400213071	YES	AUSTRALIA	WHITE	MALE	76	Mouth ulceration	口腔内潰瘍形成			MILD	NO	YES	2		YES	UNCHANGED
Enoxaparin/VKA	400213071	YES	AUSTRALIA	WHITE	MALE	76	Colitis	大腸炎			MODERATE	YES	YES	48	8	NO	RESOLVED
Enoxaparin/VKA	400213071	YES	AUSTRALIA	WHITE	MALE	76	Neutropenia	好中球減少症			SEVERE	YES	YES	48	71	NO	RESOLVED
Enoxaparin/VKA	400213071	YES	AUSTRALIA	WHITE	MALE	76	Cardiomyopathy	心筋症			SEVERE	YES	NO	70		NO	IMPROVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Ascites	腹水			MILD	NO	YES			NO	WORSENED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Haematochezia	血便排泄			MILD	YES	YES	1	24	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Chest pain	胸痛			SEVERE	NO	YES	4	1	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Constipation	便秘			MILD	NO	YES	4	1	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Diarrhoea	下痢			MILD	NO	YES	4	2	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Blister	水疱			MILD	NO	YES	5	2	YES	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Rash generalised	全身性皮疹			MILD	NO	YES	5	4	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Chills	悪寒			MILD	NO	YES	5	3	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Headache	頭痛			MILD	NO	YES	6	1	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Bile duct cancer non-resectable	切除不能な胆管癌			SEVERE	YES	YES	7	28	NO	DEATH
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Pyrexia	発熱			MODERATE	NO	YES	7	2	NO	IMPROVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Biliary sepsis	胆道性敗血症			MODERATE	YES	YES	8	26	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Lower gastrointestinal haemorrhage	下部消化管出血			MILD	YES	YES	8		YES	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Jaundice	黄疸			MILD	NO	YES	8		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Tachycardia	頻脈			MILD	NO	YES	8	1	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Hypophosphataemia	低リン酸血症			MILD	NO	YES	8		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Hepatic failure	肝不全			SEVERE	YES	YES	8		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Asthenia	無力症			MODERATE	NO	YES	8		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Lethargy	嗜眠			MODERATE	NO	YES	8		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Urinary incontinence	尿失禁			MILD	NO	YES	8		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Hypoalbuminaemia	低アルブミン血症			SEVERE	NO	YES	8		NO	UNCHANGED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Pyrexia	発熱			MILD	NO	YES	8		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Contusion	挫傷			MILD	NO	YES	9		YES	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Dehydration	脱水			SEVERE	YES	YES	9	4	NO	IMPROVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Hypoxia	低酸素症			MILD	NO	YES	9		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Dyspnoea exertional	労作性呼吸困難			MILD	NO	YES	9		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Bilirubinuria	ビリルビン尿			MODERATE	NO	YES	9		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Contusion	挫傷			MILD	NO	NO	10	1	YES	WORSENED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Contusion	挫傷			MILD	NO	NO	11		YES	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Headache	頭痛			MILD	NO	NO	11	1	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Arthralgia	関節痛			MILD	NO	NO	12		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Malnutrition	栄養障害			MODERATE	NO	NO	14		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Haemoptysis	喀血			MILD	YES	NO	15	1	YES	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Portal vein thrombosis	門脈血栓症			MILD	NO	NO	15		NO	INSUFFICIENT FOLLOW-

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
																	UP
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Splenic lesion	脾臓病変			MILD	NO	NO	15		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Abdominal hernia	腹部ヘルニア			MILD	NO	NO	15		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Splenomegaly	脾腫			MILD	NO	NO	15		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Chest pain	胸痛			MILD	NO	NO	16	1	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Vomiting	嘔吐			MILD	NO	NO	16	1	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Type 2 diabetes mellitus	２型糖尿病			MILD	NO	NO	16		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Blood potassium decreased	血中カリウム減少			MILD	NO	NO	18	4	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Oedema	浮腫			MILD	NO	NO	19		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Catheter site haemorrhage	カテーテル留置部位出血			MILD	NO	NO	23		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Wound secretion	創部分泌			MILD	NO	NO	23		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Oedema peripheral	末梢性浮腫			MILD	NO	NO	24	1	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Tachycardia	頻脈			MILD	NO	NO	24		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Blood urine present	尿中血陽性			MILD	NO	NO	27		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Ascites	腹水			SEVERE	NO	NO	27		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Skin disorder	皮膚障害			MILD	NO	NO	27		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Dyspnoea	呼吸困難			MILD	NO	NO	30		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Back pain	背部痛			MODERATE	NO	NO	30		NO	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Visual impairment	視力障害			MILD	NO	NO	32		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	440013005	YES	AUSTRIA	WHITE	MALE	50	Skin ulcer	皮膚潰瘍			MODERATE	NO	YES			NO	UNCHANGED
Rivaroxaban	440013005	YES	AUSTRIA	WHITE	MALE	50	Lung neoplasm malignant	肺の悪性新生物	20 mg	F	SEVERE	YES	YES	24		NO	UNCHANGED
Rivaroxaban	440013005	YES	AUSTRIA	WHITE	MALE	50	Pyrexia	発熱	20 mg	F	MILD	NO	NO	28	1	NO	RESOLVED
Rivaroxaban	440013005	YES	AUSTRIA	WHITE	MALE	50	Pulmonary embolism	肺塞栓症	20 mg	F	SEVERE	YES	NO	41	3	NO	DEATH
Rivaroxaban	440013005	YES	AUSTRIA	WHITE	MALE	50	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	20 mg	F	SEVERE	YES	NO	43		NO	UNCHANGED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	440013005	YES	AUSTRIA	WHITE	MALE	50	Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	20 mg	F	SEVERE	YES	NO	43		NO	UNCHANGED
Enoxaparin/VKA	460033012	YES	HUNGARY	WHITE	MALE	46	Pulmonary embolism	肺塞栓症			SEVERE	YES	YES	2	1	NO	DEATH
Rivaroxaban	460063056	YES	HUNGARY	WHITE	FEMALE	77	Duodenal ulcer	十二指腸潰瘍			SEVERE	YES	YES	232	3	NO	DEATH
Rivaroxaban	460093059	YES	HUNGARY	WHITE	MALE	57	Pneumonia	肺炎			SEVERE	NO	YES			NO	UNCHANGED
Rivaroxaban	460093059	YES	HUNGARY	WHITE	MALE	57	Lung neoplasm malignant	肺の悪性新生物	20 mg	.	SEVERE	YES	YES	50	23	NO	DEATH
Rivaroxaban	460093059	YES	HUNGARY	WHITE	MALE	57	Pleural haemorrhage	胸腔内出血	20 mg	.	SEVERE	NO	YES	50		NO	UNCHANGED
Enoxaparin/VKA	500033011	YES	BRAZIL	WHITE	FEMALE	81	Constipation	便秘			MILD	NO	YES	3	1	NO	RESOLVED
Enoxaparin/VKA	500033011	YES	BRAZIL	WHITE	FEMALE	81	Productive cough	湿性咳嗽			MILD	NO	YES	3	1	NO	RESOLVED
Enoxaparin/VKA	500033011	YES	BRAZIL	WHITE	FEMALE	81	Pain in extremity	四肢痛			MODERATE	NO	YES	3	1	NO	RESOLVED
Enoxaparin/VKA	500033011	YES	BRAZIL	WHITE	FEMALE	81	Eye haemorrhage	眼出血			MILD	NO	YES	4		NO	UNCHANGED
Enoxaparin/VKA	500033011	YES	BRAZIL	WHITE	FEMALE	81	Productive cough	湿性咳嗽			MODERATE	NO	YES	4	3	NO	RESOLVED
Enoxaparin/VKA	500033011	YES	BRAZIL	WHITE	FEMALE	81	Convulsion	痙攣			SEVERE	YES	YES	31	1	NO	RESOLVED
Enoxaparin/VKA	500033011	YES	BRAZIL	WHITE	FEMALE	81	Pneumonia	肺炎			SEVERE	NO	YES	32	41	NO	WORSENED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	500033011	YES	BRAZIL	WHITE	FEMALE	81	Pyrexia	発熱			MILD	NO	NO	42	1	NO	RESOLVED
Enoxaparin/VKA	500033011	YES	BRAZIL	WHITE	FEMALE	81	Haemoglobin decreased	ヘモグロビン減少			MILD	NO	NO	55	2	NO	RESOLVED
Enoxaparin/VKA	500033011	YES	BRAZIL	WHITE	FEMALE	81	Acute respiratory failure	急性呼吸不全			SEVERE	YES	NO	56	20	NO	DEATH
Enoxaparin/VKA	500033011	YES	BRAZIL	WHITE	FEMALE	81	Haematoma	血腫			SEVERE	NO	NO	57	10	YES	RESOLVED
Rivaroxaban	540053036	YES	CHINA	ASIAN	FEMALE	57	Epistaxis	鼻出血	15 mg	.	MILD	NO	YES	7	1	NO	RESOLVED
Rivaroxaban	540053036	YES	CHINA	ASIAN	FEMALE	57	Haemoglobin decreased	ヘモグロビン減少	15 mg	.	SEVERE	YES	YES	8		NO	UNCHANGED
Rivaroxaban	540053036	YES	CHINA	ASIAN	FEMALE	57	Gastrointestinal haemorrhage	胃腸出血	15 mg	.	MODERATE	NO	YES	11	11	NO	RESOLVED
Rivaroxaban	540053036	YES	CHINA	ASIAN	FEMALE	57	Gastric cancer	胃癌	15 mg	.	SEVERE	YES	YES	13	58	NO	DEATH
Rivaroxaban	540053036	YES	CHINA	ASIAN	FEMALE	57	Metastases to liver	肝転移	15 mg	.	SEVERE	YES	YES	13	58	NO	DEATH
Rivaroxaban	540053036	YES	CHINA	ASIAN	FEMALE	57	Hypokalaemia	低カリウム血症	15 mg	F	MILD	NO	NO	20	4	NO	RESOLVED
Rivaroxaban	540053036	YES	CHINA	ASIAN	FEMALE	57	Leukopenia	白血球減少症	15 mg	F	MILD	NO	NO	23	4	NO	RESOLVED
Rivaroxaban	540153004	YES	CHINA	ASIAN	MALE	51	Headache	頭痛	15 mg	.	MILD	NO	YES	8	3	NO	RESOLVED
Rivaroxaban	540153004	YES	CHINA	ASIAN	MALE	51	Right ventricular failure	右室不全	20 mg	.	SEVERE	YES	YES	35	32	NO	DEATH
Rivaroxaban	540153004	YES	CHINA	ASIAN	MALE	51	Dermatomyositis	皮膚筋炎	20 mg	.	SEVERE	YES	YES	40	27	NO	DEATH
Rivaroxaban	540153004	YES	CHINA	ASIAN	MALE	51	Rheumatoid arthritis	関節リウマチ	20 mg	.	SEVERE	YES	YES	40	27	NO	DEATH

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	540153005	YES	CHINA	ASIAN	MALE	58	Lung neoplasm malignant	肺の悪性新生物	20 mg	.	SEVERE	YES	YES	28	1	NO	DEATH
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Nausea	悪心			MILD	NO	YES	2	2	NO	RESOLVED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Abdominal discomfort	腹部不快感			MILD	NO	YES	2	4	NO	RESOLVED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Metastases to lung	肺転移			SEVERE	YES	YES	16		NO	UNCHANGED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Metastases to liver	肝転移			MODERATE	YES	YES	16		NO	UNCHANGED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Petechiae	点状出血			MILD	NO	YES	19	6	YES	RESOLVED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Drug eruption	薬疹			MODERATE	NO	YES	19	6	NO	RESOLVED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Liver abscess	肝膿瘍			MODERATE	NO	YES	27		NO	IMPROVED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Thrombocytopenia	血小板減少症			MILD	NO	YES	30	10	NO	WORSENED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Rash	発疹			MILD	NO	YES	33	1	NO	RESOLVED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Thrombocytopenia	血小板減少症			SEVERE	NO	YES	40		NO	UNCHANGED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Hypokalaemia	低カリウム血症			MILD	NO	NO	43	4	NO	RESOLVED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Haemothorax	血胸			MODERATE	NO	NO	46		NO	UNCHANGED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Hypovolaemic shock	血液量減少性ショック			SEVERE	YES	NO	68	1	NO	DEATH

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	540183011	YES	CHINA	ASIAN	FEMALE	74	Cor pulmonale	肺性心	20 mg	.	SEVERE	YES	YES	81		NO	UNCHANGED
Rivaroxaban	540183011	YES	CHINA	ASIAN	FEMALE	74	Pulmonary embolism	肺塞栓症	20 mg	.	SEVERE	YES	YES	87	1	NO	DEATH
Rivaroxaban	540193013	YES	CHINA	ASIAN	MALE	80	Bronchitis	気管支炎	15 mg	.	SEVERE	YES	YES	12	14	NO	RESOLVED
Rivaroxaban	540193013	YES	CHINA	ASIAN	MALE	80	Bronchitis	気管支炎	20 mg	.	MODERATE	YES	YES	126	20	NO	RESOLVED
Rivaroxaban	540193013	YES	CHINA	ASIAN	MALE	80	Melaena	メレナ	20 mg	.	MODERATE	NO	YES	138	7	NO	RESOLVED
Rivaroxaban	540193013	YES	CHINA	ASIAN	MALE	80	Colon cancer	結腸癌	20 mg	F	SEVERE	YES	NO	144	1	NO	RESOLVED
Rivaroxaban	540193013	YES	CHINA	ASIAN	MALE	80	Intestinal fistula	腸管瘻	20 mg	F	SEVERE	YES	NO	150	4	NO	DEATH
Rivaroxaban	540193013	YES	CHINA	ASIAN	MALE	80	Sepsis	敗血症	20 mg	F	SEVERE	YES	NO	151	3	NO	DEATH
Enoxaparin/VKA	540193029	YES	CHINA	ASIAN	FEMALE	80	Cerebral haemorrhage	脳出血			SEVERE	YES	YES	39	6	YES	DEATH
Enoxaparin/VKA	540203003	YES	CHINA	ASIAN	MALE	65	Cor pulmonale	肺性心			MILD	NO	YES	3		NO	UNCHANGED
Enoxaparin/VKA	540203003	YES	CHINA	ASIAN	MALE	65	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患			MILD	NO	YES	7		NO	UNCHANGED
Enoxaparin/VKA	540203003	YES	CHINA	ASIAN	MALE	65	Pneumonia	肺炎			SEVERE	YES	NO	35	1	NO	DEATH
Rivaroxaban	570023005	YES	LITHUANIA	WHITE	MALE	50	Pneumonia	肺炎	15 mg	.	MODERATE	YES	YES	14	21	NO	RESOLVED
Rivaroxaban	570023005	YES	LITHUANIA	WHITE	MALE	50	Dyspepsia	消化不良	20 mg	.	MILD	NO	YES	22	27	YES	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	570023005	YES	LITHUANIA	WHITE	MALE	50	Pneumonia	肺炎	20 mg	.	MODERATE	YES	YES	56	14	NO	RESOLVED
Rivaroxaban	570023005	YES	LITHUANIA	WHITE	MALE	50	Lung neoplasm malignant	肺の悪性新生物	20 mg	.	SEVERE	YES	YES	65		NO	UNCHANGED
Rivaroxaban	570023005	YES	LITHUANIA	WHITE	MALE	50	Dyspnoea	呼吸困難	20 mg	.	MODERATE	NO	YES	67	30	NO	WORSENED
Rivaroxaban	570023005	YES	LITHUANIA	WHITE	MALE	50	Pneumonia	肺炎	20 mg	.	SEVERE	YES	YES	96	19	NO	DEATH
Rivaroxaban	570023005	YES	LITHUANIA	WHITE	MALE	50	Dyspnoea	呼吸困難	20 mg	.	SEVERE	NO	YES	96		NO	UNCHANGED
Enoxaparin/VKA	580043002	YES	SWITZERLAND	WHITE	FEMALE	61	Pneumothorax	気胸			MODERATE	YES	YES	134		NO	UNCHANGED
Enoxaparin/VKA	580043002	YES	SWITZERLAND	WHITE	FEMALE	61	Nausea	悪心			MODERATE	NO	YES	186	21	NO	RESOLVED
Enoxaparin/VKA	580043002	YES	SWITZERLAND	WHITE	FEMALE	61	Constipation	便秘			MILD	NO	YES	186	33	NO	RESOLVED
Enoxaparin/VKA	580043002	YES	SWITZERLAND	WHITE	FEMALE	61	Atrial fibrillation	心房細動			MODERATE	NO	YES	192		NO	IMPROVED
Enoxaparin/VKA	580043002	YES	SWITZERLAND	WHITE	FEMALE	61	International normalised ratio fluctuation	ＩＮＲ変動			MODERATE	NO	YES	195	2	YES	RESOLVED
Enoxaparin/VKA	580043002	YES	SWITZERLAND	WHITE	FEMALE	61	Metastatic neoplasm	転移性新生物			SEVERE	YES	YES	218	5	NO	DEATH
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Lung neoplasm malignant	肺の悪性新生物	20 mg	.	SEVERE	YES	YES	26	14	NO	IMPROVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Lobar pneumonia	大葉性肺炎	20 mg	.	MODERATE	YES	YES	74	14	NO	RESOLVED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Hypertension	高血圧	20 mg	.	MILD	NO	YES	78		NO	IMPROVED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Mouth ulceration	口腔内潰瘍形成	20 mg	.	MILD	NO	YES	79		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Diarrhoea	下痢	20 mg	.	MILD	NO	YES	182	11	NO	RESOLVED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Dyspnoea	呼吸困難	20 mg	.	MODERATE	YES	YES	187	4	NO	RESOLVED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Pneumonia	肺炎	20 mg	.	MODERATE	YES	YES	187	4	NO	RESOLVED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Oedema peripheral	末梢性浮腫	20 mg	.	MODERATE	YES	YES	227	16	NO	RESOLVED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Muscular weakness	筋力低下	20 mg	.	MODERATE	YES	YES	227	16	NO	RESOLVED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Listeriosis	リステリア症	20 mg	.	MILD	NO	YES	228	14	NO	RESOLVED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Decreased appetite	食欲減退	20 mg	.	MILD	NO	YES	250		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Headache	頭痛	20 mg	.	MILD	NO	YES	250		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Lung neoplasm malignant	肺の悪性新生物	20 mg	F	SEVERE	YES	YES	261	1	NO	DEATH
No study medication	610013005	NO	TAIWAN	ASIAN	FEMALE	84	Oral candidiasis	口腔カンジダ症			MILD	NO	NO		4	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
No study medication	610013005	NO	TAIWAN	ASIAN	FEMALE	84	Haemoptysis	喀血			MODERATE	NO	NO		1	NO	RESOLVED
No study medication	610013005	NO	TAIWAN	ASIAN	FEMALE	84	Pneumonia	肺炎			MODERATE	NO	NO			NO	INSUFFICIENT FOLLOW-UP
No study medication	610013005	NO	TAIWAN	ASIAN	FEMALE	84	Insomnia	不眠症			MILD	NO	NO			NO	INSUFFICIENT FOLLOW-UP
No study medication	610013005	NO	TAIWAN	ASIAN	FEMALE	84	Dermatitis diaper	おむつ皮膚炎			MILD	NO	NO			NO	INSUFFICIENT FOLLOW-UP
No study medication	610013005	NO	TAIWAN	ASIAN	FEMALE	84	Delirium	譫妄			MODERATE	NO	NO			NO	INSUFFICIENT FOLLOW-UP
No study medication	610013005	NO	TAIWAN	ASIAN	FEMALE	84	Non-small cell lung cancer	非小細胞肺癌			SEVERE	YES	NO		22	NO	DEATH
No study medication	610013005	NO	TAIWAN	ASIAN	FEMALE	84	Malignant pleural effusion	悪性胸水			MODERATE	YES	NO		22	NO	DEATH
No study medication	610013005	NO	TAIWAN	ASIAN	FEMALE	84	Lymphangiosis carcinomatosa	癌性リンパ管症			MODERATE	YES	NO		22	NO	DEATH
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Haematoma	血腫			MILD	NO	YES	4	13	YES	RESOLVED
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Haematoma	血腫			MILD	NO	YES	5	12	YES	RESOLVED
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Ascites	腹水			MODERATE	YES	YES	55		NO	IMPROVED
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Cough	咳嗽			MILD	NO	YES	91	11	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Metastases to lung	肺転移			SEVERE	NO	YES	121		NO	UNCHANGED
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Hepatic cirrhosis	肝硬変			MILD	NO	YES	121		NO	UNCHANGED
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Metastases to liver	肝転移			SEVERE	YES	YES	121		NO	UNCHANGED
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Abdominal pain	腹痛			MILD	NO	YES	129		NO	UNCHANGED
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Hypoaesthesia	感覚鈍麻			MILD	NO	YES	135		NO	UNCHANGED
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Muscle fatigue	筋肉疲労			MILD	NO	YES	135		NO	UNCHANGED
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Pleural effusion	胸水			MODERATE	YES	YES	222	10	NO	IMPROVED
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Acute respiratory failure	急性呼吸不全			SEVERE	YES	NO	229	3	NO	DEATH
Rivaroxaban	670013021	YES	PHILIPPINES	ASIAN	MALE	83	Constipation	便秘	15 mg	.	MILD	NO	YES	1		NO	UNCHANGED
Rivaroxaban	670013021	YES	PHILIPPINES	ASIAN	MALE	83	Cerebrovascular accident	脳血管発作	15 mg	.	SEVERE	YES	YES	6		YES	UNCHANGED
Rivaroxaban	670013021	YES	PHILIPPINES	ASIAN	MALE	83	Cardio-respiratory arrest	心肺停止	15 mg	F	SEVERE	YES	YES	7	1	NO	DEATH
Rivaroxaban	710023020	YES	THAILAND	ASIAN	FEMALE	79	Urinary tract infection	尿路感染	20 mg	.	MODERATE	NO	YES	29	17	NO	RESOLVED
Rivaroxaban	710023020	YES	THAILAND	ASIAN	FEMALE	79	Pneumonia bacterial	細菌性肺炎	20 mg	.	MODERATE	NO	YES	51	13	NO	RESOLVED

表 2.7.4.7-17 死亡例一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	710023020	YES	THAILAND	ASIAN	FEMALE	79	Muscular weakness	筋力低下	20 mg	.	MODERATE	YES	YES	72	38	NO	RESOLVED
Rivaroxaban	710023020	YES	THAILAND	ASIAN	FEMALE	79	Diverticular perforation	憩室穿孔	20 mg	.	MODERATE	NO	YES	77	51	NO	RESOLVED
Rivaroxaban	710023020	YES	THAILAND	ASIAN	FEMALE	79	Drug hypersensitivity	薬物過敏症	20 mg	.	MODERATE	NO	YES	93	9	NO	RESOLVED
Rivaroxaban	710023020	YES	THAILAND	ASIAN	FEMALE	79	Conjunctivitis	結膜炎	20 mg	.	MODERATE	NO	YES	97	32	NO	RESOLVED
Rivaroxaban	710023020	YES	THAILAND	ASIAN	FEMALE	79	Convulsion	痙攣	20 mg	.	SEVERE	NO	YES	98		NO	UNCHANGED
Rivaroxaban	710023020	YES	THAILAND	ASIAN	FEMALE	79	Altered state of consciousness	意識変容状態	20 mg	.	SEVERE	YES	YES	127	4	NO	RESOLVED
Rivaroxaban	710023020	YES	THAILAND	ASIAN	FEMALE	79	Sepsis	敗血症	20 mg	.	SEVERE	YES	YES	137	41	NO	DEATH
Enoxaparin/VKA	710023023	YES	THAILAND	ASIAN	FEMALE	83	Colon cancer metastatic	転移性結腸癌			SEVERE	YES	YES	106	61	NO	DEATH

All AEs for death patients adjudicated by CIAC are presented.
Relative day is calculated from the first day of study drug administration: The formula for this calculation is (onset day of death minus medication day) plus 1 day.
Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase, F will be listed.

表 2.7.4.7-18 死亡例一覧（試験 11899、割り付けられた被験者）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {12.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Placebo	160264001	NO	FRANCE	N.A.	MALE	68	Renal failure	腎不全			SEVERE	YES	YES	149		NO	UNCHANGED
Placebo	160264001	NO	FRANCE	N.A.	MALE	68	Haematuria	血尿			MILD	NO	YES	149	1	NO	RESOLVED
Placebo	160264001	NO	FRANCE	N.A.	MALE	68	Urinary tract infection	尿路感染			MILD	NO	YES	149	29	NO	RESOLVED
Placebo	160264001	NO	FRANCE	N.A.	MALE	68	Pyelonephritis	腎盂腎炎			SEVERE	YES	YES	149	2	NO	RESOLVED
Placebo	160264001	NO	FRANCE	N.A.	MALE	68	Septic shock	敗血症性ショック			SEVERE	YES	YES	150	4	NO	RESOLVED
Placebo	160264001	NO	FRANCE	N.A.	MALE	68	Multi-organ failure	多臓器不全			SEVERE	YES	YES	150	9	NO	RESOLVED
Placebo	160264001	NO	FRANCE	N.A.	MALE	68	General physical health deterioration	全身健康状態低下			SEVERE	YES	NO	176	2	NO	DEATH
BAY 59-7939	220014004	YES	ITALY	WHITE	FEMALE	74	Oedema peripheral	末梢性浮腫	20 mg	.	MILD	NO	YES	27	3	NO	RESOLVED
BAY 59-7939	220014004	YES	ITALY	WHITE	FEMALE	74	Oedema peripheral	末梢性浮腫	20 mg	.	MODERATE	NO	YES	52		NO	UNCHANGED
BAY 59-7939	220014004	YES	ITALY	WHITE	FEMALE	74	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	MODERATE	YES	YES	106	16	NO	RESOLVED
BAY 59-7939	220014004	YES	ITALY	WHITE	FEMALE	74	Influenza	インフルエンザ	20 mg	.	MILD	NO	YES	209	4	NO	RESOLVED
BAY 59-7939	220014004	YES	ITALY	WHITE	FEMALE	74	Influenza	インフルエンザ	20 mg	.	MILD	NO	YES	228	2	NO	RESOLVED
BAY 59-7939	220014004	YES	ITALY	WHITE	FEMALE	74	Diarrhoea	下痢	20 mg	.	MODERATE	NO	YES	271	2	NO	RESOLVED

表 2.7.4.7-18 死亡例一覧（試験 11899、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {12.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
BAY 59-7939	220014004	YES	ITALY	WHITE	FEMALE	74	Cardiac arrest	心停止	20 mg	.	SEVERE	YES	YES	272	1	NO	DEATH
Placebo	380043014	YES	CZECH REPUBLIC	WHITE	FEMALE	73	Weight decreased	体重減少			MODERATE	NO	YES	96	96	NO	RESOLVED
Placebo	380043014	YES	CZECH REPUBLIC	WHITE	FEMALE	73	Nasopharyngitis	鼻咽頭炎			MILD	NO	YES	103	14	NO	RESOLVED
Placebo	380043014	YES	CZECH REPUBLIC	WHITE	FEMALE	73	Nasopharyngitis	鼻咽頭炎			MILD	NO	YES	130	6	NO	RESOLVED
Placebo	380043014	YES	CZECH REPUBLIC	WHITE	FEMALE	73	Hydronephrosis	水腎症			SEVERE	YES	YES	147	15	NO	RESOLVED
Placebo	380043014	YES	CZECH REPUBLIC	WHITE	FEMALE	73	Gastritis	胃炎			MODERATE	NO	YES	147	45	NO	RESOLVED
Placebo	380043014	YES	CZECH REPUBLIC	WHITE	FEMALE	73	Colon cancer	結腸癌			SEVERE	YES	YES	149		NO	UNCHANGED
Placebo	380043014	YES	CZECH REPUBLIC	WHITE	FEMALE	73	Respiratory tract infection	気道感染			MODERATE	NO	YES	162	30	NO	RESOLVED
Placebo	380043014	YES	CZECH REPUBLIC	WHITE	FEMALE	73	Cardiac failure	心不全			SEVERE	YES	NO	191	1	NO	DEATH
Placebo	460034003	YES	HUNGARY	WHITE	MALE	46	Goitre	甲状腺腫			MILD	NO	YES	122		NO	IMPROVED
Placebo	460034003	YES	HUNGARY	WHITE	MALE	46	Hypothyroidism	甲状腺機能低下症			MILD	NO	YES	122		NO	IMPROVED
Placebo	460034003	YES	HUNGARY	WHITE	MALE	46	Pulmonary embolism	肺塞栓症			SEVERE	YES	YES	134	1	YES	DEATH

表 2.7.4.7-18　死亡例一覧（試験 11899、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {12.0})		Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
All AEs for death patients adjudicated by CIAC are presented. Relative day is calculated from the first day of study drug administration: The formula for this calculation is (onset day of death minus medication day) plus 1 day. Concomitant Medication: Medications that are ongoing at, or began after the start of study drug are presented. Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed. Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase, F will be listed.																	

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	100034004	YES	GERMANY	WHITE	FEMALE	47	Leukocytoclastic vasculitis	白血球破砕性血管炎			MODERATE	YES	24	2	YES	IMPROVED
Enoxaparin/VKA	100034004	YES	GERMANY	WHITE	FEMALE	47	Skin ulcer	皮膚潰瘍			MODERATE	YES	41	142	YES	IMPROVED
Enoxaparin/VKA	100034008	YES	GERMANY	WHITE	FEMALE	78	Hypertensive crisis	高血圧クリーゼ			SEVERE	YES	357	10	NO	RESOLVED
Rivaroxaban	100034009	YES	GERMANY	WHITE	MALE	33	Maculopathy	黄斑症	20 mg	F	MODERATE	NO	196	6	NO	RESOLVED
Rivaroxaban	100034014	YES	GERMANY	WHITE	FEMALE	75	Osteoarthritis	変形性関節症	20 mg	.	SEVERE	YES	202	34	NO	RESOLVED
Rivaroxaban	100034020	YES	GERMANY	WHITE	FEMALE	65	Pulmonary fibrosis	肺線維症	20 mg	.	MODERATE	YES	69	6	NO	RESOLVED
Rivaroxaban	100034020	YES	GERMANY	WHITE	FEMALE	65	Bronchopneumonia	気管支肺炎	20 mg	I	MODERATE	YES	258	13	NO	RESOLVED
Rivaroxaban	100034020	YES	GERMANY	WHITE	FEMALE	65	Pulmonary fibrosis	肺線維症	20 mg	I	MODERATE	YES	286	15	NO	RESOLVED
Rivaroxaban	100034021	YES	GERMANY	WHITE	MALE	52	Atrial fibrillation	心房細動	20 mg	F	MODERATE	NO	207	2	NO	RESOLVED
Enoxaparin/VKA	100034024	YES	GERMANY	WHITE	MALE	56	Abdominal abscess	腹部膿瘍			MODERATE	YES	284	9	NO	RESOLVED
Enoxaparin/VKA	100034031	YES	GERMANY	WHITE	MALE	75	Back pain	背部痛			MODERATE	YES	18	5	NO	RESOLVED
Rivaroxaban	100054001	YES	GERMANY	WHITE	MALE	67	Intervertebral disc protrusion	椎間板突出	20 mg	F	SEVERE	NO	200	2	NO	RESOLVED
Rivaroxaban	100054010	YES	GERMANY	WHITE	MALE	61	Rectal haemorrhage	直腸出血	15 mg	.	MODERATE	YES	4	4	YES	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	100064005	YES	GERMANY	WHITE	MALE	57	Wegener's granulomatosis	ウェゲナー肉芽腫症	20 mg	.	MODERATE	YES	204	14	NO	RESOLVED
Rivaroxaban	100074001	YES	GERMANY	WHITE	FEMALE	68	Urinary tract infection	尿路感染	20 mg	.	MODERATE	YES	121	11	YES	RESOLVED
Rivaroxaban	100074001	YES	GERMANY	WHITE	FEMALE	68	Circulatory collapse	循環虚脱	20 mg	.	MILD	YES	124	3	YES	RESOLVED
Rivaroxaban	100074001	YES	GERMANY	WHITE	FEMALE	68	Back pain	背部痛	20 mg	.	SEVERE	YES	221	3	NO	RESOLVED
Enoxaparin/VKA	100074006	YES	GERMANY	WHITE	MALE	59	Rectal haemorrhage	直腸出血			MODERATE	YES	236	4	YES	RESOLVED
Rivaroxaban	100094033	YES	GERMANY	WHITE	FEMALE	69	Bronchitis	気管支炎	20 mg	.	MODERATE	YES	41	11	NO	RESOLVED
Enoxaparin/VKA	100094038	YES	GERMANY	WHITE	FEMALE	71	Reflux oesophagitis	逆流性食道炎			SEVERE	YES	54	19	NO	RESOLVED
Enoxaparin/VKA	100094038	YES	GERMANY	WHITE	FEMALE	71	Oesophageal ulcer haemorrhage	食道潰瘍出血			SEVERE	YES	60	2	NO	RESOLVED
Enoxaparin/VKA	100094038	YES	GERMANY	WHITE	FEMALE	71	Acute psychosis	急性精神病			SEVERE	YES	60	5	NO	RESOLVED
Enoxaparin/VKA	100124002	YES	GERMANY	WHITE	MALE	73	Muscle haemorrhage	筋肉内出血			SEVERE	YES	7	23	YES	RESOLVED
Rivaroxaban	100134008	YES	GERMANY	WHITE	FEMALE	45	Menorrhagia	月経過多			SEVERE	YES	27	4	NO	RESOLVED
Rivaroxaban	100134015	YES	GERMANY	WHITE	MALE	78	Oesophageal adenocarcinoma	食道腺癌	20 mg	.	SEVERE	YES	106	121	NO	DEATH
Enoxaparin/VKA	100134016	YES	GERMANY	WHITE	FEMALE	69	Meningioma	髄膜腫			MILD	YES	204	52	NO	RESOLVED
Rivaroxaban	100134024	YES	GERMANY	WHITE	MALE	84	Thrombocytopenia	血小板減少症	20 mg	.	SEVERE	YES	65	14	YES	IMPROVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	100134024	YES	GERMANY	WHITE	MALE	84	Epistaxis	鼻出血	20 mg	.	SEVERE	YES	65	14	YES	RESOLVED
Enoxaparin/VKA	100134036	YES	GERMANY	WHITE	MALE	50	Thoracic vertebral fracture	胸椎骨折			MODERATE	YES	94	8	NO	RESOLVED
Rivaroxaban	100134038	YES	GERMANY	WHITE	MALE	54	Multi-organ failure	多臓器不全	20 mg	.	SEVERE	YES	84	25	NO	DEATH
Rivaroxaban	100134038	YES	GERMANY	WHITE	MALE	54	Bile duct cancer	胆管癌	20 mg	F	SEVERE	NO	87		NO	UNCHANGED
Enoxaparin/VKA	100224001	YES	GERMANY	WHITE	FEMALE	48	Anaemia	貧血			MODERATE	YES	21	6	YES	RESOLVED
Enoxaparin/VKA	100224022	YES	GERMANY	WHITE	MALE	63	Angina pectoris	狭心症			SEVERE	NO	74	2	NO	RESOLVED
Rivaroxaban	100224049	YES	GERMANY	WHITE	FEMALE	65	Abdominal pain	腹痛	15 mg	.	MILD	YES	3	3	NO	RESOLVED
Rivaroxaban	100224049	YES	GERMANY	WHITE	FEMALE	65	Weight decreased	体重減少	20 mg	.	MODERATE	YES	50	6	NO	IMPROVED
Rivaroxaban	100224053	YES	GERMANY	WHITE	FEMALE	56	Tachyarrhythmia	頻脈性不整脈	20 mg	.	MODERATE	YES	44	5	NO	RESOLVED
Enoxaparin/VKA	100224054	YES	GERMANY	WHITE	MALE	69	Arterial thrombosis limb	四肢動脈血栓症			MODERATE	YES	98	47	YES	RESOLVED
Rivaroxaban	100264003	YES	GERMANY	WHITE	MALE	57	Acute myocardial infarction	急性心筋梗塞	20 mg	.	SEVERE	YES	327	11	NO	RESOLVED
Enoxaparin/VKA	100394026	YES	GERMANY	WHITE	FEMALE	30	Ovarian cyst	卵巣嚢胞			MODERATE	NO	264	2	NO	RESOLVED
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Endometrial cancer	子宮内膜癌	20 mg	.	SEVERE	YES	32	119	NO	DEATH
Rivaroxaban	120034001	YES	UNITED KINGDOM	WHITE	FEMALE	40	Anaemia	貧血	20 mg	.	SEVERE	YES	53		YES	IMPROVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	120034010	YES	UNITED KINGDOM	WHITE	FEMALE	39	Cellulitis	蜂巣炎			SEVERE	YES	11	8	NO	IMPROVED
Enoxaparin/VKA	120034010	YES	UNITED KINGDOM	WHITE	FEMALE	39	Asthma	喘息			SEVERE	YES	20	5	NO	RESOLVED
Rivaroxaban	140034002	YES	UNITED STATES	BLACK	FEMALE	51	Asthma	喘息	15 mg	.	SEVERE	YES	12	7	NO	RESOLVED
Rivaroxaban	140034002	YES	UNITED STATES	BLACK	FEMALE	51	Oedema peripheral	末梢性浮腫	15 mg	.	MODERATE	YES	12	7	NO	RESOLVED
Enoxaparin/VKA	140154013	YES	UNITED STATES	WHITE	MALE	56	Post thrombotic syndrome	血栓後症候群			SEVERE	YES	16	12	NO	RESOLVED
Enoxaparin/VKA	140154013	YES	UNITED STATES	WHITE	MALE	56	Thrombosis	血栓症			MODERATE	YES	16		NO	IMPROVED
Enoxaparin/VKA	140154013	YES	UNITED STATES	WHITE	MALE	56	May-Thurner syndrome	マイ・トゥルナー症候群			SEVERE	YES	23	5	NO	RESOLVED
Rivaroxaban	140164005	YES	UNITED STATES	WHITE	MALE	52	Small cell lung cancer metastatic	転移性小細胞肺癌			SEVERE	YES	183	41	NO	DEATH
Rivaroxaban	140164006	YES	UNITED STATES	WHITE	MALE	53	Non-Hodgkin's lymphoma	非ホジキンリンパ腫	15 mg	.	SEVERE	YES	3	262	NO	RESOLVED
Rivaroxaban	140164006	YES	UNITED STATES	WHITE	MALE	53	Renal cell carcinoma	腎細胞癌	20 mg	I	MODERATE	YES	51	46	NO	RESOLVED
Rivaroxaban	140164012	YES	UNITED STATES	WHITE	MALE	69	Abdominal pain upper	上腹部痛	20 mg	.	MODERATE	YES	105	3	NO	RESOLVED
Rivaroxaban	140164024	YES	UNITED STATES	WHITE	MALE	87	Gastrointestinal haemorrhage	胃腸出血	20 mg	.	SEVERE	YES	92	22	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	140164029	YES	UNITED STATES	HISPANIC	FEMALE	39	Anaemia	貧血	20 mg	F	SEVERE	YES	130	3	YES	RESOLVED
Rivaroxaban	140164029	YES	UNITED STATES	HISPANIC	FEMALE	39	Uterine leiomyoma	子宮平滑筋腫	20 mg	F	MODERATE	NO	134	1	NO	RESOLVED
Rivaroxaban	140164040	YES	UNITED STATES	HISPANIC	FEMALE	48	Nausea	悪心	20 mg	.	MODERATE	YES	28		NO	UNCHANGED
Rivaroxaban	140164040	YES	UNITED STATES	HISPANIC	FEMALE	48	Vomiting	嘔吐	20 mg	.	MODERATE	YES	28		NO	UNCHANGED
Rivaroxaban	140164040	YES	UNITED STATES	HISPANIC	FEMALE	48	Cervix carcinoma	子宮頚部癌	20 mg	.	SEVERE	YES	28	30	NO	DEATH
Rivaroxaban	140174004	YES	UNITED STATES	WHITE	MALE	48	Clavicle fracture	鎖骨骨折	20 mg	F	SEVERE	NO	127	2	NO	RESOLVED
Enoxaparin/VKA	140174012	YES	UNITED STATES	WHITE	MALE	69	Device related infection	医療機器関連感染			SEVERE	YES	30	3	NO	RESOLVED
Enoxaparin/VKA	140174012	YES	UNITED STATES	WHITE	MALE	69	Pneumonia	肺炎			SEVERE	YES	32	6	NO	RESOLVED
Enoxaparin/VKA	140174012	YES	UNITED STATES	WHITE	MALE	69	Liver function test abnormal	肝機能検査異常			MILD	YES	115	32	NO	RESOLVED
Rivaroxaban	140194003	YES	UNITED STATES	WHITE	MALE	57	Pyrexia	発熱	20 mg	.	MILD	YES	345	2	NO	RESOLVED
Rivaroxaban	140194005	YES	UNITED STATES	BLACK	FEMALE	46	Vaginal haemorrhage	腟出血	15 mg	.	MODERATE	YES	19	2	YES	RESOLVED
Rivaroxaban	140194005	YES	UNITED STATES	BLACK	FEMALE	46	Anaemia	貧血	20 mg	.	MODERATE	YES	23	3	YES	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	140194005	YES	UNITED STATES	BLACK	FEMALE	46	Vaginal haemorrhage	膣出血	20 mg	.	MODERATE	YES	37	3	YES	RESOLVED
Rivaroxaban	140194007	YES	UNITED STATES	WHITE	FEMALE	46	Diarrhoea	下痢	20 mg	.	MODERATE	YES	53	5	NO	RESOLVED
Rivaroxaban	140194012	YES	UNITED STATES	WHITE	FEMALE	51	Bacteraemia	菌血症	20 mg	.	MODERATE	YES	137	39	NO	RESOLVED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	Vaginal haemorrhage	膣出血			MODERATE	NO	119	8	NO	RESOLVED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	Haematuria	血尿			MODERATE	NO	120		NO	IMPROVED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	Renal failure acute	急性腎不全			SEVERE	NO	120	47	NO	RESOLVED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	International normalised ratio increased	ＩＮＲ増加			MODERATE	NO	120	5	NO	RESOLVED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	Hydronephrosis	水腎症			MODERATE	NO	120	2	NO	RESOLVED
Enoxaparin/VKA	140194014	YES	UNITED STATES	WHITE	FEMALE	40	Cervix carcinoma	子宮頚部癌			SEVERE	NO	178	8	NO	DEATH
Rivaroxaban	140204002	YES	UNITED STATES	WHITE	FEMALE	65	Cellulitis	蜂巣炎	15 mg	.	SEVERE	YES	17	16	NO	RESOLVED
Rivaroxaban	140204035	YES	UNITED STATES	WHITE	FEMALE	65	Joint range of motion decreased	関節可動域減少	20 mg	.	MILD	YES	61	2	NO	RESOLVED
Enoxaparin/VKA	140314005	YES	UNITED STATES	WHITE	FEMALE	55	Epiglottitis	喉頭蓋炎			MODERATE	YES	69	3	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	140314012	YES	UNITED STATES	WHITE	MALE	67	Sepsis	敗血症			SEVERE	YES	6	18	NO	DEATH
Enoxaparin/VKA	140314012	YES	UNITED STATES	WHITE	MALE	67	Gastric ulcer perforation	穿孔性胃潰瘍			MODERATE	YES	10	1	NO	RESOLVED
Enoxaparin/VKA	140314012	YES	UNITED STATES	WHITE	MALE	67	Post procedural haemorrhage	処置後出血			MODERATE	NO	14	2	NO	RESOLVED
Enoxaparin/VKA	140314012	YES	UNITED STATES	WHITE	MALE	67	Gastrointestinal necrosis	消化管壊死			SEVERE	NO	17		NO	UNCHANGED
Enoxaparin/VKA	140314013	YES	UNITED STATES	WHITE	FEMALE	51	Small intestinal obstruction	小腸閉塞			MILD	YES	313	4	NO	RESOLVED
Enoxaparin/VKA	140314013	YES	UNITED STATES	WHITE	FEMALE	51	Pelvic pain	骨盤痛			MODERATE	NO	367	2	NO	RESOLVED
Enoxaparin/VKA	140314032	YES	UNITED STATES	WHITE	MALE	53	Back pain	背部痛			MODERATE	YES	21	16	NO	RESOLVED
Rivaroxaban	140314033	YES	UNITED STATES	WHITE	MALE	35	Diabetic ketoacidosis	糖尿病性ケトアシドーシス	20 mg	.	MODERATE	YES	24	3	NO	RESOLVED
Rivaroxaban	140324005	YES	UNITED STATES	WHITE	FEMALE	83	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	MODERATE	YES	126	6	NO	RESOLVED
Enoxaparin/VKA	140324031	YES	UNITED STATES	WHITE	FEMALE	87	Gastroenteritis	胃腸炎			MODERATE	YES	68	14	NO	RESOLVED
Enoxaparin/VKA	140374008	YES	UNITED STATES	HISPANIC	FEMALE	85	Haematoma	血腫			MODERATE	YES	19	26	YES	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	140374037	YES	UNITED STATES	ASIAN	FEMALE	51	Lower gastrointestinal haemorrhage	下部消化管出血			MODERATE	NO	80	3	YES	RESOLVED
Enoxaparin/VKA	140414003	YES	UNITED STATES	WHITE	FEMALE	68	Renal failure acute	急性腎不全			MILD	YES	2	3	NO	RESOLVED
Rivaroxaban	140424011	YES	UNITED STATES	WHITE	FEMALE	84	Humerus fracture	上腕骨骨折	15 mg	.	SEVERE	YES	7	34	NO	RESOLVED
Rivaroxaban	160014003	YES	FRANCE	N.A.	MALE	78	Bladder catheter removal	膀胱カテーテル除去	20 mg	.	MODERATE	YES	30	2	NO	RESOLVED
Rivaroxaban	160014038	YES	FRANCE	N.A.	MALE	70	Bladder cancer	膀胱癌	15 mg	.	MILD	YES	9	154	NO	RESOLVED
Rivaroxaban	160014038	YES	FRANCE	N.A.	MALE	70	Rectal polyp	直腸ポリープ	20 mg	I	MILD	YES	29	1	NO	RESOLVED
Rivaroxaban	160014038	YES	FRANCE	N.A.	MALE	70	Post procedural haematuria	処置後血尿	20 mg	.	MILD	YES	109	2	YES	RESOLVED
Enoxaparin/VKA	160014055	YES	FRANCE	N.A.	MALE	41	Depression	うつ病			MODERATE	YES	150	47	NO	RESOLVED
Rivaroxaban	160014061	YES	FRANCE	N.A.	FEMALE	79	Breast cancer	乳癌	20 mg	I	MODERATE	YES	42		NO	IMPROVED
Enoxaparin/VKA	160054002	YES	FRANCE	N.A.	MALE	61	International normalised ratio fluctuation	ＩＮＲ変動			MILD	YES	55	2	YES	RESOLVED
Enoxaparin/VKA	160054002	YES	FRANCE	N.A.	MALE	61	Peripheral ischaemia	末梢性虚血			MILD	YES	326		NO	UNCHANGED
Enoxaparin/VKA	160074003	YES	FRANCE	N.A.	FEMALE	40	International normalised ratio increased	ＩＮＲ増加			MILD	YES	28	6	YES	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	160104010	YES	FRANCE	N.A.	MALE	46	Renal cell carcinoma recurrent	再発腎細胞癌			SEVERE	YES	187		NO	WORSENED
Enoxaparin/VKA	160104010	YES	FRANCE	N.A.	MALE	46	Splenic haemorrhage	脾臓出血			SEVERE	NO	240	2	NO	RESOLVED
Enoxaparin/VKA	160104015	YES	FRANCE	N.A.	MALE	56	Chest X-ray abnormal	胸部X線異常			SEVERE	YES	22		NO	UNCHANGED
Enoxaparin/VKA	160104015	YES	FRANCE	N.A.	MALE	56	Pneumonia bacterial	細菌性肺炎			SEVERE	YES	313	32	NO	DEATH
Enoxaparin/VKA	160104015	YES	FRANCE	N.A.	MALE	56	Liver function test abnormal	肝機能検査異常			SEVERE	YES	313	5	NO	RESOLVED
Rivaroxaban	160104020	YES	FRANCE	N.A.	FEMALE	58	Chest pain	胸痛	20 mg	.	MILD	YES	166	11	NO	RESOLVED
Rivaroxaban	160104020	YES	FRANCE	N.A.	FEMALE	58	Pleural effusion	胸水	20 mg	.	MILD	YES	219		NO	UNCHANGED
Rivaroxaban	160104020	YES	FRANCE	N.A.	FEMALE	58	Metastases to liver	肝転移	20 mg	.	SEVERE	YES	246	30	NO	DEATH
Rivaroxaban	160124008	YES	FRANCE	N.A.	MALE	81	Syncope	失神	15 mg	.	SEVERE	YES	4	1	NO	RESOLVED
Enoxaparin/VKA	160124014	YES	FRANCE	N.A.	MALE	58	Rotator cuff syndrome	肩回旋筋腱板症候群			MODERATE	YES	3	194	NO	RESOLVED
Enoxaparin/VKA	160124014	YES	FRANCE	N.A.	MALE	58	Arterial haemorrhage	動脈出血			MILD	YES	19	1	NO	RESOLVED
Rivaroxaban	160124020	YES	FRANCE	N.A.	FEMALE	76	Oedema peripheral	末梢性浮腫	15 mg	.	MODERATE	YES	20	12	NO	RESOLVED
Rivaroxaban	160124020	YES	FRANCE	N.A.	FEMALE	76	Colitis ulcerative	潰瘍性大腸炎	20 mg	.	SEVERE	YES	52	11	NO	RESOLVED
Rivaroxaban	160124020	YES	FRANCE	N.A.	FEMALE	76	Anaemia	貧血	20 mg	.	SEVERE	YES	171	11	YES	RESOLVED
Rivaroxaban	160134003	YES	FRANCE	N.A.	MALE	70	Depression	うつ病	20 mg	.	SEVERE	YES	34	91	NO	RESOLVED
Enoxaparin/V	160134004	YES	FRANCE	N.A.	FEMALE	49	Renal colic	腎仙痛			SEVERE	YES	16	4	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA																
Rivaroxaban	160174031	YES	FRANCE	N.A.	FEMALE	70	Goitre	甲状腺腫	20 mg	I	MODERATE	YES	108	3	NO	RESOLVED
Rivaroxaban	160174041	YES	FRANCE	N.A.	MALE	79	Diabetes mellitus inadequate control	コントロール不良の糖尿病	20 mg	F	SEVERE	NO	188	19	NO	RESOLVED
Enoxaparin/VKA	160184002	YES	FRANCE	N.A.	MALE	57	Dermatitis exfoliative	剥脱性皮膚炎			MODERATE	YES	95	8	NO	RESOLVED
Enoxaparin/VKA	160184002	YES	FRANCE	N.A.	MALE	57	Anaemia	貧血			MILD	YES	158	2	NO	RESOLVED
Enoxaparin/VKA	160184002	YES	FRANCE	N.A.	MALE	57	Septic shock	敗血症性ショック			SEVERE	YES	166	2	NO	DEATH
Rivaroxaban	160194005	YES	FRANCE	N.A.	MALE	72	Haematuria	血尿	20 mg	.	MODERATE	YES	50	2	YES	RESOLVED
Enoxaparin/VKA	160194013	YES	FRANCE	N.A.	MALE	81	Haemorrhage intracranial	頭蓋内出血			SEVERE	YES	98	3	YES	DEATH
Enoxaparin/VKA	160194017	YES	FRANCE	N.A.	FEMALE	66	Haemoptysis	喀血			MODERATE	YES	12	3	YES	RESOLVED
Enoxaparin/VKA	160194023	YES	FRANCE	N.A.	MALE	69	Pneumonia	肺炎			SEVERE	YES	106	7	NO	RESOLVED
Rivaroxaban	160214005	YES	FRANCE	N.A.	MALE	39	Cholelithiasis	胆石症	20 mg	.	MODERATE	YES	22	4	NO	RESOLVED
Enoxaparin/VKA	160214010	YES	FRANCE	N.A.	FEMALE	86	Muscle haemorrhage	筋肉内出血			SEVERE	YES	13	19	YES	RESOLVED
Enoxaparin/VKA	160214010	YES	FRANCE	N.A.	FEMALE	86	Shock haemorrhagic	出血性ショック			SEVERE	YES	13	19	YES	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	160234001	YES	FRANCE	N.A.	MALE	58	Alcohol abuse	アルコール乱用			MILD	YES	78	3	NO	RESOLVED
Enoxaparin/VKA	160234002	YES	FRANCE	N.A.	FEMALE	87	Pain in extremity	四肢痛			MODERATE	YES	19	13	YES	RESOLVED
Enoxaparin/VKA	160234002	YES	FRANCE	N.A.	FEMALE	87	Bacterial sepsis	細菌性敗血症			MODERATE	YES	24	8	NO	RESOLVED
Enoxaparin/VKA	160234002	YES	FRANCE	N.A.	FEMALE	87	Erysipelas	丹毒			MODERATE	YES	24	8	NO	RESOLVED
Enoxaparin/VKA	160234023	YES	FRANCE	N.A.	FEMALE	35	Complex regional pain syndrome	複合性局所疼痛症候群			MODERATE	YES	57	4	NO	RESOLVED
Enoxaparin/VKA	160234066	YES	FRANCE	N.A.	FEMALE	85	Subdural haematoma	硬膜下血腫			SEVERE	NO	30	20	NO	RESOLVED
Enoxaparin/VKA	160254002	YES	FRANCE	N.A.	FEMALE	41	Post abortion haemorrhage	流産後の出血			MILD	NO	31	23	NO	RESOLVED
Enoxaparin/VKA	160254003	YES	FRANCE	N.A.	MALE	42	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MODERATE	YES	16	37	YES	RESOLVED
Enoxaparin/VKA	160254010	YES	FRANCE	N.A.	MALE	65	Renal neoplasm	腎新生物			SEVERE	YES	63	95	NO	RESOLVED
Rivaroxaban	160254011	YES	FRANCE	N.A.	MALE	50	Atrial flutter	心房粗動	20 mg	.	MODERATE	YES	137	1	NO	RESOLVED
Enoxaparin/VKA	160264001	YES	FRANCE	N.A.	MALE	67	Urinary tract infection	尿路感染			MODERATE	YES	96	11	NO	RESOLVED
Enoxaparin/VKA	160264001	YES	FRANCE	N.A.	MALE	67	Haematuria	血尿			MODERATE	YES	322	3	YES	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	160264001	YES	FRANCE	N.A.	MALE	67	Haematuria	血尿			MODERATE	YES	356	4	YES	RESOLVED
Enoxaparin/VKA	160264008	YES	FRANCE	N.A.	FEMALE	56	Extremity necrosis	四肢壊死			MODERATE	YES	167	14	NO	RESOLVED
Enoxaparin/VKA	160264014	YES	FRANCE	N.A.	FEMALE	97	Anaemia	貧血			MODERATE	YES	3	3	NO	RESOLVED
Enoxaparin/VKA	160264014	YES	FRANCE	N.A.	FEMALE	97	Epilepsy	てんかん			SEVERE	NO	13	25	NO	RESOLVED
Enoxaparin/VKA	160264014	YES	FRANCE	N.A.	FEMALE	97	General physical health deterioration	全身健康状態低下			SEVERE	NO	14	24	NO	DEATH
Enoxaparin/VKA	160274004	YES	FRANCE	N.A.	MALE	79	Rectal haemorrhage	直腸出血			SEVERE	YES	54	2	YES	RESOLVED
Rivaroxaban	160294013	YES	FRANCE	N.A.	MALE	74	Lung neoplasm	肺新生物	20 mg	F	SEVERE	NO	201	6	NO	DEATH
Rivaroxaban	160304008	YES	FRANCE	N.A.	MALE	86	Waldenstrom's macroglobulinaemia	ワルデンストローム・マクログロブリン血症	20 mg	.	SEVERE	YES	34		NO	UNCHANGED
Rivaroxaban	160304008	YES	FRANCE	N.A.	MALE	86	Panic attack	パニック発作	20 mg	.	MILD	YES	62	3	NO	RESOLVED
Enoxaparin/VKA	160324003	YES	FRANCE	N.A.	FEMALE	59	Post procedural sepsis	処置後敗血症			SEVERE	YES	47	9	NO	IMPROVED
Enoxaparin/VKA	160324003	YES	FRANCE	N.A.	FEMALE	59	Impaired healing	治癒不良			MODERATE	YES	62	6	NO	IMPROVED
Enoxaparin/VKA	160334002	YES	FRANCE	N.A.	FEMALE	42	Iliac artery stenosis	腸骨動脈狭窄			SEVERE	YES	140	3	NO	IMPROVED
Enoxaparin/VKA	160334021	YES	FRANCE	N.A.	MALE	72	Ear neoplasm malignant	耳の悪性新生物			SEVERE	YES	173	1	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	180014008	YES	POLAND	WHITE	FEMALE	39	Major depression	大うつ病	20 mg	.	MODERATE	YES	77		NO	IMPROVED
Rivaroxaban	180014008	YES	POLAND	WHITE	FEMALE	39	Menorrhagia	月経過多	20 mg	F	SEVERE	YES	125	3	YES	RESOLVED
Rivaroxaban	180044009	YES	POLAND	WHITE	MALE	54	Pericarditis	心膜炎	20 mg	.	SEVERE	YES	166	11	NO	RESOLVED
Rivaroxaban	180094002	YES	POLAND	WHITE	MALE	60	Haemorrhage intracranial	頭蓋内出血	20 mg	F	SEVERE	YES	151		YES	IMPROVED
Rivaroxaban	180104013	YES	POLAND	WHITE	MALE	56	Pyelonephritis	腎盂腎炎	20 mg	.	MODERATE	YES	311	5	NO	RESOLVED
Rivaroxaban	180114003	YES	POLAND	WHITE	MALE	60	Bladder cancer	膀胱癌	20 mg	F	MODERATE	YES	183		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	180114003	YES	POLAND	WHITE	MALE	60	Acute myocardial infarction	急性心筋梗塞	20 mg	F	MODERATE	NO	186		NO	IMPROVED
Rivaroxaban	180124002	YES	POLAND	WHITE	MALE	78	Ischaemic stroke	虚血性脳卒中	20 mg	.	MODERATE	YES	154	16	NO	RESOLVED
Rivaroxaban	180124004	YES	POLAND	WHITE	MALE	79	Oedema peripheral	末梢性浮腫	20 mg	.	MILD	YES	61	6	NO	RESOLVED
Rivaroxaban	180124004	YES	POLAND	WHITE	MALE	79	Dyspnoea at rest	安静時呼吸困難	20 mg	I	MODERATE	YES	66	7	NO	RESOLVED
Rivaroxaban	180124004	YES	POLAND	WHITE	MALE	79	Lung disorder	肺障害	20 mg	.	MODERATE	YES	157	6	NO	RESOLVED
Enoxaparin/VKA	180124005	YES	POLAND	WHITE	FEMALE	59	Angina unstable	不安定狭心症			SEVERE	YES	6	14	NO	RESOLVED
Enoxaparin/VKA	180124005	YES	POLAND	WHITE	FEMALE	59	Metastatic neoplasm	転移性新生物			MODERATE	NO	39		NO	UNCHANGED
Enoxaparin/V	180174001	YES	POLAND	WHITE	FEMALE	69	Ischaemic stroke	虚血性脳卒			SEVERE	YES	42	37	NO	IMPROVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA								中								
Rivaroxaban	180174002	YES	POLAND	WHITE	MALE	69	Acute myocardial infarction	急性心筋梗塞	20 mg	.	SEVERE	YES	328	8	NO	RESOLVED
Enoxaparin/VKA	180194001	YES	POLAND	WHITE	FEMALE	86	Cardiac arrest	心停止			SEVERE	YES	4	1	NO	DEATH
Rivaroxaban	220014002	YES	ITALY	WHITE	MALE	84	Anaemia	貧血	20 mg	.	SEVERE	YES	124	11	YES	RESOLVED
Rivaroxaban	220014002	YES	ITALY	WHITE	MALE	84	Anaemia	貧血	20 mg	I	SEVERE	YES	167	24	YES	RESOLVED
Enoxaparin/VKA	220014004	YES	ITALY	WHITE	FEMALE	74	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患			MODERATE	YES	71	16	NO	RESOLVED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Respiratory failure	呼吸不全	20 mg	.	SEVERE	YES	54	23	NO	RESOLVED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Breast cancer	乳癌	20 mg	F	SEVERE	YES	95		NO	UNCHANGED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Respiratory failure	呼吸不全	20 mg	F	SEVERE	YES	95	2	NO	DEATH
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Arrhythmia	不整脈	20 mg	F	SEVERE	YES	95		NO	UNCHANGED
Rivaroxaban	220014008	YES	ITALY	WHITE	FEMALE	51	Metastases to lung	肺転移	20 mg	F	SEVERE	YES	95		NO	UNCHANGED
Enoxaparin/VKA	220014010	YES	ITALY	WHITE	MALE	61	Henoch-Schonlein purpura	ヘノッホ・シェーンライン紫斑病			MODERATE	YES	16	124	NO	RESOLVED
Enoxaparin/VKA	220014021	YES	ITALY	WHITE	FEMALE	77	Interstitial lung disease	間質性肺疾患			SEVERE	YES	89	8	NO	DEATH
Enoxaparin/VKA	220014022	YES	ITALY	WHITE	MALE	59	Acute leukaemia	急性白血病			SEVERE	YES	28		NO	UNCHANGED
Enoxaparin/VKA	220014029	YES	ITALY	WHITE	FEMALE	73	Anaemia	貧血			SEVERE	YES	113	6	YES	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	220014042	YES	ITALY	WHITE	FEMALE	73	Cardiac failure chronic	慢性心不全			MODERATE	YES	11	8	NO	RESOLVED
Enoxaparin/VKA	220034002	YES	ITALY	WHITE	MALE	72	Lung adenocarcinoma	肺腺癌			SEVERE	YES	4		NO	UNCHANGED
Enoxaparin/VKA	220034002	YES	ITALY	WHITE	MALE	72	Haemothorax	血胸			SEVERE	YES	8	2	YES	DEATH
Rivaroxaban	220034006	YES	ITALY	WHITE	MALE	83	Anaemia	貧血	20 mg	.	MILD	YES	114		NO	IMPROVED
Rivaroxaban	220034006	YES	ITALY	WHITE	MALE	83	Cellulitis	蜂巣炎	20 mg	.	SEVERE	YES	170	50	NO	RESOLVED
Rivaroxaban	220034006	YES	ITALY	WHITE	MALE	83	Bursitis	滑液包炎	20 mg	.	MILD	YES	170	50	NO	RESOLVED
Enoxaparin/VKA	220084004	YES	ITALY	BLACK	MALE	38	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MILD	YES	16	12	YES	RESOLVED
Rivaroxaban	220084042	YES	ITALY	WHITE	MALE	76	Nephrotic syndrome	ネフローゼ症候群	20 mg	I	MODERATE	YES	162		NO	UNCHANGED
Enoxaparin/VKA	220084048	YES	ITALY	WHITE	MALE	80	Completed suicide	自殺既遂			SEVERE	YES	102	1	NO	DEATH
Rivaroxaban	220094002	YES	ITALY	WHITE	MALE	81	Ischaemic stroke	虚血性脳卒中	20 mg	.	SEVERE	YES	95	6	NO	DEATH
Rivaroxaban	220104006	YES	ITALY	WHITE	FEMALE	65	Hepatitis acute	急性肝炎	20 mg	.	SEVERE	YES	49	16	YES	RESOLVED
Rivaroxaban	220104008	YES	ITALY	WHITE	FEMALE	73	Rib fracture	肋骨骨折	20 mg	.	MILD	YES	106	65	NO	RESOLVED
Enoxaparin/VKA	220114010	YES	ITALY	WHITE	MALE	83	Transient ischaemic attack	一過性脳虚血発作			MODERATE	YES	92	4	NO	RESOLVED
Rivaroxaban	220134002	YES	ITALY	WHITE	FEMALE	61	Ischaemic stroke	虚血性脳卒中	20 mg	.	MODERATE	YES	32	8	NO	RESOLVED
Rivaroxaban	220134002	YES	ITALY	WHITE	FEMALE	61	Pyrexia	発熱	20 mg	.	MILD	YES	51	14	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

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Rivaroxaban	220134002	YES	ITALY	WHITE	FEMALE	61	Acute myocardial infarction	急性心筋梗塞	20 mg	.	SEVERE	YES	57	13	NO	RESOLVED
Rivaroxaban	220134002	YES	ITALY	WHITE	FEMALE	61	Anaemia	貧血	20 mg	.	MODERATE	YES	72	5	NO	RESOLVED
Rivaroxaban	220134002	YES	ITALY	WHITE	FEMALE	61	Renal failure acute	急性腎不全	20 mg	.	SEVERE	YES	93	18	NO	DEATH
Rivaroxaban	220134004	YES	ITALY	WHITE	MALE	71	Hepatic enzyme increased	肝酵素上昇	20 mg	.	MODERATE	YES	27	22	NO	RESOLVED
Rivaroxaban	220134004	YES	ITALY	WHITE	MALE	71	Blood bilirubin increased	血中ビリルビン増加	20 mg	.	MODERATE	YES	27	22	NO	RESOLVED
Rivaroxaban	220134004	YES	ITALY	WHITE	MALE	71	Death	死亡	20 mg	F	SEVERE	NO	58	1	NO	DEATH
Enoxaparin/VKA	220134008	YES	ITALY	WHITE	FEMALE	54	Haematuria	血尿			MILD	YES	7	3	YES	RESOLVED
Enoxaparin/VKA	220134015	YES	ITALY	WHITE	MALE	36	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MODERATE	YES	18	46	YES	RESOLVED
Enoxaparin/VKA	220134016	YES	ITALY	WHITE	MALE	65	Haematuria	血尿			MILD	YES	70	2	YES	RESOLVED
Rivaroxaban	220134022	YES	ITALY	WHITE	FEMALE	75	Gastritis	胃炎	20 mg	.	MODERATE	YES	47	11	NO	RESOLVED
Rivaroxaban	220144014	YES	ITALY	WHITE	FEMALE	84	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	F	MILD	NO	189	21	NO	RESOLVED
Enoxaparin/VKA	220144025	YES	ITALY	WHITE	MALE	84	Anaemia	貧血			MODERATE	YES	85	58	YES	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	220144025	YES	ITALY	WHITE	MALE	84	Gastric cancer	胃癌			SEVERE	YES	88	20	NO	RESOLVED
Enoxaparin/VKA	220144033	YES	ITALY	WHITE	FEMALE	82	Joint dislocation	関節脱臼			MODERATE	YES	29	17	NO	RESOLVED
Rivaroxaban	220154010	YES	ITALY	WHITE	MALE	67	Retinal detachment	網膜剥離	20 mg	.	MODERATE	YES	151	4	NO	RESOLVED
Enoxaparin/VKA	240024012	YES	SPAIN	WHITE	FEMALE	49	Mastitis	乳腺炎			SEVERE	YES	49	15	NO	RESOLVED
Enoxaparin/VKA	240024012	YES	SPAIN	WHITE	FEMALE	49	Peripheral ischaemia	末梢性虚血			SEVERE	NO	378	15	NO	RESOLVED
Enoxaparin/VKA	240024014	YES	SPAIN	WHITE	FEMALE	70	Gastroenteritis	胃腸炎			MODERATE	YES	57	6	NO	RESOLVED
Enoxaparin/VKA	240024014	YES	SPAIN	WHITE	FEMALE	70	Colitis ulcerative	潰瘍性大腸炎			SEVERE	YES	71	28	NO	IMPROVED
Enoxaparin/VKA	240024014	YES	SPAIN	WHITE	FEMALE	70	Pneumonia	肺炎			SEVERE	YES	146	8	NO	IMPROVED
Enoxaparin/VKA	240024021	YES	SPAIN	WHITE	FEMALE	73	Transient ischaemic attack	一過性脳虚血発作			MILD	YES	112	1	NO	RESOLVED
Enoxaparin/VKA	240024021	YES	SPAIN	WHITE	FEMALE	73	Confusional state	錯乱状態			MILD	YES	135	3	NO	RESOLVED
Enoxaparin/VKA	240024021	YES	SPAIN	WHITE	FEMALE	73	Hypoglycaemia	低血糖症			MILD	YES	137	2	NO	RESOLVED
Enoxaparin/VKA	240024021	YES	SPAIN	WHITE	FEMALE	73	Peripheral vascular disorder	末梢血管障害			SEVERE	YES	145	14	NO	RESOLVED
Enoxaparin/VKA	260054001	YES	CANADA	WHITE	FEMALE	69	Pneumonia	肺炎			SEVERE	YES	290	5	NO	DEATH
Enoxaparin/VKA	260054001	YES	CANADA	WHITE	FEMALE	69	Cardiac failure congestive	うっ血性心不全			SEVERE	YES	291		NO	UNCHANGED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

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Rivaroxaban	260054008	YES	CANADA	WHITE	MALE	48	Haematuria	血尿	20 mg	.	MILD	YES	33	67	YES	RESOLVED
Rivaroxaban	260054009	YES	CANADA	WHITE	FEMALE	47	Menorrhagia	月経過多	15 mg	.	SEVERE	YES	5	7	YES	RESOLVED
Rivaroxaban	260054009	YES	CANADA	WHITE	FEMALE	47	Menorrhagia	月経過多	20 mg	.	SEVERE	YES	57	16	YES	RESOLVED
Enoxaparin/VKA	260054028	YES	CANADA	WHITE	FEMALE	73	Haemarthrosis	出血性関節症			SEVERE	YES	131	42	YES	RESOLVED
Enoxaparin/VKA	260054028	YES	CANADA	WHITE	FEMALE	73	Haematoma	血腫			SEVERE	YES	131	42	YES	RESOLVED
Rivaroxaban	260054034	YES	CANADA	WHITE	MALE	44	Depression	うつ病	20 mg	.	SEVERE	YES	202	4	NO	RESOLVED
Rivaroxaban	260054034	YES	CANADA	WHITE	MALE	44	Psychotic disorder	精神病性障害	20 mg	.	SEVERE	YES	202	4	NO	RESOLVED
Rivaroxaban	260054034	YES	CANADA	WHITE	MALE	44	Depression	うつ病	20 mg	.	SEVERE	YES	311	77	NO	RESOLVED
Rivaroxaban	260054034	YES	CANADA	WHITE	MALE	44	Psychotic disorder	精神病性障害	20 mg	.	SEVERE	YES	311	77	NO	RESOLVED
Rivaroxaban	260054048	YES	CANADA	WHITE	MALE	81	Urinary tract infection	尿路感染			SEVERE	YES			NO	RESOLVED
Rivaroxaban	260054048	YES	CANADA	WHITE	MALE	81	Spinal compression fracture	脊椎圧迫骨折	20 mg	I	SEVERE	YES	102		NO	IMPROVED
Rivaroxaban	260054053	YES	CANADA	WHITE	MALE	71	Overdose	過量投与	20 mg	.	SEVERE	YES	89	26	NO	RESOLVED
Enoxaparin/VKA	260054054	YES	CANADA	WHITE	MALE	44	Pneumonia	肺炎			SEVERE	YES	206	31	NO	RESOLVED
Enoxaparin/VKA	260054054	YES	CANADA	WHITE	MALE	44	Scrotal swelling	陰嚢腫脹			SEVERE	YES	219	6	NO	RESOLVED
Enoxaparin/VKA	260054054	YES	CANADA	WHITE	MALE	44	Penile swelling	陰茎腫脹			SEVERE	YES	219	6	NO	RESOLVED
Rivaroxaban	260054058	YES	CANADA	WHITE	MALE	52	Transaminases increased	トランスアミナーゼ上昇	15 mg	.	SEVERE	YES	15	350	NO	WORSENED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	260054058	YES	CANADA	WHITE	MALE	52	Transaminases increased	トランスアミナーゼ上昇	20 mg	.	SEVERE	YES	365		NO	IMPROVED
Rivaroxaban	260054065	YES	CANADA	WHITE	FEMALE	20	Migraine	片頭痛	15 mg	.	SEVERE	YES	4	9	NO	RESOLVED
Rivaroxaban	260054069	YES	CANADA	WHITE	MALE	76	Gastrointestinal haemorrhage	胃腸出血	20 mg	.	SEVERE	YES	204	2	YES	RESOLVED
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Liver function test abnormal	肝機能検査異常			SEVERE	YES	25		NO	UNCHANGED
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Pancreatic carcinoma metastatic	転移性膵癌			SEVERE	NO	27	14	NO	WORSENED
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Upper gastrointestinal haemorrhage	上部消化管出血			SEVERE	NO	41	3	NO	RESOLVED
Enoxaparin/VKA	260054085	YES	CANADA	BLACK	FEMALE	54	Pancreatic carcinoma metastatic	転移性膵癌			SEVERE	NO	41	16	NO	DEATH
Rivaroxaban	260124016	YES	CANADA	WHITE	MALE	82	Lung carcinoma cell type unspecified recurrent	再発肺癌、細胞タイプ不明	20 mg	.	SEVERE	YES	159		NO	UNCHANGED
Rivaroxaban	260124016	YES	CANADA	WHITE	MALE	82	Gastric cancer recurrent	再発胃癌	20 mg	.	SEVERE	YES	159		NO	UNCHANGED
Rivaroxaban	260124058	YES	CANADA	WHITE	FEMALE	58	Ovarian cancer	卵巣癌	20 mg	.	SEVERE	YES	43		NO	UNCHANGED
Rivaroxaban	280034001	YES	BELGIUM	WHITE	MALE	76	Cough	咳嗽	20 mg	.	MILD	YES	62	6	NO	RESOLVED
Rivaroxaban	280034001	YES	BELGIUM	WHITE	MALE	76	Sputum retention	痰貯留	20 mg	.	MILD	YES	62	6	NO	RESOLVED
Rivaroxaban	280034001	YES	BELGIUM	WHITE	MALE	76	Device occlusion	医療機器閉塞	20 mg	.	MILD	YES	77	2	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	280034004	YES	BELGIUM	WHITE	FEMALE	82	Pneumonia	肺炎			MODERATE	YES	32	75	NO	RESOLVED
Enoxaparin/VKA	280054003	YES	BELGIUM	WHITE	MALE	53	Alcohol poisoning	アルコール中毒			SEVERE	YES	113	4	NO	RESOLVED
Enoxaparin/VKA	280064004	YES	BELGIUM	WHITE	MALE	64	Metabolic disorder	代謝障害			SEVERE	YES	142	26	NO	RESOLVED
Enoxaparin/VKA	280064004	YES	BELGIUM	WHITE	MALE	64	Atrial fibrillation	心房細動			MODERATE	YES	142	2	NO	RESOLVED
Enoxaparin/VKA	280064004	YES	BELGIUM	WHITE	MALE	64	Anaemia	貧血			MODERATE	YES	143		YES	UNCHANGED
Enoxaparin/VKA	280074017	YES	BELGIUM	WHITE	MALE	72	Non-small cell lung cancer	非小細胞肺癌			SEVERE	NO	30		NO	UNCHANGED
Enoxaparin/VKA	280074017	YES	BELGIUM	WHITE	MALE	72	Metastases to central nervous system	中枢神経系転移			MODERATE	NO	45		NO	UNCHANGED
Rivaroxaban	280084001	YES	BELGIUM	WHITE	FEMALE	76	Lymphoma	リンパ腫	20 mg	.	SEVERE	YES	66		NO	UNCHANGED
Enoxaparin/VKA	280084008	YES	BELGIUM	WHITE	FEMALE	57	Liver transplant rejection	肝移植拒絶反応			MODERATE	YES	66	5	NO	RESOLVED
Enoxaparin/VKA	280084008	YES	BELGIUM	WHITE	FEMALE	57	Liver transplant rejection	肝移植拒絶反応			MODERATE	YES	165	10	NO	RESOLVED
Enoxaparin/VKA	280084008	YES	BELGIUM	WHITE	FEMALE	57	Pancreatic cyst	膵嚢胞			MODERATE	NO	196	2	NO	RESOLVED
Enoxaparin/VKA	280084008	YES	BELGIUM	WHITE	FEMALE	57	Hernial eventration	内臓ヘルニア			MODERATE	NO	208	2	NO	RESOLVED
Enoxaparin/VKA	280114008	YES	BELGIUM	WHITE	MALE	64	Cholecystitis acute	急性胆嚢炎			MODERATE	YES	66	12	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

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Enoxaparin/VKA	280134004	YES	BELGIUM	WHITE	MALE	60	Liver function test abnormal	肝機能検査異常			MODERATE	YES	61	32	NO	RESOLVED
Enoxaparin/VKA	280134004	YES	BELGIUM	WHITE	MALE	60	Gastritis	胃炎			MODERATE	YES	61	5	NO	RESOLVED
Enoxaparin/VKA	280134004	YES	BELGIUM	WHITE	MALE	60	Oesophagitis	食道炎			MODERATE	YES	61	5	NO	RESOLVED
Enoxaparin/VKA	280134004	YES	BELGIUM	WHITE	MALE	60	Hepatic steatosis	脂肪肝			MILD	YES	61		NO	IMPROVED
Enoxaparin/VKA	280134004	YES	BELGIUM	WHITE	MALE	60	Malaise	倦怠感			SEVERE	YES	61	5	NO	RESOLVED
Enoxaparin/VKA	280134004	YES	BELGIUM	WHITE	MALE	60	Myocardial ischaemia	心筋虚血			MILD	YES	61	3	NO	RESOLVED
Enoxaparin/VKA	280134004	YES	BELGIUM	WHITE	MALE	60	Liver function test abnormal	肝機能検査異常			SEVERE	NO	183	15	NO	RESOLVED
Enoxaparin/VKA	280134004	YES	BELGIUM	WHITE	MALE	60	Pancreatitis	膵炎			MODERATE	NO	183	4	NO	RESOLVED
Enoxaparin/VKA	280134004	YES	BELGIUM	WHITE	MALE	60	Malaise	倦怠感			SEVERE	NO	183	4	NO	RESOLVED
Enoxaparin/VKA	280134004	YES	BELGIUM	WHITE	MALE	60	Vomiting	嘔吐			MILD	NO	183	2	NO	RESOLVED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Lymphadenopathy mediastinal	縦隔リンパ節腫脹			SEVERE	YES	2	22	NO	WORSENED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Metastatic squamous cell carcinoma	転移性扁平上皮癌			SEVERE	YES	23		NO	IMPROVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

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Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪			SEVERE	YES	86	27	NO	IMPROVED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Radiation pneumonitis	放射線性肺臓炎			SEVERE	NO	147		NO	UNCHANGED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Lung infection	肺感染			SEVERE	NO	147	24	NO	DEATH
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Thrombocytopenia	血小板減少症			SEVERE	NO	151		NO	UNCHANGED
Enoxaparin/VKA	280134010	YES	BELGIUM	WHITE	MALE	70	Sepsis	敗血症			SEVERE	NO	155		NO	UNCHANGED
Rivaroxaban	300064006	YES	NETHERLANDS	WHITE	FEMALE	83	Microcytic anaemia	小球性貧血	20 mg	.	SEVERE	YES	182	21	YES	RESOLVED
Rivaroxaban	300064024	YES	NETHERLANDS	WHITE	FEMALE	67	Arthralgia	関節痛	20 mg	.	SEVERE	YES	89		NO	UNCHANGED
Rivaroxaban	300064024	YES	NETHERLANDS	WHITE	FEMALE	67	Death	死亡	20 mg	F	SEVERE	NO	108	1	NO	DEATH
Enoxaparin/VKA	300064034	YES	NETHERLANDS	WHITE	FEMALE	60	Muscle haemorrhage	筋肉内出血			SEVERE	YES	144	36	YES	RESOLVED
Enoxaparin/VKA	300064038	YES	NETHERLANDS	WHITE	FEMALE	35	Abdominal pain	腹痛			SEVERE	NO	22		NO	UNCHANGED
Enoxaparin/VKA	300064042	YES	NETHERLANDS	WHITE	FEMALE	64	Gastroenteritis	胃腸炎			SEVERE	YES	102	2	NO	RESOLVED
Enoxaparin/VKA	300064066	YES	NETHERLANDS	WHITE	FEMALE	41	Urinary tract infection	尿路感染			SEVERE	YES	10	19	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

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Rivaroxaban	300074005	YES	NETHERLANDS	WHITE	FEMALE	51	Wound dehiscence	創し開	15 mg	.	MILD	YES	1	10	NO	RESOLVED
Rivaroxaban	300074005	YES	NETHERLANDS	WHITE	FEMALE	51	Ascites	腹水	15 mg	.	MILD	YES	1	10	NO	RESOLVED
Rivaroxaban	300074005	YES	NETHERLANDS	WHITE	FEMALE	51	Wound dehiscence	創し開	15 mg	.	MODERATE	YES	11	16	NO	RESOLVED
Rivaroxaban	300074005	YES	NETHERLANDS	WHITE	FEMALE	51	Ascites	腹水	15 mg	.	MODERATE	YES	11	16	NO	RESOLVED
Rivaroxaban	300074018	YES	NETHERLANDS	WHITE	MALE	56	Abdominal wall cyst	腹壁嚢胞	20 mg	I	SEVERE	YES	62	4	NO	RESOLVED
Rivaroxaban	300074037	YES	NETHERLANDS	WHITE	FEMALE	62	Wound abscess	創部膿瘍	20 mg	.	SEVERE	YES	22	10	NO	RESOLVED
Enoxaparin/VKA	300074043	YES	NETHERLANDS	WHITE	FEMALE	28	Abortion induced	人工流産			MILD	YES	155	1	NO	RESOLVED
Enoxaparin/VKA	300074054	YES	NETHERLANDS	WHITE	FEMALE	53	Uterine polypectomy	子宮ポリープ切除			MILD	YES	164	3	NO	RESOLVED
Enoxaparin/VKA	300074083	YES	NETHERLANDS	WHITE	FEMALE	62	Lung adenocarcinoma	肺腺癌			SEVERE	YES	38		NO	UNCHANGED
Enoxaparin/VKA	300074089	YES	NETHERLANDS	WHITE	MALE	74	Pneumonia	肺炎			SEVERE	YES	178	7	NO	RESOLVED
Rivaroxaban	300074094	YES	NETHERLANDS	WHITE	MALE	60	Prostate cancer	前立腺癌	20 mg	F	SEVERE	YES	181		NO	UNCHANGED
Enoxaparin/VKA	300074100	YES	NETHERLANDS	WHITE	MALE	81	Lower respiratory tract infection	下気道感染			MODERATE	YES	6	19	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

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Enoxaparin/VKA	300074100	YES	NETHERLANDS	WHITE	MALE	81	Respiratory tract infection	気道感染			SEVERE	YES	29	3	NO	DEATH
Rivaroxaban	300074109	YES	NETHERLANDS	WHITE	FEMALE	50	Rectal haemorrhage	直腸出血	15 mg	.	SEVERE	YES	1	2	YES	RESOLVED
Rivaroxaban	300074111	YES	NETHERLANDS	WHITE	FEMALE	65	Pancreatic carcinoma	膵癌	15 mg	.	SEVERE	YES	20	4	NO	DEATH
Rivaroxaban	300074117	YES	NETHERLANDS	WHITE	MALE	61	Cerebral haemorrhage	脳出血	20 mg	.	SEVERE	YES	163	10	YES	RESOLVED
Enoxaparin/VKA	300074126	YES	NETHERLANDS	WHITE	FEMALE	79	Large cell carcinoma of the respiratory tract stage unspecified	呼吸器大細胞癌、病期不明			SEVERE	YES	20	36	NO	DEATH
Enoxaparin/VKA	300074137	YES	NETHERLANDS	WHITE	MALE	60	Colon cancer	結腸癌			SEVERE	YES	65		NO	UNCHANGED
Rivaroxaban	300074142	YES	NETHERLANDS	WHITE	FEMALE	78	Epilepsy	てんかん			SEVERE	YES	55	10	NO	RESOLVED
Rivaroxaban	300074142	YES	NETHERLANDS	WHITE	FEMALE	78	Anaemia	貧血			SEVERE	NO	100	23	YES	RESOLVED
Rivaroxaban	300074142	YES	NETHERLANDS	WHITE	FEMALE	78	Ischaemic stroke	虚血性脳卒中			MODERATE	NO	131	8	NO	RESOLVED
Rivaroxaban	300074156	YES	NETHERLANDS	WHITE	FEMALE	54	Post procedural haemorrhage	処置後出血	20 mg	.	SEVERE	YES	161	5	YES	RESOLVED
Enoxaparin/VKA	300074161	YES	NETHERLANDS	WHITE	MALE	52	Alanine aminotransferase increased	アラニン・アミノトランスフェラ			MILD	YES	10	20	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
								ーゼ増加								
Enoxaparin/VKA	300074172	YES	NETHERLANDS	WHITE	FEMALE	61	Cardiac failure	心不全			MODERATE	YES	53	11	NO	IMPROVED
Rivaroxaban	300074191	YES	NETHERLANDS	WHITE	MALE	58	Constipation	便秘	15 mg	.	MILD	YES	4	6	NO	RESOLVED
Enoxaparin/VKA	300074203	YES	NETHERLANDS	WHITE	FEMALE	91	Cervix carcinoma	子宮頚部癌			SEVERE	YES	10	11	NO	DEATH
Enoxaparin/VKA	300074223	YES	NETHERLANDS	WHITE	FEMALE	30	Cerebral toxoplasmosis	脳トキソプラズマ症			SEVERE	YES	17	132	NO	DEATH
Enoxaparin/VKA	300074227	YES	NETHERLANDS	WHITE	FEMALE	77	Crohn's disease	クローン病			MILD	YES	16	9	NO	RESOLVED
Rivaroxaban	300074231	YES	NETHERLANDS	WHITE	MALE	85	Lymphoma	リンパ腫	20 mg	I	SEVERE	YES	158		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	300074235	YES	NETHERLANDS	WHITE	MALE	66	Scar	瘢痕			MODERATE	YES	58	3	NO	RESOLVED
Enoxaparin/VKA	300074235	YES	NETHERLANDS	WHITE	MALE	66	Scar	瘢痕			MODERATE	YES	156	3	NO	RESOLVED
Rivaroxaban	300074241	YES	NETHERLANDS	WHITE	MALE	29	Dyspnoea	呼吸困難	20 mg	F	SEVERE	YES	74	3	NO	RESOLVED
Rivaroxaban	300074257	YES	NETHERLANDS	WHITE	FEMALE	78	Non-Hodgkin's lymphoma	非ホジキンリンパ腫	15 mg	F	SEVERE	YES	7		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	300084043	YES	NETHERLANDS	WHITE	MALE	47	Hepatic enzyme increased	肝酵素上昇			MILD	YES	14	87	YES	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	300094006	YES	NETHERLANDS	WHITE	MALE	28	Hepatic enzyme increased	肝酵素上昇			MODERATE	YES	16	30	YES	RESOLVED
Rivaroxaban	300094033	YES	NETHERLANDS	WHITE	FEMALE	72	Myalgia	筋肉痛	15 mg	.	MODERATE	YES	6	3	NO	IMPROVED
Rivaroxaban	300104013	YES	NETHERLANDS	WHITE	MALE	56	Febrile neutropenia	発熱性好中球減少症	15 mg	.	MODERATE	YES	10	5	NO	RESOLVED
Rivaroxaban	300104013	YES	NETHERLANDS	WHITE	MALE	56	Prostatitis	前立腺炎	15 mg	.	SEVERE	YES	17	8	NO	RESOLVED
Enoxaparin/VKA	300104019	YES	NETHERLANDS	WHITE	FEMALE	51	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患			SEVERE	YES	39	8	NO	RESOLVED
Enoxaparin/VKA	300104019	YES	NETHERLANDS	WHITE	FEMALE	51	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患			SEVERE	YES	111	10	NO	RESOLVED
Enoxaparin/VKA	340014010	YES	SWEDEN	WHITE	FEMALE	77	Breast cancer	乳癌			SEVERE	YES	69		NO	UNCHANGED
Rivaroxaban	340024007	YES	SWEDEN	WHITE	MALE	65	Vitreous detachment	硝子体剥離	20 mg	.	MODERATE	YES	43	14	YES	RESOLVED
Rivaroxaban	340024007	YES	SWEDEN	WHITE	MALE	65	Eye haemorrhage	眼出血	20 mg	.	MODERATE	YES	43	14	YES	RESOLVED
Rivaroxaban	350024002	YES	DENMARK	WHITE	FEMALE	70	Osteoporosis	骨粗鬆症	20 mg	.	MILD	YES	44	2	NO	RESOLVED
Rivaroxaban	350024003	YES	DENMARK	WHITE	MALE	59	Melaena	メレナ	15 mg	.	MODERATE	YES	8	4	YES	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	350024003	YES	DENMARK	WHITE	MALE	59	Bradycardia	徐脈	15 mg	F	MODERATE	NO	14	5	NO	RESOLVED
Enoxaparin/VKA	350024004	YES	DENMARK	WHITE	FEMALE	49	Foot deformity	足変形			MODERATE	YES	329		NO	IMPROVED
Rivaroxaban	350024011	YES	DENMARK	WHITE	MALE	57	Spontaneous haematoma	特発性血腫	15 mg	.	SEVERE	YES	3	6	YES	RESOLVED
Rivaroxaban	350044002	YES	DENMARK	WHITE	MALE	72	Haematoma	血腫	20 mg	.	MODERATE	YES	25	67	YES	RESOLVED
Rivaroxaban	360014005	YES	NORWAY	WHITE	FEMALE	35	Multiple sclerosis	多発性硬化症	20 mg	.	MODERATE	YES	191		NO	IMPROVED
Rivaroxaban	360014011	YES	NORWAY	WHITE	MALE	36	Tachycardia	頻脈	15 mg	.	MILD	YES	6	2	NO	RESOLVED
Rivaroxaban	360014013	YES	NORWAY	WHITE	FEMALE	26	Depression	うつ病	15 mg	.	MODERATE	YES	8		NO	IMPROVED
Rivaroxaban	360014013	YES	NORWAY	WHITE	FEMALE	26	Suicide attempt	自殺企図	20 mg	.	SEVERE	YES	38	13	NO	RESOLVED
Rivaroxaban	360014013	YES	NORWAY	WHITE	FEMALE	26	Drug toxicity	薬物毒性	20 mg	.	SEVERE	YES	62	2	YES	RESOLVED
Rivaroxaban	360044006	YES	NORWAY	WHITE	MALE	63	Malignant melanoma	悪性黒色腫	20 mg	I	SEVERE	YES	146	23	NO	RESOLVED
Enoxaparin/VKA	360044008	YES	NORWAY	WHITE	FEMALE	81	Nephrolithiasis	腎結石症			SEVERE	YES	36	8	NO	RESOLVED
Rivaroxaban	360054014	YES	NORWAY	WHITE	MALE	75	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	F	MILD	NO	107	4	NO	RESOLVED
Rivaroxaban	370014011	YES	SOUTH AFRICA	WHITE	FEMALE	70	Headache	頭痛	20 mg	.	SEVERE	YES	120	2	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370024006	YES	SOUTH AFRICA	WHITE	MALE	63	Anaemia	貧血			MODERATE	YES	30	222	NO	RESOLVED
Rivaroxaban	370024010	YES	SOUTH AFRICA	BLACK	FEMALE	18	Menorrhagia	月経過多	15 mg	.	MODERATE	YES	7	8	YES	RESOLVED
Enoxaparin/VKA	370024012	YES	SOUTH AFRICA	BLACK	FEMALE	66	Intestinal haemorrhage	腸出血			MODERATE	YES	10	15	YES	RESOLVED
Enoxaparin/VKA	370024012	YES	SOUTH AFRICA	BLACK	FEMALE	66	Radius fracture	橈骨骨折			MODERATE	YES	316	6	NO	RESOLVED
Enoxaparin/VKA	370024012	YES	SOUTH AFRICA	BLACK	FEMALE	66	Ulna fracture	尺骨骨折			MODERATE	YES	316	6	NO	RESOLVED
Rivaroxaban	370024017	YES	SOUTH AFRICA	WHITE	MALE	28	Arterial thrombosis limb	四肢動脈血栓症	15 mg	.	SEVERE	YES	2	9	NO	RESOLVED
Enoxaparin/VKA	370024018	YES	SOUTH AFRICA	BLACK	MALE	38	Haematemesis	吐血			MODERATE	YES	2	14	NO	RESOLVED
Rivaroxaban	370024021	YES	SOUTH AFRICA	BLACK	FEMALE	53	Cervix carcinoma	子宮頚部癌	20 mg	F	SEVERE	YES	24	1	NO	DEATH
Enoxaparin/VKA	370044001	YES	SOUTH AFRICA	WHITE	FEMALE	80	Lung neoplasm malignant	肺の悪性新生物			MODERATE	YES	8	41	NO	WORSENED
Enoxaparin/VKA	370044001	YES	SOUTH AFRICA	WHITE	FEMALE	80	Lung neoplasm malignant	肺の悪性新生物			SEVERE	YES	49	6	NO	DEATH
Enoxaparin/VKA	370054019	YES	SOUTH AFRICA	WHITE	MALE	75	Angina unstable	不安定狭心症			MILD	YES	60	36	NO	RESOLVED
Enoxaparin/VKA	370054026	YES	SOUTH AFRICA	BLACK	MALE	40	Anal abscess	肛門膿瘍			MILD	YES	123	4	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370054037	YES	SOUTH AFRICA	WHITE	MALE	39	Postoperative wound infection	術後創感染			MODERATE	YES	84	102	NO	RESOLVED
Enoxaparin/VKA	370054037	YES	SOUTH AFRICA	WHITE	MALE	39	Haemorrhoidal haemorrhage	痔出血			MODERATE	YES	182	4	NO	RESOLVED
Rivaroxaban	370054040	YES	SOUTH AFRICA	BLACK	FEMALE	44	Menorrhagia	月経過多	20 mg	.	MODERATE	YES	105	2	NO	RESOLVED
Enoxaparin/VKA	370054044	YES	SOUTH AFRICA	WHITE	MALE	72	Rectal haemorrhage	直腸出血			SEVERE	YES	53	12	NO	RESOLVED
Enoxaparin/VKA	370054044	YES	SOUTH AFRICA	WHITE	MALE	72	Duodenal ulcer	十二指腸潰瘍			MODERATE	YES	57	34	NO	RESOLVED
Enoxaparin/VKA	370054071	YES	SOUTH AFRICA	WHITE	MALE	66	Respiratory tract infection	気道感染			MILD	YES	35	5	NO	RESOLVED
Enoxaparin/VKA	370054077	YES	SOUTH AFRICA	BLACK	MALE	32	Lobar pneumonia	大葉性肺炎			MILD	YES	39	7	NO	RESOLVED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Abdominal pain	腹痛	20 mg	.	MILD	YES	37	20	NO	RESOLVED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Enterocutaneous fistula	腸管皮膚瘻	20 mg	.	SEVERE	YES	75		NO	UNCHANGED
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Sepsis	敗血症	20 mg	.	SEVERE	YES	110	3	NO	DEATH
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Multi-organ failure	多臓器不全	20 mg	.	SEVERE	YES	111	2	NO	DEATH
Rivaroxaban	370054082	YES	SOUTH AFRICA	WHITE	FEMALE	55	Anuria	無尿	20 mg	.	SEVERE	YES	111	1	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370064004	YES	SOUTH AFRICA	BLACK	MALE	68	Vitreous haemorrhage	硝子体出血			MODERATE	YES	50	134	NO	RESOLVED
Enoxaparin/VKA	370064007	YES	SOUTH AFRICA	WHITE	FEMALE	74	Hepatic enzyme increased	肝酵素上昇			MILD	YES	31	37	NO	RESOLVED
Enoxaparin/VKA	370064016	YES	SOUTH AFRICA	BLACK	FEMALE	25	Respiratory distress	呼吸窮迫			MODERATE	YES	5		NO	RESOLVED
Enoxaparin/VKA	370074003	YES	SOUTH AFRICA	WHITE	MALE	54	Therapeutic agent toxicity	治療薬毒性			MILD	YES	10	3	YES	RESOLVED
Enoxaparin/VKA	370074003	YES	SOUTH AFRICA	WHITE	MALE	54	Haematuria	血尿			MILD	YES	12	6	YES	RESOLVED
Rivaroxaban	370084002	YES	SOUTH AFRICA	WHITE	FEMALE	73	Intestinal obstruction	腸閉塞	20 mg	.	SEVERE	YES	39	4	NO	RESOLVED
Enoxaparin/VKA	370104001	YES	SOUTH AFRICA	WHITE	FEMALE	81	Myocardial infarction	心筋梗塞			SEVERE	YES	43	1	NO	DEATH
Enoxaparin/VKA	370154002	YES	SOUTH AFRICA	BLACK	MALE	37	Aortic valve disease	大動脈弁疾患			MODERATE	YES	202		NO	IMPROVED
Enoxaparin/VKA	370154002	YES	SOUTH AFRICA	BLACK	MALE	37	Cardiac failure congestive	うっ血性心不全			MODERATE	YES	202	14	NO	IMPROVED
Enoxaparin/VKA	370154002	YES	SOUTH AFRICA	BLACK	MALE	37	Cardiac failure congestive	うっ血性心不全			MODERATE	YES	242		NO	IMPROVED
Enoxaparin/VKA	370154002	YES	SOUTH AFRICA	BLACK	MALE	37	Aortic valve disease	大動脈弁疾患			SEVERE	NO	313	11	NO	IMPROVED
Enoxaparin/VKA	370154002	YES	SOUTH AFRICA	BLACK	MALE	37	Cardiac failure congestive	うっ血性心不全			SEVERE	NO	313	11	NO	IMPROVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	370154011	YES	SOUTH AFRICA	BLACK	MALE	38	Right ventricular failure	右室不全			SEVERE	YES	132	22	NO	RESOLVED
Rivaroxaban	370154011	YES	SOUTH AFRICA	BLACK	MALE	38	Right ventricular failure	右室不全			SEVERE	YES	207		NO	IMPROVED
Enoxaparin/VKA	380024003	YES	CZECH REPUBLIC	WHITE	MALE	57	Colon cancer	結腸癌			SEVERE	YES	150	210	NO	RESOLVED
Enoxaparin/VKA	380044002	YES	CZECH REPUBLIC	WHITE	MALE	69	Femoral neck fracture	大腿骨頚部骨折			MODERATE	YES	72	126	NO	RESOLVED
Enoxaparin/VKA	380044002	YES	CZECH REPUBLIC	WHITE	MALE	69	Angina unstable	不安定狭心症			MILD	YES	124	1	NO	RESOLVED
Enoxaparin/VKA	380044010	YES	CZECH REPUBLIC	WHITE	FEMALE	72	Contusion	挫傷			MILD	YES	111	4	NO	RESOLVED
Rivaroxaban	380044022	YES	CZECH REPUBLIC	WHITE	FEMALE	52	Liver function test abnormal	肝機能検査異常	15 mg	.	MODERATE	YES	3	67	YES	WORSENED
Rivaroxaban	380044022	YES	CZECH REPUBLIC	WHITE	FEMALE	52	Liver function test abnormal	肝機能検査異常	20 mg	.	SEVERE	YES	69	18	YES	RESOLVED
Rivaroxaban	380044036	YES	CZECH REPUBLIC	WHITE	FEMALE	47	Anaemia	貧血	20 mg	.	MODERATE	YES	182	3	YES	RESOLVED
Rivaroxaban	380044041	YES	CZECH REPUBLIC	WHITE	MALE	48	Peripheral ischaemia	末梢性虚血	20 mg	I	SEVERE	YES	256	14	NO	RESOLVED
Rivaroxaban	380044058	YES	CZECH REPUBLIC	WHITE	MALE	65	Bronchopneumonia	気管支肺炎	20 mg	.	MODERATE	YES	68	27	NO	RESOLVED
Rivaroxaban	380044058	YES	CZECH REPUBLIC	WHITE	MALE	65	Liver function test abnormal	肝機能検査異常	20 mg	.	MODERATE	YES	68	24	YES	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

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Enoxaparin/VKA	380044060	YES	CZECH REPUBLIC	WHITE	FEMALE	52	Hydronephrosis	水腎症			MODERATE	YES	287	15	NO	RESOLVED
Enoxaparin/VKA	380044060	YES	CZECH REPUBLIC	WHITE	FEMALE	52	Cervix carcinoma	子宮頚部癌			SEVERE	YES	313		NO	UNCHANGED
Enoxaparin/VKA	380044060	YES	CZECH REPUBLIC	WHITE	FEMALE	52	Renal failure acute	急性腎不全			MODERATE	YES	342		NO	IMPROVED
Enoxaparin/VKA	380044074	YES	CZECH REPUBLIC	WHITE	FEMALE	38	Abortion	流産			MILD	NO	187	1	NO	RESOLVED
Enoxaparin/VKA	380044090	YES	CZECH REPUBLIC	WHITE	MALE	66	Prostate cancer metastatic	転移性前立腺癌			MODERATE	YES	109	99	NO	RESOLVED
Enoxaparin/VKA	380044108	YES	CZECH REPUBLIC	WHITE	MALE	26	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MODERATE	YES	7	31	YES	RESOLVED
Enoxaparin/VKA	380054006	YES	CZECH REPUBLIC	WHITE	FEMALE	70	Biliary colic	胆道仙痛			MODERATE	YES	181	8	NO	RESOLVED
Rivaroxaban	380054015	YES	CZECH REPUBLIC	WHITE	MALE	65	Large intestine carcinoma	大腸癌	20 mg	F	SEVERE	YES	43		NO	UNCHANGED
Enoxaparin/VKA	380064002	YES	CZECH REPUBLIC	WHITE	MALE	68	International normalised ratio increased	ＩＮＲ増加			MILD	YES	16	3	YES	RESOLVED
Enoxaparin/VKA	380064002	YES	CZECH REPUBLIC	WHITE	MALE	68	International normalised ratio increased	ＩＮＲ増加			MILD	YES	93	2	YES	RESOLVED
Enoxaparin/VKA	380064005	YES	CZECH REPUBLIC	WHITE	FEMALE	47	Crohn's disease	クローン病			MODERATE	YES	11	15	NO	IMPROVED

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Enoxaparin/VKA	380064005	YES	CZECH REPUBLIC	WHITE	FEMALE	47	Crohn's disease	クローン病			MODERATE	NO	78	120	NO	IMPROVED
Enoxaparin/VKA	380064005	YES	CZECH REPUBLIC	WHITE	FEMALE	47	Abdominal abscess	腹部膿瘍			MODERATE	NO	98	26	NO	RESOLVED
Enoxaparin/VKA	380064005	YES	CZECH REPUBLIC	WHITE	FEMALE	47	Pneumothorax traumatic	外傷性気胸			MODERATE	NO	155	7	NO	RESOLVED
Rivaroxaban	380064017	YES	CZECH REPUBLIC	WHITE	MALE	44	Urinary tract infection	尿路感染	20 mg	.	MODERATE	YES	34	6	NO	RESOLVED
Rivaroxaban	380064019	YES	CZECH REPUBLIC	WHITE	MALE	37	Haematuria	血尿	20 mg	F	MODERATE	NO	370	3	NO	RESOLVED
Rivaroxaban	380064020	YES	CZECH REPUBLIC	WHITE	MALE	43	Transaminases increased	トランスアミナーゼ上昇	20 mg	.	MODERATE	YES	215	24	YES	RESOLVED
Rivaroxaban	380064020	YES	CZECH REPUBLIC	WHITE	MALE	43	Grand mal convulsion	大発作痙攣	20 mg	F	MODERATE	NO	234	9	NO	RESOLVED
Enoxaparin/VKA	380064022	YES	CZECH REPUBLIC	WHITE	MALE	69	Jugular vein thrombosis	頚静脈血栓症			MODERATE	YES	14	16	NO	RESOLVED
Enoxaparin/VKA	380064022	YES	CZECH REPUBLIC	WHITE	MALE	69	Lung neoplasm	肺新生物			SEVERE	YES	55	24	NO	IMPROVED
Enoxaparin/VKA	380064023	YES	CZECH REPUBLIC	WHITE	FEMALE	74	Ovarian cancer	卵巣癌			MODERATE	YES	5	177	NO	RESOLVED
Enoxaparin/VKA	380064023	YES	CZECH REPUBLIC	WHITE	FEMALE	74	Incision site infection	切開部位感染			MODERATE	YES	165	58	NO	RESOLVED
Enoxaparin/VKA	380064025	YES	CZECH REPUBLIC	WHITE	MALE	61	Aortic aneurysm	大動脈瘤			MODERATE	YES	158	13	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

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Rivaroxaban	380064028	YES	CZECH REPUBLIC	WHITE	FEMALE	82	Cerebral arteriosclerosis	脳動脈硬化症	15 mg	.	MODERATE	YES	14	12	NO	IMPROVED
Rivaroxaban	380064028	YES	CZECH REPUBLIC	WHITE	FEMALE	82	Hepatic cancer metastatic	転移性肝癌	15 mg	F	SEVERE	YES	21	13	NO	DEATH
Enoxaparin/VKA	380064034	YES	CZECH REPUBLIC	WHITE	MALE	69	Appendicitis	虫垂炎			MODERATE	YES	49	11	NO	RESOLVED
Enoxaparin/VKA	380064035	YES	CZECH REPUBLIC	WHITE	MALE	71	Prostate cancer	前立腺癌			MODERATE	YES	131	8	NO	RESOLVED
Rivaroxaban	380074015	YES	CZECH REPUBLIC	WHITE	MALE	70	Pelvic neoplasm	骨盤新生物	20 mg	.	SEVERE	YES	45		NO	UNCHANGED
Enoxaparin/VKA	380074018	YES	CZECH REPUBLIC	WHITE	FEMALE	84	Sudden death	突然死			SEVERE	YES	103	1	NO	DEATH
Enoxaparin/VKA	380074025	YES	CZECH REPUBLIC	WHITE	FEMALE	54	Epistaxis	鼻出血			SEVERE	YES	122	7	YES	RESOLVED
Enoxaparin/VKA	380074025	YES	CZECH REPUBLIC	WHITE	FEMALE	54	Ear haemorrhage	耳出血			SEVERE	YES	122	7	YES	RESOLVED
Enoxaparin/VKA	380074035	YES	CZECH REPUBLIC	WHITE	MALE	66	Colon cancer	結腸癌			SEVERE	YES	130	227	NO	RESOLVED
Enoxaparin/VKA	380074035	YES	CZECH REPUBLIC	WHITE	MALE	66	Metastases to liver	肝転移			SEVERE	YES	132	281	NO	RESOLVED
Enoxaparin/VKA	380084002	YES	CZECH REPUBLIC	WHITE	MALE	61	Ventricular tachycardia	心室性頻脈			MILD	YES	282	3	NO	RESOLVED
Rivaroxaban	380094016	YES	CZECH REPUBLIC	WHITE	MALE	73	Cardiac failure	心不全	20 mg	.	SEVERE	YES	32	4	NO	DEATH

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	380094038	YES	CZECH REPUBLIC	WHITE	MALE	73	Bronchopneumonia	気管支肺炎	20 mg	.	SEVERE	YES	311	4	NO	DEATH
Rivaroxaban	380094053	YES	CZECH REPUBLIC	WHITE	MALE	74	Rectal cancer	直腸癌	15 mg	I	MODERATE	YES	7	31	NO	RESOLVED
Rivaroxaban	390014002	YES	ISRAEL	WHITE	MALE	61	Contusion	挫傷	15 mg	.	MILD	YES	11	2	NO	RESOLVED
Rivaroxaban	390014002	YES	ISRAEL	WHITE	MALE	61	Skin laceration	皮膚裂傷	15 mg	.	MILD	YES	11	2	NO	RESOLVED
Enoxaparin/VKA	390014004	YES	ISRAEL	WHITE	MALE	35	Dyspnoea	呼吸困難			MILD	YES	13	3	NO	RESOLVED
Enoxaparin/VKA	390014004	YES	ISRAEL	WHITE	MALE	35	Vertigo	回転性めまい			MILD	YES	13	3	NO	RESOLVED
Enoxaparin/VKA	390014004	YES	ISRAEL	WHITE	MALE	35	Dizziness	浮動性めまい			MILD	YES	61	4	NO	RESOLVED
Enoxaparin/VKA	390014004	YES	ISRAEL	WHITE	MALE	35	Headache	頭痛			MILD	YES	61	4	NO	RESOLVED
Enoxaparin/VKA	390014021	YES	ISRAEL	WHITE	FEMALE	76	Pulmonary oedema	肺水腫			MODERATE	YES	129	5	NO	RESOLVED
Enoxaparin/VKA	390014021	YES	ISRAEL	WHITE	FEMALE	76	Ischaemic stroke	虚血性脳卒中			SEVERE	NO	201	3	NO	DEATH
Enoxaparin/VKA	390014025	YES	ISRAEL	WHITE	MALE	75	Dyspnoea	呼吸困難			MODERATE	YES	134	11	NO	WORSENED
Enoxaparin/VKA	390014025	YES	ISRAEL	WHITE	MALE	75	Metastases to lung	肺転移			SEVERE	NO	150	5	NO	DEATH
Enoxaparin/VKA	390014025	YES	ISRAEL	WHITE	MALE	75	Metastases to liver	肝転移			SEVERE	NO	150	5	NO	DEATH
Enoxaparin/VKA	390014026	YES	ISRAEL	WHITE	FEMALE	74	Skin laceration	皮膚裂傷			MILD	YES	98	2	NO	RESOLVED
Enoxaparin/VKA	390024001	YES	ISRAEL	WHITE	FEMALE	76	Ischaemic stroke	虚血性脳卒中			SEVERE	YES	11	4	NO	IMPROVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	390024003	YES	ISRAEL	WHITE	FEMALE	48	Lymphoedema	リンパ浮腫	20 mg	.	MODERATE	YES	24	3	NO	RESOLVED
Rivaroxaban	390024014	YES	ISRAEL	WHITE	MALE	72	Acute coronary syndrome	急性冠動脈症候群	15 mg	I	MODERATE	YES	17	8	NO	RESOLVED
Rivaroxaban	390034008	YES	ISRAEL	WHITE	MALE	72	Gastric cancer	胃癌	15 mg	F	SEVERE	YES	6		NO	IMPROVED
Rivaroxaban	390034008	YES	ISRAEL	WHITE	MALE	72	Gastrointestinal disorder postoperative	術後胃腸障害	15 mg	F	SEVERE	NO	31	23	NO	RESOLVED
Enoxaparin/VKA	390034009	YES	ISRAEL	WHITE	FEMALE	58	Hepatic neoplasm malignant	肝の悪性新生物			SEVERE	YES	7	46	NO	DEATH
Enoxaparin/VKA	390034011	YES	ISRAEL	WHITE	FEMALE	78	Endocarditis staphylococcal	ブドウ球菌性心内膜炎			MODERATE	YES	4	42	NO	RESOLVED
Enoxaparin/VKA	390034015	YES	ISRAEL	WHITE	MALE	60	Medical device complication	医療機器合併症			MILD	YES	55	3	NO	RESOLVED
Rivaroxaban	390034016	YES	ISRAEL	WHITE	MALE	53	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	20 mg	.	MODERATE	YES	154	139	YES	RESOLVED
Rivaroxaban	390034025	YES	ISRAEL	WHITE	FEMALE	71	Parkinson's disease	パーキンソン病	20 mg	.	SEVERE	YES	287		NO	UNCHANGED
Rivaroxaban	390044001	YES	ISRAEL	WHITE	FEMALE	79	Sudden cardiac death	心突然死	20 mg	.	SEVERE	YES	44	1	NO	DEATH
Rivaroxaban	390044003	YES	ISRAEL	WHITE	FEMALE	86	Abdominal pain	腹痛	15 mg	.	MODERATE	YES	21	2	NO	RESOLVED
Rivaroxaban	390044004	YES	ISRAEL	WHITE	MALE	70	Peripheral artery aneurysm	末梢動脈瘤	15 mg	.	MODERATE	YES	7	22	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	390044004	YES	ISRAEL	WHITE	MALE	70	Angiosarcoma	血管肉腫	15 mg	F	MODERATE	NO	13		NO	UNCHANGED
Enoxaparin/VKA	390044006	YES	ISRAEL	WHITE	MALE	72	Overdose	過量投与			MODERATE	YES	12	6	YES	RESOLVED
Enoxaparin/VKA	390044006	YES	ISRAEL	WHITE	MALE	72	Cellulitis	蜂巣炎			MODERATE	YES	99	4	NO	IMPROVED
Enoxaparin/VKA	390044006	YES	ISRAEL	WHITE	MALE	72	Arteriosclerosis	動脈硬化症			MODERATE	YES	144	6	NO	RESOLVED
Rivaroxaban	390044007	YES	ISRAEL	WHITE	MALE	60	Viral infection	ウイルス感染	15 mg	.	MODERATE	YES	10	4	NO	RESOLVED
Rivaroxaban	390044007	YES	ISRAEL	WHITE	MALE	60	Intestinal perforation	腸管穿孔	20 mg	.	SEVERE	YES	27	10	NO	RESOLVED
Rivaroxaban	390054006	YES	ISRAEL	WHITE	MALE	82	Femoral artery occlusion	大腿動脈閉塞	20 mg	.	MODERATE	YES	35	19	NO	RESOLVED
Rivaroxaban	390054006	YES	ISRAEL	WHITE	MALE	82	Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	20 mg	.	MODERATE	YES	35	19	NO	RESOLVED
Rivaroxaban	390054008	YES	ISRAEL	WHITE	MALE	59	Postoperative wound infection	術後創感染	20 mg	.	MODERATE	YES	176	14	NO	RESOLVED
Enoxaparin/VKA	390054012	YES	ISRAEL	WHITE	FEMALE	65	International normalised ratio increased	ＩＮＲ増加			MODERATE	YES	13	2	YES	RESOLVED
Enoxaparin/VKA	390054012	YES	ISRAEL	WHITE	FEMALE	65	International normalised ratio increased	ＩＮＲ増加			MILD	YES	95	5	YES	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	390054016	YES	ISRAEL	WHITE	FEMALE	55	Cellulitis	蜂巣炎			MODERATE	YES	17	5	NO	IMPROVED
Enoxaparin/VKA	390054016	YES	ISRAEL	WHITE	FEMALE	55	Drug eruption	薬疹			MODERATE	YES	23	5	NO	RESOLVED
Rivaroxaban	390054020	YES	ISRAEL	WHITE	FEMALE	29	Musculoskeletal pain	筋骨格痛	15 mg	F	MILD	YES	19	2	NO	RESOLVED
Enoxaparin/VKA	390064009	YES	ISRAEL	WHITE	MALE	78	Accident	事故			MILD	YES	46	1	NO	RESOLVED
Enoxaparin/VKA	390064009	YES	ISRAEL	WHITE	MALE	78	Urinary tract infection	尿路感染			MODERATE	YES	46	5	NO	IMPROVED
Enoxaparin/VKA	390064009	YES	ISRAEL	WHITE	MALE	78	Pyrexia	発熱			MILD	YES	61	5	NO	RESOLVED
Enoxaparin/VKA	390084001	YES	ISRAEL	WHITE	MALE	76	Melaena	メレナ			MODERATE	YES	144	4	YES	RESOLVED
Enoxaparin/VKA	390084003	YES	ISRAEL	WHITE	FEMALE	60	Endometrial cancer	子宮内膜癌			MODERATE	YES	109	11	NO	RESOLVED
Enoxaparin/VKA	390084003	YES	ISRAEL	WHITE	FEMALE	60	Chest pain	胸痛			MILD	YES	164	3	NO	RESOLVED
Enoxaparin/VKA	390094003	YES	ISRAEL	WHITE	FEMALE	27	Sudden hearing loss	突発難聴			MODERATE	NO	184	8	NO	IMPROVED
Enoxaparin/VKA	390104002	YES	ISRAEL	WHITE	FEMALE	69	Transient ischaemic attack	一過性脳虚血発作			MODERATE	YES	330	4	NO	RESOLVED
Rivaroxaban	390104015	YES	ISRAEL	WHITE	MALE	78	Chest pain	胸痛	20 mg	.	MILD	YES	31	5	NO	RESOLVED
Rivaroxaban	390104018	YES	ISRAEL	WHITE	MALE	51	Cough	咳嗽	15 mg	.	MILD	YES	19	3	NO	RESOLVED
Rivaroxaban	390104018	YES	ISRAEL	WHITE	MALE	51	Hypertension	高血圧	20 mg	.	MILD	YES	35	2	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	390104020	YES	ISRAEL	WHITE	FEMALE	82	Chest pain	胸痛	15 mg	.	MILD	YES	4	1	NO	RESOLVED
Rivaroxaban	390104020	YES	ISRAEL	WHITE	FEMALE	82	Vascular pseudoaneurysm	血管偽動脈瘤	15 mg	.	MODERATE	YES	8	15	NO	RESOLVED
Rivaroxaban	390104020	YES	ISRAEL	WHITE	FEMALE	82	Malaise	倦怠感	20 mg	.	MILD	YES	32	2	NO	RESOLVED
Rivaroxaban	390104020	YES	ISRAEL	WHITE	FEMALE	82	Chest pain	胸痛	20 mg	.	MILD	YES	48	2	NO	RESOLVED
Rivaroxaban	390104020	YES	ISRAEL	WHITE	FEMALE	82	Chest pain	胸痛	20 mg	.	MILD	YES	51	3	NO	RESOLVED
Rivaroxaban	390104020	YES	ISRAEL	WHITE	FEMALE	82	Chest pain	胸痛	20 mg	.	MILD	YES	56	13	NO	RESOLVED
Enoxaparin/VKA	390104042	YES	ISRAEL	WHITE	FEMALE	26	Arthritis	関節炎			MILD	YES	10	2	NO	RESOLVED
Enoxaparin/VKA	390104042	YES	ISRAEL	WHITE	FEMALE	26	Arthritis	関節炎			MILD	YES	13	4	NO	RESOLVED
Rivaroxaban	390104045	YES	ISRAEL	WHITE	MALE	34	Presyncope	失神寸前の状態	15 mg	.	MILD	YES	7	2	NO	RESOLVED
Enoxaparin/VKA	390104058	YES	ISRAEL	WHITE	MALE	55	Pancreatitis	膵炎			MILD	YES	34	6	NO	RESOLVED
Enoxaparin/VKA	390104058	YES	ISRAEL	WHITE	MALE	55	Pancreatitis acute	急性膵炎			MODERATE	YES	81	12	NO	RESOLVED
Enoxaparin/VKA	390104058	YES	ISRAEL	WHITE	MALE	55	Diabetic foot	糖尿病性足病変			MILD	YES	124	6	NO	RESOLVED
Enoxaparin/VKA	390104058	YES	ISRAEL	WHITE	MALE	55	Arteriosclerosis	動脈硬化症			MODERATE	YES	178		NO	IMPROVED
Rivaroxaban	390114006	YES	ISRAEL	WHITE	MALE	64	Haematuria	血尿	15 mg	.	MODERATE	YES	18	11	YES	RESOLVED
Enoxaparin/VKA	400014012	YES	AUSTRALIA	WHITE	FEMALE	41	Hepatic enzyme increased	肝酵素上昇			MILD	YES	2	27	NO	RESOLVED
Enoxaparin/V	400014012	YES	AUSTRALI	WHITE	FEMALE	41	Hepatic enzyme	肝酵素上昇			MILD	YES	59	35	YES	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA			A				increased									
Rivaroxaban	400024005	YES	AUSTRALIA	UNCODABLE	FEMALE	63	Humerus fracture	上腕骨骨折	20 mg	F	SEVERE	NO	188	9	NO	RESOLVED
Enoxaparin/VKA	400024021	YES	AUSTRALIA	WHITE	MALE	41	Hepatic enzyme increased	肝酵素上昇			SEVERE	YES	8	11	YES	RESOLVED
Rivaroxaban	400024025	YES	AUSTRALIA	WHITE	FEMALE	43	Induced abortion haemorrhage	人工流産による出血	20 mg	I	SEVERE	YES	120	2	NO	RESOLVED
Rivaroxaban	400034002	YES	AUSTRALIA	WHITE	MALE	92	Acute myocardial infarction	急性心筋梗塞	20 mg	.	SEVERE	YES	358	5	NO	RESOLVED
Enoxaparin/VKA	400034014	YES	AUSTRALIA	WHITE	FEMALE	40	Depression	うつ病			MODERATE	YES	72	23	NO	RESOLVED
Enoxaparin/VKA	400034028	YES	AUSTRALIA	WHITE	MALE	62	Dyspnoea	呼吸困難			MODERATE	NO	174	8	NO	RESOLVED
Enoxaparin/VKA	400034028	YES	AUSTRALIA	WHITE	MALE	62	Lung neoplasm malignant	肺の悪性新生物			SEVERE	NO	203	1	NO	DEATH
Rivaroxaban	400034031	YES	AUSTRALIA	WHITE	FEMALE	86	Cholangitis	胆管炎	15 mg	.	MODERATE	YES	7	7	NO	RESOLVED
Rivaroxaban	400034031	YES	AUSTRALIA	WHITE	FEMALE	86	Pancreatic carcinoma	膵癌	20 mg	.	SEVERE	YES	27	13	NO	DEATH
Enoxaparin/VKA	400034045	YES	AUSTRALIA	WHITE	FEMALE	80	Food poisoning	食中毒			MILD	YES	33	4	NO	RESOLVED
Rivaroxaban	400034056	YES	AUSTRALIA	WHITE	MALE	58	Colon cancer	結腸癌	15 mg	.	SEVERE	YES	8	84	NO	RESOLVED
Rivaroxaban	400034056	YES	AUSTRALIA	WHITE	MALE	58	Dyspnoea	呼吸困難	20 mg	.	MODERATE	YES	119	3	NO	RESOLVED
Rivaroxaban	400054010	YES	AUSTRALIA	WHITE	FEMALE	64	Uterine polyp	子宮ポリープ	20 mg	I	MODERATE	YES	23	8	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	400054016	YES	AUSTRALIA	WHITE	FEMALE	34	Thrombocytopenia	血小板減少症	20 mg	.	MILD	YES	23	43	YES	RESOLVED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Oesophageal carcinoma	食道癌			SEVERE	YES	13		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Hypotension	低血圧			SEVERE	NO	85		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Escherichia sepsis	大腸菌性敗血症			SEVERE	NO	96	3	NO	DEATH
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Lobar pneumonia	大葉性肺炎			SEVERE	NO	96		NO	UNCHANGED
Enoxaparin/VKA	400054026	YES	AUSTRALIA	WHITE	MALE	66	Acute hepatic failure	急性肝不全			SEVERE	NO	96		NO	UNCHANGED
Rivaroxaban	400064004	YES	AUSTRALIA	UNCODABLE	FEMALE	20	Mononeuritis	単神経炎	20 mg	.	MODERATE	YES	98	5	NO	RESOLVED
Enoxaparin/VKA	400064016	YES	AUSTRALIA	WHITE	MALE	26	Thrombophlebitis superficial	表在性血栓性静脈炎			MODERATE	YES	11	6	NO	RESOLVED
Enoxaparin/VKA	400064029	YES	AUSTRALIA	WHITE	MALE	82	Penis carcinoma	陰茎癌			SEVERE	YES	145	24	NO	RESOLVED
Enoxaparin/VKA	400074025	YES	AUSTRALIA	WHITE	MALE	37	Juvenile arthritis	若年性関節炎			SEVERE	YES	147	11	NO	RESOLVED
Enoxaparin/VKA	400084009	YES	AUSTRALIA	WHITE	MALE	39	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MODERATE	YES	15	39	NO	RESOLVED
Enoxaparin/VKA	400094008	YES	AUSTRALIA	ASIAN	FEMALE	66	Pancreatic carcinoma metastatic	転移性膵癌			SEVERE	NO	95	43	NO	DEATH
Enoxaparin/VKA	400094031	YES	AUSTRALIA	WHITE	MALE	22	Conjunctival haemorrhage	結膜出血			MODERATE	YES	168	23	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

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Rivaroxaban	400124003	YES	AUSTRALIA	WHITE	FEMALE	81	Cognitive disorder	認知障害	15 mg	.	SEVERE	YES	5		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	400124028	YES	AUSTRALIA	WHITE	MALE	61	IIIrd nerve paresis	第３脳神経不全麻痺			MODERATE	YES	106	189	NO	RESOLVED
Enoxaparin/VKA	400154008	YES	AUSTRALIA	WHITE	FEMALE	40	Autoimmune thrombocytopenia	自己免疫性血小板減少症			SEVERE	YES	214		NO	IMPROVED
Enoxaparin/VKA	400174005	YES	AUSTRALIA	WHITE	MALE	56	Syncope	失神			MILD	YES	8	2	NO	RESOLVED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Lung adenocarcinoma	肺腺癌			MODERATE	YES	27		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Atrial fibrillation	心房細動			MODERATE	YES	33	3	NO	RESOLVED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Ischaemic stroke	虚血性脳卒中			SEVERE	YES	34		NO	UNCHANGED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Cardiac valve vegetation	心臓弁疣贅			MODERATE	YES	36		NO	UNCHANGED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Dizziness	浮動性めまい			SEVERE	NO	60		NO	UNCHANGED
Enoxaparin/VKA	400204011	YES	AUSTRALIA	WHITE	MALE	63	Cardiac arrest	心停止			SEVERE	NO	61	1	NO	DEATH
Enoxaparin/VKA	400214010	YES	AUSTRALIA	WHITE	FEMALE	81	Femur fracture	大腿骨骨折			MODERATE	YES	3	89	NO	RESOLVED
Rivaroxaban	400214017	YES	AUSTRALIA	WHITE	MALE	74	Pancreatitis	膵炎	20 mg	.	MODERATE	YES	178	10	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	400214027	YES	AUSTRALIA	WHITE	MALE	75	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	MODERATE	YES	117	6	NO	RESOLVED
Rivaroxaban	400214027	YES	AUSTRALIA	WHITE	MALE	75	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	MODERATE	YES	130	16	NO	RESOLVED
Enoxaparin/VKA	400214029	YES	AUSTRALIA	WHITE	MALE	81	Haematoma	血腫			MODERATE	YES	7	43	YES	RESOLVED
Rivaroxaban	400214030	YES	AUSTRALIA	WHITE	MALE	69	Colorectal cancer	結腸直腸癌	15 mg	.	SEVERE	YES	13	20	NO	RESOLVED
Rivaroxaban	400214030	YES	AUSTRALIA	WHITE	MALE	69	Ileostomy closure	回腸瘻閉鎖	20 mg	I	MILD	YES	172	1	NO	RESOLVED
Rivaroxaban	400214030	YES	AUSTRALIA	WHITE	MALE	69	Lobar pneumonia	大葉性肺炎	20 mg	I	MODERATE	YES	173	4	NO	RESOLVED
Rivaroxaban	400214030	YES	AUSTRALIA	WHITE	MALE	69	Intestinal dilatation	腸管拡張症	20 mg	I	MODERATE	YES	174	3	NO	RESOLVED
Enoxaparin/VKA	400214062	YES	AUSTRALIA	WHITE	FEMALE	81	Spinal compression fracture	脊椎圧迫骨折			MODERATE	YES	105	41	NO	RESOLVED
Enoxaparin/VKA	400214062	YES	AUSTRALIA	WHITE	FEMALE	81	Colon cancer	結腸癌			MODERATE	YES	106	40	NO	RESOLVED
Rivaroxaban	400214067	YES	AUSTRALIA	WHITE	MALE	84	Lymphoma cutis	皮膚型リンパ腫	20 mg	.	MODERATE	YES	148		NO	UNCHANGED
Enoxaparin/VKA	440014032	YES	AUSTRIA	WHITE	MALE	49	Panic attack	パニック発作			MODERATE	YES	48	1	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	440014032	YES	AUSTRIA	WHITE	MALE	49	Dehydration	脱水			MILD	YES	48	1	NO	RESOLVED
Enoxaparin/VKA	440014032	YES	AUSTRIA	WHITE	MALE	49	Gastroenteritis	胃腸炎			MODERATE	YES	178	2	NO	RESOLVED
Rivaroxaban	440014076	YES	AUSTRIA	WHITE	FEMALE	48	Vaginal haemorrhage	膣出血	15 mg	.	SEVERE	YES	5	8	YES	RESOLVED
Rivaroxaban	440014076	YES	AUSTRIA	WHITE	FEMALE	48	Anaemia	貧血	15 mg	.	SEVERE	YES	5	8	YES	IMPROVED
Rivaroxaban	440014076	YES	AUSTRIA	WHITE	FEMALE	48	Vertigo	回転性めまい	20 mg	.	MODERATE	YES	107	7	NO	IMPROVED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Pyrexia	発熱	20 mg	.	SEVERE	YES	53	9	NO	RESOLVED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Basedow's disease	バセドウ病	20 mg	.	MODERATE	YES	182	7	NO	RESOLVED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Large intestine perforation	大腸穿孔	20 mg	F	SEVERE	NO	198	3	NO	DEATH
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Metastases to peritoneum	腹膜転移	20 mg	F	SEVERE	NO	198		NO	UNCHANGED
Rivaroxaban	440034004	YES	AUSTRIA	WHITE	FEMALE	62	Ovarian cancer	卵巣癌	20 mg	F	SEVERE	NO	198		NO	UNCHANGED
Enoxaparin/VKA	440034025	YES	AUSTRIA	WHITE	MALE	49	Phimosis	包茎			MODERATE	YES	5	74	NO	RESOLVED
Enoxaparin/VKA	440034025	YES	AUSTRIA	WHITE	MALE	49	Post procedural haemorrhage	処置後出血			MODERATE	YES	85	8	NO	RESOLVED
Rivaroxaban	440044016	YES	AUSTRIA	WHITE	MALE	43	Contusion	挫傷	20 mg	.	MILD	YES	230	2	NO	RESOLVED
Enoxaparin/VKA	440054004	YES	AUSTRIA	WHITE	FEMALE	82	Acute myocardial infarction	急性心筋梗塞			MODERATE	YES	86	32	NO	RESOLVED
Enoxaparin/VKA	440054004	YES	AUSTRIA	WHITE	FEMALE	82	Uterine cancer	子宮癌			SEVERE	NO	128		NO	UNCHANGED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	440054027	YES	AUSTRIA	WHITE	MALE	75	Haematoma	血腫			MILD	YES	14	31	NO	RESOLVED
Enoxaparin/VKA	440054027	YES	AUSTRIA	WHITE	MALE	75	Colonic polyp	結腸ポリープ			MILD	YES	92	21	NO	RESOLVED
Enoxaparin/VKA	440064002	YES	AUSTRIA	WHITE	MALE	86	Basal cell carcinoma	基底細胞癌			MODERATE	YES	170	2	NO	IMPROVED
Rivaroxaban	440064006	YES	AUSTRIA	WHITE	MALE	69	Lung neoplasm	肺新生物	20 mg	I	MILD	YES	91		NO	UNCHANGED
Enoxaparin/VKA	440064009	YES	AUSTRIA	WHITE	FEMALE	41	Blepharochalasis	眼瞼皮膚弛緩症			MILD	YES	265	2	NO	RESOLVED
Enoxaparin/VKA	440064009	YES	AUSTRIA	WHITE	FEMALE	41	Cholecystitis	胆嚢炎			MODERATE	YES	324	5	NO	RESOLVED
Enoxaparin/VKA	440064019	YES	AUSTRIA	WHITE	FEMALE	46	Colonic polyp	結腸ポリープ			MILD	YES	93	3	NO	RESOLVED
Rivaroxaban	460014001	YES	HUNGARY	WHITE	FEMALE	56	Gastrointestinal haemorrhage	胃腸出血	15 mg	.	SEVERE	YES	10	10	YES	RESOLVED
Rivaroxaban	460014009	YES	HUNGARY	WHITE	MALE	60	Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	20 mg	I	SEVERE	YES	132	9	NO	RESOLVED
Enoxaparin/VKA	460034014	YES	HUNGARY	WHITE	FEMALE	77	International normalised ratio increased	ＩＮＲ増加			MODERATE	YES	16	8	YES	RESOLVED
Enoxaparin/VKA	460034014	YES	HUNGARY	WHITE	FEMALE	77	Pneumonia	肺炎			MILD	YES	17	7	NO	RESOLVED
Enoxaparin/VKA	460034014	YES	HUNGARY	WHITE	FEMALE	77	Erysipelas	丹毒			MILD	YES	130	6	NO	RESOLVED
Rivaroxaban	460044013	YES	HUNGARY	WHITE	FEMALE	46	Vaginal haemorrhage	腟出血	20 mg	.	MODERATE	YES	169	16	YES	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	460044025	YES	HUNGARY	WHITE	FEMALE	52	Postmenopausal haemorrhage	閉経後出血	20 mg	.	MILD	YES	75	24	NO	RESOLVED
Rivaroxaban	460044028	YES	HUNGARY	WHITE	MALE	67	Angina unstable	不安定狭心症	15 mg	.	MILD	YES	8	2	NO	RESOLVED
Rivaroxaban	460054001	YES	HUNGARY	WHITE	FEMALE	58	Metastases to central nervous system	中枢神経系転移	15 mg	.	SEVERE	YES	18		NO	UNCHANGED
Rivaroxaban	460054001	YES	HUNGARY	WHITE	FEMALE	58	Metastases to lymph nodes	リンパ節転移	20 mg	.	MODERATE	YES	51		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	460054011	YES	HUNGARY	WHITE	MALE	58	Abscess limb	四肢膿瘍			SEVERE	YES	100	28	NO	RESOLVED
Enoxaparin/VKA	460054022	YES	HUNGARY	WHITE	FEMALE	76	Metastases to liver	肝転移			MODERATE	YES	34		NO	UNCHANGED
Enoxaparin/VKA	460054022	YES	HUNGARY	WHITE	FEMALE	76	Metastases to lung	肺転移			MODERATE	YES	57		NO	UNCHANGED
Enoxaparin/VKA	460054022	YES	HUNGARY	WHITE	FEMALE	76	Metastases to lymph nodes	リンパ節転移			MODERATE	YES	57		NO	UNCHANGED
Enoxaparin/VKA	460054022	YES	HUNGARY	WHITE	FEMALE	76	Ovarian cancer metastatic	転移性卵巣癌			SEVERE	YES	72		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	460064008	YES	HUNGARY	WHITE	MALE	66	Haematuria	血尿			MILD	YES	17	3	NO	RESOLVED
Enoxaparin/VKA	460064019	YES	HUNGARY	WHITE	FEMALE	55	Intervertebral disc protrusion	椎間板突出			SEVERE	YES	148	12	NO	RESOLVED
Enoxaparin/VKA	460064019	YES	HUNGARY	WHITE	FEMALE	55	Cartilage injury	軟骨損傷			SEVERE	YES	300	4	NO	RESOLVED
Rivaroxaban	460064021	YES	HUNGARY	WHITE	FEMALE	21	Haemorrhagic	出血性卵巣	20 mg	.	MILD	YES	217	6	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							ovarian cyst	嚢胞								
Rivaroxaban	460064022	YES	HUNGARY	WHITE	FEMALE	73	Back pain	背部痛	20 mg	F	MODERATE	NO	380		NO	IMPROVED
Enoxaparin/VKA	460064027	YES	HUNGARY	WHITE	MALE	30	Calculus ureteric	尿管結石			MODERATE	NO	1	90	NO	RESOLVED
Rivaroxaban	460064028	YES	HUNGARY	WHITE	MALE	55	Atrial fibrillation	心房細動	20 mg	.	MILD	YES	132	1	NO	RESOLVED
Rivaroxaban	460064028	YES	HUNGARY	WHITE	MALE	55	Atrioventricular block second degree	第二度房室ブロック	20 mg	.	MILD	YES	135		NO	IMPROVED
Rivaroxaban	460094010	YES	HUNGARY	WHITE	MALE	62	Calculus ureteric	尿管結石	20 mg	I	MODERATE	YES	49	7	NO	RESOLVED
Enoxaparin/VKA	460094025	YES	HUNGARY	WHITE	FEMALE	80	Femoral neck fracture	大腿骨頚部骨折			SEVERE	YES	72	16	NO	RESOLVED
Enoxaparin/VKA	460094046	YES	HUNGARY	WHITE	FEMALE	65	Peripheral embolism	末梢血管塞栓症			SEVERE	YES	5	14	NO	RESOLVED
Enoxaparin/VKA	460094046	YES	HUNGARY	WHITE	FEMALE	65	Pneumonia	肺炎			SEVERE	YES	41	10	NO	DEATH
Enoxaparin/VKA	460104008	YES	HUNGARY	WHITE	FEMALE	66	Crohn's disease	クローン病			SEVERE	YES	33	61	NO	RESOLVED
Rivaroxaban	460104010	YES	HUNGARY	WHITE	MALE	59	Lung neoplasm malignant	肺の悪性新生物	20 mg	.	SEVERE	YES	23	11	NO	DEATH
Rivaroxaban	460104014	YES	HUNGARY	WHITE	FEMALE	81	Hypertension	高血圧	20 mg	.	SEVERE	YES	150	12	NO	RESOLVED
Enoxaparin/VKA	460104016	YES	HUNGARY	WHITE	FEMALE	85	Sick sinus syndrome	洞不全症候群			SEVERE	YES	196	9	NO	RESOLVED
Rivaroxaban	460104021	YES	HUNGARY	WHITE	FEMALE	65	Breast cancer metastatic	転移性乳癌	15 mg	.	MODERATE	YES	15		NO	IMPROVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	460104021	YES	HUNGARY	WHITE	FEMALE	65	Metastatic neoplasm	転移性新生物	20 mg	.	SEVERE	YES	133	4	NO	DEATH
Enoxaparin/VKA	500014009	YES	BRAZIL	WHITE	FEMALE	53	Crohn's disease	クローン病			MODERATE	YES	62	7	NO	RESOLVED
Enoxaparin/VKA	500014009	YES	BRAZIL	WHITE	FEMALE	53	Crohn's disease	クローン病			MODERATE	NO	186	9	NO	RESOLVED
Rivaroxaban	500024005	YES	BRAZIL	BLACK	FEMALE	72	Generalised oedema	全身性浮腫	20 mg	.	SEVERE	YES	164	13	NO	RESOLVED
Rivaroxaban	500024008	YES	BRAZIL	WHITE	MALE	56	Pulmonary embolism	肺塞栓症	20 mg	F	SEVERE	YES	44	32	NO	DEATH
Rivaroxaban	500024008	YES	BRAZIL	WHITE	MALE	56	Pancreatic carcinoma	膵癌	20 mg	F	SEVERE	NO	75		NO	UNCHANGED
Rivaroxaban	500034023	YES	BRAZIL	WHITE	MALE	83	Tracheobronchitis	気管気管支炎	20 mg	.	SEVERE	YES	105	3	NO	RESOLVED
Rivaroxaban	500034023	YES	BRAZIL	WHITE	MALE	83	Pneumonia	肺炎	20 mg	F	SEVERE	NO	185	8	NO	RESOLVED
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Pneumonia	肺炎	15 mg	.	MODERATE	YES	4		NO	UNCHANGED
Rivaroxaban	500084005	YES	BRAZIL	WHITE	FEMALE	65	Breast cancer	乳癌	15 mg	.	SEVERE	YES	5	21	NO	DEATH
Enoxaparin/VKA	500114001	YES	BRAZIL	WHITE	FEMALE	76	Therapeutic agent toxicity	治療薬毒性			MODERATE	YES	15		YES	UNCHANGED
Enoxaparin/VKA	500114001	YES	BRAZIL	WHITE	FEMALE	76	Pulmonary embolism	肺塞栓症			SEVERE	NO	18	1	NO	DEATH
Enoxaparin/VKA	540014003	YES	CHINA	ASIAN	MALE	64	Upper gastrointestinal haemorrhage	上部消化管出血			SEVERE	NO	20	2	YES	RESOLVED
Enoxaparin/VKA	540014003	YES	CHINA	ASIAN	MALE	64	Duodenal ulcer	十二指腸潰瘍			SEVERE	NO	20	29	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	540014003	YES	CHINA	ASIAN	MALE	64	Haemorrhagic anaemia	出血性貧血			MODERATE	NO	20	29	NO	RESOLVED
Rivaroxaban	540024004	YES	CHINA	ASIAN	MALE	51	Pulmonary mass	肺腫瘤	15 mg	F	SEVERE	YES	4		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	540024013	YES	CHINA	ASIAN	FEMALE	75	Pneumonia	肺炎	20 mg	.	MILD	YES	72	14	NO	RESOLVED
Rivaroxaban	540024013	YES	CHINA	ASIAN	FEMALE	75	Pneumonia	肺炎	20 mg	I	MILD	YES	120	15	NO	RESOLVED
Rivaroxaban	540024023	YES	CHINA	ASIAN	MALE	81	Hepatic mass	肝腫瘤	15 mg	.	SEVERE	YES	3		NO	UNCHANGED
Enoxaparin/VKA	540024025	YES	CHINA	ASIAN	FEMALE	86	Intestinal mass	腸管腫瘤			SEVERE	NO	15		NO	IMPROVED
Enoxaparin/VKA	540024030	YES	CHINA	ASIAN	FEMALE	87	Multi-organ failure	多臓器不全			SEVERE	NO	14	1	YES	DEATH
Enoxaparin/VKA	540024033	YES	CHINA	ASIAN	FEMALE	75	Jaundice cholestatic	胆汁うっ滞性黄疸			SEVERE	YES	19		NO	UNCHANGED
Enoxaparin/VKA	540024033	YES	CHINA	ASIAN	FEMALE	75	Hepatic failure	肝不全			SEVERE	NO	53	2	NO	DEATH
Rivaroxaban	540024036	YES	CHINA	ASIAN	MALE	61	Lung neoplasm malignant	肺の悪性新生物	15 mg	.	MILD	YES	21		NO	IMPROVED
Enoxaparin/VKA	540034001	YES	CHINA	ASIAN	FEMALE	52	Lung neoplasm malignant	肺の悪性新生物			SEVERE	YES	7	21	NO	RESOLVED
Enoxaparin/VKA	540034007	YES	CHINA	ASIAN	FEMALE	52	Cervix carcinoma	子宮頚部癌			SEVERE	YES	80	1	NO	DEATH
Rivaroxaban	540044003	YES	CHINA	ASIAN	FEMALE	64	Lung cancer metastatic	転移性肺癌	15 mg	I	SEVERE	YES	24		NO	UNCHANGED
Enoxaparin/VKA	540044007	YES	CHINA	ASIAN	MALE	59	Retroperitoneal fibrosis	後腹膜線維症			SEVERE	YES	30		NO	IMPROVED
Enoxaparin/VKA	540064016	YES	CHINA	ASIAN	MALE	62	Metastases to liver	肝転移			SEVERE	YES	29	24	NO	DEATH

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	540064018	YES	CHINA	ASIAN	FEMALE	24	Metastatic neoplasm	転移性新生物	20 mg	I	SEVERE	YES	118		NO	UNCHANGED
Enoxaparin/VKA	540064024	YES	CHINA	ASIAN	MALE	74	Rectal cancer	直腸癌			SEVERE	YES	1		NO	UNCHANGED
Enoxaparin/VKA	540064035	YES	CHINA	ASIAN	FEMALE	51	Haemorrhoids	痔核			MILD	YES	42	22	NO	RESOLVED
Enoxaparin/VKA	540064044	YES	CHINA	ASIAN	FEMALE	67	Dyspnoea	呼吸困難			MILD	YES			NO	IMPROVED
Enoxaparin/VKA	540074002	YES	CHINA	ASIAN	FEMALE	54	Ovarian cancer recurrent	再発卵巣癌			SEVERE	YES	193		NO	IMPROVED
Enoxaparin/VKA	540074002	YES	CHINA	ASIAN	FEMALE	54	Intestinal obstruction	腸閉塞			MODERATE	YES	290	4	NO	RESOLVED
Rivaroxaban	540074003	YES	CHINA	ASIAN	MALE	46	Rectal cancer recurrent	再発直腸癌	15 mg	.	SEVERE	YES	16	124	NO	DEATH
Enoxaparin/VKA	540074004	YES	CHINA	ASIAN	MALE	74	Asthma	喘息			MODERATE	YES	5	4	NO	IMPROVED
Enoxaparin/VKA	540074004	YES	CHINA	ASIAN	MALE	74	Asthma	喘息			MILD	YES	8	6	NO	WORSENED
Enoxaparin/VKA	540074004	YES	CHINA	ASIAN	MALE	74	Cholecystitis acute	急性胆嚢炎			SEVERE	NO	11		NO	WORSENED
Enoxaparin/VKA	540074004	YES	CHINA	ASIAN	MALE	74	Asthma	喘息			SEVERE	NO	13		NO	WORSENED
Enoxaparin/VKA	540074004	YES	CHINA	ASIAN	MALE	74	Respiratory failure	呼吸不全			SEVERE	NO	14	1	NO	DEATH
Enoxaparin/VKA	540074004	YES	CHINA	ASIAN	MALE	74	Septic shock	敗血症性ショック			SEVERE	NO	14	1	NO	DEATH
Enoxaparin/VKA	540074011	YES	CHINA	ASIAN	FEMALE	80	Paronychia	爪囲炎			MODERATE	YES	16	16	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	540074015	YES	CHINA	ASIAN	FEMALE	71	Arthritis	関節炎			SEVERE	YES	184	14	NO	RESOLVED
Enoxaparin/VKA	540074023	YES	CHINA	ASIAN	MALE	56	Hepatic neoplasm malignant	肝の悪性新生物			SEVERE	YES	11	137	NO	DEATH
Enoxaparin/VKA	540104016	YES	CHINA	ASIAN	FEMALE	59	Conjunctival haemorrhage	結膜出血			MILD	YES	9		YES	INSUFFICIENT FOLLOW-UP
Rivaroxaban	540114001	YES	CHINA	ASIAN	MALE	26	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	20 mg	.	MODERATE	YES	274	40	YES	RESOLVED
Enoxaparin/VKA	540114002	YES	CHINA	ASIAN	FEMALE	61	Ischaemic stroke	虚血性脳卒中			MODERATE	NO	376		NO	IMPROVED
Enoxaparin/VKA	540114003	YES	CHINA	ASIAN	MALE	53	Retroperitoneal neoplasm	後腹膜新生物			SEVERE	YES	5	106	NO	DEATH
Rivaroxaban	540134004	YES	CHINA	ASIAN	FEMALE	44	Systemic lupus erythematosus	全身性エリテマトーデス	15 mg	.	MODERATE	YES	13	11	NO	RESOLVED
Enoxaparin/VKA	540134019	YES	CHINA	ASIAN	MALE	63	Cerebral haemorrhage	脳出血			SEVERE	YES	63	1	YES	DEATH
Rivaroxaban	540134023	YES	CHINA	ASIAN	FEMALE	55	Hepatic neoplasm malignant	肝の悪性新生物	20 mg	.	SEVERE	YES	30		NO	UNCHANGED
Rivaroxaban	540194006	YES	CHINA	ASIAN	MALE	72	Intra-abdominal haematoma	腹腔内血腫	20 mg	F	MODERATE	NO	73	14	NO	RESOLVED
Rivaroxaban	540194008	YES	CHINA	ASIAN	FEMALE	53	Rectal haemorrhage	直腸出血	20 mg	F	MODERATE	NO	124	12	NO	RESOLVED
Rivaroxaban	540194008	YES	CHINA	ASIAN	FEMALE	53	Intestinal obstruction	腸閉塞	20 mg	F	MODERATE	NO	124	12	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	550014003	YES	INDONESIA	ASIAN	MALE	61	Cardiac disorder	心障害			SEVERE	YES			NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	550014004	YES	INDONESIA	ASIAN	MALE	32	Pyrexia	発熱			MODERATE	YES	24	6	NO	RESOLVED
Enoxaparin/VKA	550014004	YES	INDONESIA	ASIAN	MALE	32	Dengue fever	デング熱			MODERATE	YES	102	8	NO	RESOLVED
Enoxaparin/VKA	550014009	YES	INDONESIA	ASIAN	FEMALE	66	Haematuria	血尿			MODERATE	YES	23	6	YES	RESOLVED
Enoxaparin/VKA	550014009	YES	INDONESIA	ASIAN	FEMALE	66	Sinus arrhythmia	洞性不整脈			MILD	YES	93	71	NO	RESOLVED
Rivaroxaban	550014010	YES	INDONESIA	ASIAN	MALE	31	Haemoptysis	喀血	15 mg	.	MODERATE	YES	19	1	YES	RESOLVED
Enoxaparin/VKA	550014012	YES	INDONESIA	ASIAN	FEMALE	28	Neutropenia	好中球減少症			MODERATE	NO	1	6	NO	RESOLVED
Enoxaparin/VKA	550024001	YES	INDONESIA	ASIAN	FEMALE	42	Haematuria	血尿			SEVERE	NO	87		NO	UNCHANGED
Enoxaparin/VKA	550024001	YES	INDONESIA	ASIAN	FEMALE	42	Anaemia	貧血			SEVERE	NO	177		NO	IMPROVED
Enoxaparin/VKA	550024001	YES	INDONESIA	ASIAN	FEMALE	42	Cervix carcinoma	子宮頚部癌			SEVERE	NO	182	1	NO	DEATH
Rivaroxaban	550034002	YES	INDONESIA	ASIAN	MALE	66	Rhabdomyosarcoma	横紋筋肉腫	15 mg	.	SEVERE	YES	16	1	NO	DEATH
Enoxaparin/VKA	550034003	YES	INDONESIA	ASIAN	FEMALE	72	Dyspnoea	呼吸困難			SEVERE	YES	27		NO	UNCHANGED
Enoxaparin/VKA	550034003	YES	INDONESIA	ASIAN	FEMALE	72	Pulmonary embolism	肺塞栓症			SEVERE	YES	27	1	NO	DEATH
Enoxaparin/V	550034003	YES	INDONESI	ASIAN	FEMALE	72	Tachypnoea	頻呼吸			SEVERE	YES	27		NO	UNCHANGED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA			A													
Enoxaparin/VKA	550034004	YES	INDONESIA	ASIAN	FEMALE	19	Haematochezia	血便排泄			SEVERE	YES	7	6	YES	RESOLVED
Enoxaparin/VKA	550034004	YES	INDONESIA	ASIAN	FEMALE	19	Haematochezia	血便排泄			MODERATE	YES	26		YES	UNCHANGED
Enoxaparin/VKA	550034004	YES	INDONESIA	ASIAN	FEMALE	19	Pulmonary sepsis	肺敗血症			SEVERE	YES	28		NO	WORSENED
Enoxaparin/VKA	550034004	YES	INDONESIA	ASIAN	FEMALE	19	Septic shock	敗血症性ショック			SEVERE	NO	29	1	NO	DEATH
Rivaroxaban	550034006	YES	INDONESIA	ASIAN	FEMALE	65	Transient ischaemic attack	一過性脳虚血発作	15 mg	.	MILD	YES	2	1	NO	RESOLVED
Enoxaparin/VKA	550034007	YES	INDONESIA	ASIAN	FEMALE	55	Gingival bleeding	歯肉出血			MODERATE	YES	20	3	YES	RESOLVED
Enoxaparin/VKA	550034007	YES	INDONESIA	ASIAN	FEMALE	55	Vaginal haemorrhage	腟出血			MODERATE	YES	20	3	YES	RESOLVED
Enoxaparin/VKA	550034007	YES	INDONESIA	ASIAN	FEMALE	55	Cervix carcinoma	子宮頚部癌			SEVERE	YES	121	1	NO	DEATH
Rivaroxaban	550034008	YES	INDONESIA	ASIAN	FEMALE	48	Hepatic neoplasm malignant	肝の悪性新生物	15 mg	.	SEVERE	YES	11	51	NO	DEATH
Rivaroxaban	550034011	YES	INDONESIA	ASIAN	MALE	45	Hypoglycaemic coma	低血糖昏睡	20 mg	.	SEVERE	YES	34	1	NO	DEATH
Enoxaparin/VKA	550034012	YES	INDONESIA	ASIAN	FEMALE	49	Pleural effusion	胸水			MODERATE	YES	57		NO	IMPROVED
Enoxaparin/VKA	550034012	YES	INDONESIA	ASIAN	FEMALE	49	Death	死亡			SEVERE	YES	155	1	NO	DEATH
Rivaroxaban	550034013	YES	INDONESIA	ASIAN	MALE	69	Pneumonia	肺炎	15 mg	F	SEVERE	YES	10	1	NO	DEATH

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	550034015	YES	INDONESIA	ASIAN	FEMALE	60	Ischaemic stroke	虚血性脳卒中			SEVERE	YES	50		NO	UNCHANGED
Enoxaparin/VKA	550034015	YES	INDONESIA	ASIAN	FEMALE	60	Sepsis	敗血症			SEVERE	YES	50	3	NO	DEATH
Enoxaparin/VKA	550034015	YES	INDONESIA	ASIAN	FEMALE	60	Bronchopneumonia	気管支肺炎			SEVERE	YES	50		NO	UNCHANGED
Rivaroxaban	550034017	YES	INDONESIA	ASIAN	MALE	39	Pathological fracture	病的骨折	15 mg	I	MODERATE	YES	13		NO	IMPROVED
Rivaroxaban	550034018	YES	INDONESIA	ASIAN	FEMALE	33	Renal failure	腎不全	20 mg	.	SEVERE	YES	146	21	NO	DEATH
Rivaroxaban	550034018	YES	INDONESIA	ASIAN	FEMALE	33	Metastases to liver	肝転移	20 mg	F	MODERATE	YES	152		NO	UNCHANGED
Rivaroxaban	550034018	YES	INDONESIA	ASIAN	FEMALE	33	Metastases to lymph nodes	リンパ節転移	20 mg	F	MODERATE	YES	152		NO	UNCHANGED
Rivaroxaban	550034019	YES	INDONESIA	ASIAN	FEMALE	63	Colorectal cancer	結腸直腸癌	20 mg	.	SEVERE	YES	32	20	NO	DEATH
Rivaroxaban	550034021	YES	INDONESIA	ASIAN	MALE	58	Back pain	背部痛	20 mg	.	SEVERE	YES	59		NO	UNCHANGED
Rivaroxaban	550034021	YES	INDONESIA	ASIAN	MALE	58	Haematemesis	吐血	20 mg	.	SEVERE	YES	66	1	YES	DEATH
Rivaroxaban	550034022	YES	INDONESIA	ASIAN	FEMALE	41	Cervix carcinoma stage III	子宮頚部癌第３期	20 mg	.	SEVERE	YES	111	32	NO	DEATH
Enoxaparin/VKA	550034026	YES	INDONESIA	ASIAN	FEMALE	56	Haematemesis	吐血			SEVERE	YES	10	1	YES	DEATH
Rivaroxaban	550034027	YES	INDONESIA	ASIAN	FEMALE	47	Ovarian cyst	卵巣嚢胞	20 mg	.	MODERATE	YES	101		NO	UNCHANGED
Rivaroxaban	550034027	YES	INDONESIA	ASIAN	FEMALE	47	Hypokalaemia	低カリウム血症	20 mg	F	SEVERE	NO	189		NO	INSUFFICIENT FOLLOW-

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
																UP
Rivaroxaban	550034027	YES	INDONESIA	ASIAN	FEMALE	47	Systemic inflammatory response syndrome	全身性炎症反応症候群	20 mg	F	SEVERE	NO	190	1	NO	DEATH
Enoxaparin/VKA	550034028	YES	INDONESIA	ASIAN	FEMALE	77	Septic shock	敗血症性ショック			SEVERE	NO	9	2	NO	DEATH
Rivaroxaban	550044010	YES	INDONESIA	ASIAN	FEMALE	63	Abscess	膿瘍	15 mg	.	SEVERE	YES	9	49	NO	RESOLVED
Enoxaparin/VKA	550044014	YES	INDONESIA	ASIAN	FEMALE	69	Asthma	喘息			SEVERE	YES	7	21	NO	RESOLVED
Enoxaparin/VKA	550044014	YES	INDONESIA	ASIAN	FEMALE	69	Shock	ショック			SEVERE	NO	99	2	NO	DEATH
Rivaroxaban	550044015	YES	INDONESIA	ASIAN	FEMALE	70	Vertigo	回転性めまい	15 mg	.	MODERATE	YES	12	8	NO	RESOLVED
Enoxaparin/VKA	550044016	YES	INDONESIA	ASIAN	FEMALE	66	Sepsis	敗血症			SEVERE	YES	2		NO	UNCHANGED
Enoxaparin/VKA	550044016	YES	INDONESIA	ASIAN	FEMALE	66	Multi-organ failure	多臓器不全			SEVERE	YES	4	1	NO	DEATH
Enoxaparin/VKA	560014009	YES	KOREA (SOUTH)	ASIAN	MALE	61	Rectal cancer	直腸癌			MODERATE	YES	3	11	NO	RESOLVED
Enoxaparin/VKA	560014009	YES	KOREA (SOUTH)	ASIAN	MALE	61	Haematochezia	血便排泄			MODERATE	YES	11	3	YES	RESOLVED
Enoxaparin/VKA	580044008	YES	SWITZERLAND	WHITE	MALE	61	Abdominal discomfort	腹部不快感			MODERATE	YES	16	6	NO	RESOLVED
Rivaroxaban	580044024	YES	SWITZERLAND	WHITE	MALE	64	Normochromic normocytic	正色素性正球性貧血	20 mg	F	MODERATE	NO	114		NO	UNCHANGED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							anaemia									
Enoxaparin/VKA	580114001	YES	SWITZERLAND	WHITE	MALE	49	Cellulitis	蜂巣炎			MILD	YES	50	15	NO	RESOLVED
Enoxaparin/VKA	580124001	YES	SWITZERLAND	WHITE	MALE	65	Ankle fracture	足関節部骨折			SEVERE	YES	229	14	NO	RESOLVED
Enoxaparin/VKA	580124001	YES	SWITZERLAND	WHITE	MALE	65	Ligament injury	靭帯損傷			SEVERE	YES	229	14	NO	RESOLVED
Rivaroxaban	600024003	YES	INDIA	ASIAN	FEMALE	55	Tetany	テタニー	20 mg	.	MILD	YES	74	31	YES	RESOLVED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Enterocutaneous fistula	腸管皮膚瘻	15 mg	.	MODERATE	YES	9	26	NO	RESOLVED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Respiratory tract infection	気道感染	20 mg	.	MODERATE	YES	67	32	NO	RESOLVED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Incision site abscess	切開部位膿瘍	20 mg	.	MODERATE	YES	67	32	NO	RESOLVED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Hypoproteinaemia	低蛋白血症	20 mg	.	MODERATE	YES	67		NO	UNCHANGED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Enterocutaneous fistula	腸管皮膚瘻	20 mg	.	MODERATE	YES	93	8	NO	WORSENED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Metabolic encephalopathy	代謝性脳症	20 mg	F	SEVERE	YES	101	5	NO	DEATH
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Sepsis	敗血症	20 mg	F	SEVERE	YES	101	5	NO	DEATH
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Enterocutaneous fistula	腸管皮膚瘻	20 mg	F	SEVERE	YES	101		NO	UNCHANGED
Rivaroxaban	600104002	YES	INDIA	ASIAN	FEMALE	38	Multi-organ	多臓器不全	20 mg	F	SEVERE	YES	101	5	NO	DEATH

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							failure									
Rivaroxaban	600104003	YES	INDIA	ASIAN	MALE	28	Infective aneurysm	感染性動脈瘤	15 mg	.	MODERATE	YES	4	58	NO	RESOLVED
Rivaroxaban	600104003	YES	INDIA	ASIAN	MALE	28	Rectal haemorrhage	直腸出血	20 mg	.	MILD	YES	56	4	NO	RESOLVED
Enoxaparin/VKA	600104006	YES	INDIA	ASIAN	MALE	48	Haematemesis	吐血			MODERATE	YES	144	5	YES	RESOLVED
Rivaroxaban	610014002	YES	TAIWAN	ASIAN	MALE	84	Urinary tract infection	尿路感染	20 mg	.	MILD	YES	109	9	NO	RESOLVED
Rivaroxaban	610014002	YES	TAIWAN	ASIAN	MALE	84	Traumatic haemorrhage	外傷性出血	20 mg	.	MILD	YES	173	15	NO	RESOLVED
Enoxaparin/VKA	650014001	YES	HONGKONG	ASIAN	FEMALE	54	Syncope	失神			MODERATE	YES	21	2	NO	RESOLVED
Enoxaparin/VKA	660014002	YES	MALAYSIA	ASIAN	MALE	67	Inguinal hernia, obstructive	閉塞性鼠径ヘルニア			SEVERE	YES	75	51	NO	RESOLVED
Enoxaparin/VKA	660014006	YES	MALAYSIA	ASIAN	MALE	52	Neuralgia	神経痛			SEVERE	YES	42	7	NO	IMPROVED
Enoxaparin/VKA	660014008	YES	MALAYSIA	ASIAN	FEMALE	44	Synovitis	滑膜炎			MODERATE	YES	93	53	NO	IMPROVED
Rivaroxaban	660014010	YES	MALAYSIA	ASIAN	FEMALE	77	Cervix cancer metastatic	転移性子宮頚部癌	20 mg	.	MODERATE	YES	71	107	NO	DEATH
Rivaroxaban	660014010	YES	MALAYSIA	ASIAN	FEMALE	77	Anaemia	貧血	20 mg	.	MODERATE	YES	71	2	NO	IMPROVED
Rivaroxaban	660014010	YES	MALAYSIA	ASIAN	FEMALE	77	Anaemia	貧血	20 mg	.	MODERATE	YES	149	1	NO	IMPROVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	670014002	YES	PHILIPPINES	ASIAN	FEMALE	72	Ovarian cancer	卵巣癌			SEVERE	YES	248	181	NO	DEATH
Enoxaparin/VKA	670014018	YES	PHILIPPINES	ASIAN	FEMALE	75	Atrial fibrillation	心房細動			MILD	YES	4		NO	UNCHANGED
Enoxaparin/VKA	670014018	YES	PHILIPPINES	ASIAN	FEMALE	75	Ischaemic stroke	虚血性脳卒中			SEVERE	YES	33		YES	UNCHANGED
Enoxaparin/VKA	670014018	YES	PHILIPPINES	ASIAN	FEMALE	75	Sepsis	敗血症			SEVERE	NO	42		NO	UNCHANGED
Enoxaparin/VKA	670014018	YES	PHILIPPINES	ASIAN	FEMALE	75	Cardiac arrest	心停止			SEVERE	NO	42	1	NO	DEATH
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Gastrointestinal haemorrhage	胃腸出血	15 mg	.	MODERATE	YES	3	40	YES	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Lymphoma	リンパ腫	15 mg	I	MODERATE	YES	8	73	NO	WORSENED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Gastrointestinal haemorrhage	胃腸出血	20 mg	.	MODERATE	YES	76	10	YES	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Lymphoma	リンパ腫	20 mg	F	SEVERE	NO	81		NO	UNCHANGED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Gastrointestinal haemorrhage	胃腸出血	20 mg	F	SEVERE	NO	106	6	NO	RESOLVED
Rivaroxaban	670014020	YES	PHILIPPINES	ASIAN	FEMALE	92	Cardio-respiratory arrest	心肺停止	20 mg	F	SEVERE	NO	159	1	NO	DEATH
Enoxaparin/VKA	670024008	YES	PHILIPPINES	ASIAN	FEMALE	38	Cervix carcinoma	子宮頚部癌			MODERATE	YES	74	94	NO	WORSENED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	670024008	YES	PHILIPPINES	ASIAN	FEMALE	38	Cervix carcinoma	子宮頚部癌			SEVERE	NO	168	4	NO	DEATH
Rivaroxaban	680024008	YES	SINGAPORE	ASIAN	MALE	77	Pneumonia	肺炎	20 mg	.	SEVERE	YES	57	2	NO	DEATH
Enoxaparin/VKA	680024015	YES	SINGAPORE	ASIAN	FEMALE	54	Ovarian epithelial cancer	卵巣上皮癌			SEVERE	YES	68		NO	IMPROVED
Enoxaparin/VKA	680024019	YES	SINGAPORE	ASIAN	FEMALE	79	Haemoptysis	喀血			MODERATE	YES	89	1	YES	RESOLVED
Enoxaparin/VKA	680024019	YES	SINGAPORE	ASIAN	FEMALE	79	Pulmonary tuberculosis	肺結核			SEVERE	YES	91		NO	IMPROVED
Enoxaparin/VKA	700014004	YES	NEW ZEALAND	WHITE	MALE	69	Large intestine perforation	大腸穿孔			SEVERE	YES	114	11	NO	RESOLVED
Enoxaparin/VKA	700014004	YES	NEW ZEALAND	WHITE	MALE	69	Rectal haemorrhage	直腸出血			SEVERE	YES	125	4	NO	RESOLVED
Rivaroxaban	700024004	YES	NEW ZEALAND	WHITE	FEMALE	72	Colon cancer	結腸癌	20 mg	.	SEVERE	YES	106		NO	IMPROVED
Enoxaparin/VKA	700024025	YES	NEW ZEALAND	WHITE	FEMALE	75	Pelvic mass	骨盤腔内腫瘤			SEVERE	YES	22	61	NO	RESOLVED
Enoxaparin/VKA	700034003	YES	NEW ZEALAND	WHITE	MALE	39	Musculoskeletal chest pain	筋骨格系胸痛			MILD	YES	8	2	NO	RESOLVED
Enoxaparin/VKA	700034014	YES	NEW ZEALAND	WHITE	MALE	78	Haemarthrosis	出血性関節症			MODERATE	NO	366	4	NO	RESOLVED
Rivaroxaban	700034016	YES	NEW ZEALAND	WHITE	MALE	82	Rectal haemorrhage	直腸出血	15 mg	.	MODERATE	YES	6	5	NO	RESOLVED

表 2.7.4.7-19 すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	700034029	YES	NEW ZEALAND	WHITE	MALE	60	Sepsis	敗血症			MODERATE	YES	164	20	NO	RESOLVED
Enoxaparin/VKA	700034030	YES	NEW ZEALAND	WHITE	MALE	62	Bladder transitional cell carcinoma stage I	膀胱移行上皮癌第１期			MODERATE	YES	101	1	NO	RESOLVED
Rivaroxaban	700044006	YES	NEW ZEALAND	WHITE	FEMALE	83	Hyphaema	前房出血	20 mg	.	MODERATE	YES	323	21	YES	RESOLVED
Rivaroxaban	700044006	YES	NEW ZEALAND	WHITE	FEMALE	83	Diverticulitis	憩室炎	20 mg	F	SEVERE	NO	344		NO	IMPROVED
Rivaroxaban	700054002	YES	NEW ZEALAND	WHITE	MALE	45	Facial palsy	顔面神経麻痺	20 mg	F	MODERATE	NO	377		NO	IMPROVED
Enoxaparin/VKA	700054013	YES	NEW ZEALAND	WHITE	FEMALE	44	Pneumonia	肺炎			SEVERE	YES	133	10	NO	RESOLVED
Enoxaparin/VKA	700054013	YES	NEW ZEALAND	WHITE	FEMALE	44	Sepsis	敗血症			SEVERE	NO	200		NO	UNCHANGED
Enoxaparin/VKA	700054013	YES	NEW ZEALAND	WHITE	FEMALE	44	Lobar pneumonia	大葉性肺炎			SEVERE	NO	200		NO	UNCHANGED
Enoxaparin/VKA	700054027	YES	NEW ZEALAND	WHITE	MALE	73	Transient ischaemic attack	一過性脳虚血発作			MODERATE	YES	60	3	NO	RESOLVED
Rivaroxaban	700064003	YES	NEW ZEALAND	WHITE	FEMALE	53	Urinary tract infection	尿路感染	20 mg	.	SEVERE	YES	39	16	NO	RESOLVED
Rivaroxaban	700064003	YES	NEW ZEALAND	WHITE	FEMALE	53	Cystitis haemorrhagic	出血性膀胱炎	20 mg	.	SEVERE	YES	39	16	NO	RESOLVED
Rivaroxaban	710024002	YES	THAILAND	ASIAN	MALE	25	Septic shock	敗血症性ショック	20 mg	F	SEVERE	YES	113	1	NO	DEATH

表 2.7.4.7-19　すべての重篤な有害事象の一覧（試験 11702-DVT、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {13.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	710024008	YES	THAILAND	ASIAN	FEMALE	53	Cellulitis	蜂巣炎	20 mg	.	MODERATE	YES	150	15	NO	RESOLVED
Enoxaparin/VKA	710024015	YES	THAILAND	ASIAN	FEMALE	35	Influenza	インフルエンザ			SEVERE	YES	24	7	NO	RESOLVED
Enoxaparin/VKA	710024015	YES	THAILAND	ASIAN	FEMALE	35	Pneumonia bacterial	細菌性肺炎			SEVERE	YES	24	12	NO	RESOLVED
Enoxaparin/VKA	710024015	YES	THAILAND	ASIAN	FEMALE	35	Menorrhagia	月経過多			SEVERE	YES	94	20	YES	RESOLVED

Only All serious AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is (onset day of AE minus medication day) plus 1 day.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase, F will be listed.

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	100013005	YES	GERMANY	WHITE	MALE	50	Dizziness	浮動性めまい			MILD	YES	12	3	NO	RESOLVED
Enoxaparin/VKA	100013009	YES	GERMANY	WHITE	MALE	59	Osteoarthritis	変形性関節症			MODERATE	YES	248	4	NO	RESOLVED
Enoxaparin/VKA	100013015	YES	GERMANY	WHITE	FEMALE	36	Cyst	嚢胞			MODERATE	YES	103	11	NO	RESOLVED
Rivaroxaban	100023006	YES	GERMANY	WHITE	FEMALE	19	Pneumonia	肺炎	20 mg	.	MODERATE	YES	23	6	NO	IMPROVED
Rivaroxaban	100023006	YES	GERMANY	WHITE	FEMALE	19	Pneumonia	肺炎	20 mg	.	MODERATE	YES	34	22	NO	RESOLVED
Enoxaparin/VKA	100023008	YES	GERMANY	WHITE	MALE	50	Pleurisy	胸膜炎			MODERATE	YES	83	5	NO	RESOLVED
Rivaroxaban	100023009	YES	GERMANY	WHITE	MALE	69	Multiple myeloma	多発性骨髄腫	20 mg	.	SEVERE	YES	161		NO	UNCHANGED
Enoxaparin/VKA	100033011	YES	GERMANY	WHITE	MALE	64	Dermatitis	皮膚炎			MODERATE	YES	203	9	NO	RESOLVED
Enoxaparin/VKA	100033011	YES	GERMANY	WHITE	MALE	64	Skin ulcer	皮膚潰瘍			MODERATE	YES	203	9	NO	RESOLVED
Rivaroxaban	100033030	YES	GERMANY	WHITE	MALE	75	Bile duct stone	胆管結石	20 mg	I	MODERATE	YES	249	2	NO	RESOLVED
Rivaroxaban	100033034	YES	GERMANY	WHITE	FEMALE	39	Menorrhagia	月経過多	15 mg	I	SEVERE	YES	20	2	YES	RESOLVED
Rivaroxaban	100033034	YES	GERMANY	WHITE	FEMALE	39	Uterine leiomyoma	子宮平滑筋腫	15 mg	I	MODERATE	YES	44	10	NO	RESOLVED
Rivaroxaban	100033035	YES	GERMANY	WHITE	MALE	69	Urinary tract disorder	尿路障害	20 mg	I	MILD	YES	174	7	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	100033035	YES	GERMANY	WHITE	MALE	69	Urinary tract disorder	尿路障害	20 mg	I	MODERATE	YES	217	11	NO	RESOLVED
Enoxaparin/VKA	100033037	YES	GERMANY	WHITE	MALE	67	Osteoarthritis	変形性関節症			MODERATE	NO	356	14	NO	RESOLVED
Rivaroxaban	100033044	YES	GERMANY	WHITE	MALE	72	Blood potassium increased	血中カリウム増加	20 mg	.	MODERATE	YES	92	7	NO	RESOLVED
Enoxaparin/VKA	100033047	YES	GERMANY	WHITE	FEMALE	44	Hypertensive crisis	高血圧クリーゼ			MODERATE	YES	11	6	NO	RESOLVED
Enoxaparin/VKA	100033047	YES	GERMANY	WHITE	FEMALE	44	Bronchitis	気管支炎			MODERATE	YES	63	2	NO	RESOLVED
Rivaroxaban	100033053	YES	GERMANY	WHITE	MALE	75	Bronchitis	気管支炎	20 mg	.	MILD	YES	54	4	NO	RESOLVED
Rivaroxaban	100033053	YES	GERMANY	WHITE	MALE	75	Coronary artery disease	冠動脈疾患	20 mg	I	MODERATE	YES	207	3	NO	RESOLVED
Enoxaparin/VKA	100033056	YES	GERMANY	WHITE	MALE	37	C-reactive protein increased	Ｃ－反応性蛋白増加			MILD	YES	52	2	NO	RESOLVED
Enoxaparin/VKA	100033056	YES	GERMANY	WHITE	MALE	37	Implant site thrombosis	埋込み部位血栓			MODERATE	YES	203	15	NO	RESOLVED
Rivaroxaban	100053009	YES	GERMANY	WHITE	MALE	29	Miscarriage of partner	パートナーの自然流産			SEVERE	YES			YES	RESOLVED
Enoxaparin/VKA	100063007	YES	GERMANY	WHITE	FEMALE	69	Lymphadenopathy	リンパ節症			MILD	YES	224	22	NO	RESOLVED
Enoxaparin/VKA	100063007	YES	GERMANY	WHITE	FEMALE	69	Lymphoma	リンパ腫			MODERATE	YES	339		NO	IMPROVED
Enoxaparin/VKA	100063007	YES	GERMANY	WHITE	FEMALE	69	Syncope	失神			MODERATE	NO	352	1	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	100063018	YES	GERMANY	WHITE	MALE	85	Angina unstable	不安定狭心症	20 mg	.	MODERATE	YES	142	13	YES	RESOLVED
Rivaroxaban	100063018	YES	GERMANY	WHITE	MALE	85	Haematoma	血腫	20 mg	I	MODERATE	YES	154	4	YES	RESOLVED
Rivaroxaban	100063018	YES	GERMANY	WHITE	MALE	85	Upper gastrointestinal haemorrhage	上部消化管出血	20 mg	.	SEVERE	YES	158	2	YES	RESOLVED
Rivaroxaban	100063018	YES	GERMANY	WHITE	MALE	85	Upper gastrointestinal haemorrhage	上部消化管出血	20 mg	F	SEVERE	NO	163	21	NO	RESOLVED
Rivaroxaban	100063018	YES	GERMANY	WHITE	MALE	85	Renal failure acute	急性腎不全	20 mg	F	MODERATE	NO	195	7	NO	RESOLVED
Enoxaparin/VKA	100063020	YES	GERMANY	WHITE	MALE	79	Bronchitis	気管支炎			MODERATE	YES	57	4	NO	RESOLVED
Enoxaparin/VKA	100063020	YES	GERMANY	WHITE	MALE	79	Coronary artery disease	冠動脈疾患			MILD	YES	141	14	YES	RESOLVED
Enoxaparin/VKA	100063021	YES	GERMANY	WHITE	MALE	36	Lower gastrointestinal haemorrhage	下部消化管出血			MILD	YES	128	2	YES	RESOLVED
Enoxaparin/VKA	100063023	YES	GERMANY	WHITE	FEMALE	31	Eye pain	眼痛			MILD	YES	152	3	NO	RESOLVED
Enoxaparin/VKA	100063024	YES	GERMANY	WHITE	MALE	33	Craniocerebral injury	頭蓋脳損傷			MILD	YES	61		NO	IMPROVED
Rivaroxaban	100063025	YES	GERMANY	WHITE	MALE	36	Somatoform disorder	身体表現性障害	15 mg	.	MODERATE	YES	6		NO	RESOLVED
Rivaroxaban	100063025	YES	GERMANY	WHITE	MALE	36	Gastrointestinal haemorrhage	胃腸出血	20 mg	.	MILD	YES	163	7	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	100063031	YES	GERMANY	WHITE	FEMALE	61	Herpes zoster	帯状疱疹			MODERATE	YES	115	9	NO	RESOLVED
Enoxaparin/VKA	100083005	YES	GERMANY	WHITE	MALE	58	Hyperventilation	過換気			MODERATE	YES	31	5	NO	RESOLVED
Enoxaparin/VKA	100083005	YES	GERMANY	WHITE	MALE	58	Bone pain	骨痛			MILD	YES	120	3	NO	RESOLVED
Rivaroxaban	100083009	YES	GERMANY	WHITE	FEMALE	51	Diarrhoea haemorrhagic	血性下痢	15 mg	.	MODERATE	YES	4	3	NO	RESOLVED
Rivaroxaban	100093010	YES	GERMANY	WHITE	MALE	80	Lumbar vertebral fracture	腰椎骨折	20 mg	F	MODERATE	YES	36	7	NO	RESOLVED
Rivaroxaban	100093010	YES	GERMANY	WHITE	MALE	80	Cholecystitis infective	感染性胆嚢炎	20 mg	F	SEVERE	NO	46		NO	UNCHANGED
Rivaroxaban	100093010	YES	GERMANY	WHITE	MALE	80	Infectious peritonitis	感染性腹膜炎	20 mg	F	SEVERE	NO	47		NO	UNCHANGED
Rivaroxaban	100093010	YES	GERMANY	WHITE	MALE	80	Sepsis	敗血症	20 mg	F	SEVERE	NO	49	28	NO	DEATH
Enoxaparin/VKA	100093025	YES	GERMANY	WHITE	MALE	72	Tumour haemorrhage	腫瘍出血			SEVERE	YES	133		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	100093025	YES	GERMANY	WHITE	MALE	72	Gastric neoplasm	胃新生物			SEVERE	YES	133		NO	DEATH
Enoxaparin/VKA	100093025	YES	GERMANY	WHITE	MALE	72	Metastatic gastric cancer	転移性胃癌			SEVERE	YES	133		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	100093042	YES	GERMANY	WHITE	FEMALE	22	Pneumonia	肺炎			MODERATE	YES	8	11	NO	RESOLVED
Enoxaparin/VKA	100093050	YES	GERMANY	WHITE	MALE	55	Prostate cancer	前立腺癌			SEVERE	YES	51	65	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	100093056	YES	GERMANY	WHITE	FEMALE	81	Gastritis	胃炎			MODERATE	YES	23	4	NO	RESOLVED
Enoxaparin/VKA	100103003	YES	GERMANY	WHITE	MALE	55	Traumatic haematoma	外傷性血腫			MODERATE	YES	69	13	YES	RESOLVED
Enoxaparin/VKA	100103005	YES	GERMANY	WHITE	MALE	24	Pneumonia	肺炎			SEVERE	YES	35	13	NO	RESOLVED
Rivaroxaban	100103012	YES	GERMANY	WHITE	FEMALE	54	Vaginal haemorrhage	膣出血	20 mg	.	MODERATE	YES	125	15	YES	RESOLVED
Rivaroxaban	100103020	YES	GERMANY	WHITE	MALE	35	Haemoptysis	喀血	20 mg	.	MILD	YES	178	20	YES	RESOLVED
Enoxaparin/VKA	100223005	YES	GERMANY	WHITE	FEMALE	85	Pneumonia	肺炎			SEVERE	YES	3	3	NO	DEATH
Rivaroxaban	100223031	YES	GERMANY	WHITE	FEMALE	80	Bronchitis	気管支炎	15 mg	.	MILD	YES	16	3	NO	RESOLVED
Enoxaparin/VKA	100223046	YES	GERMANY	WHITE	MALE	64	Atrial fibrillation	心房細動			MODERATE	YES	221	5	NO	RESOLVED
Enoxaparin/VKA	100223055	YES	GERMANY	WHITE	FEMALE	67	Pancytopenia	汎血球減少症			SEVERE	NO	32		NO	UNCHANGED
Enoxaparin/VKA	100223056	YES	GERMANY	WHITE	FEMALE	86	Appendicitis	虫垂炎			MODERATE	YES	138	2	NO	RESOLVED
Enoxaparin/VKA	100223056	YES	GERMANY	WHITE	FEMALE	86	Impaired healing	治癒不良			SEVERE	NO	140	11	NO	RESOLVED
Enoxaparin/VKA	100223056	YES	GERMANY	WHITE	FEMALE	86	Small intestinal perforation	小腸穿孔			SEVERE	NO	157	9	NO	RESOLVED
Enoxaparin/VKA	100223056	YES	GERMANY	WHITE	FEMALE	86	Acute myocardial infarction	急性心筋梗塞			SEVERE	NO	158	54	NO	RESOLVED
Rivaroxaban	100223057	YES	GERMANY	WHITE	FEMALE	76	Ovarian epithelial cancer	卵巣上皮癌	20 mg	.	SEVERE	YES	84		NO	UNCHANGED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	100223074	YES	GERMANY	WHITE	MALE	73	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	15 mg	.	MODERATE	YES	10	6	NO	RESOLVED
Rivaroxaban	100223076	YES	GERMANY	WHITE	MALE	57	Hydrocele	陰嚢水瘤	20 mg	.	MODERATE	YES	197	7	NO	RESOLVED
Rivaroxaban	100223090	YES	GERMANY	WHITE	MALE	82	Prostate cancer	前立腺癌	20 mg	I	MODERATE	YES	24		NO	UNCHANGED
Enoxaparin/VKA	100293001	YES	GERMANY	WHITE	FEMALE	80	Thoracic vertebral fracture	胸椎骨折			MODERATE	YES	94		NO	IMPROVED
Enoxaparin/VKA	100293001	YES	GERMANY	WHITE	FEMALE	80	Bone pain	骨痛			MILD	YES	94		NO	IMPROVED
Rivaroxaban	100303005	YES	GERMANY	WHITE	FEMALE	67	Bronchopneumonia	気管支肺炎	20 mg	F	MODERATE	NO	112	10	NO	RESOLVED
Enoxaparin/VKA	100323001	YES	GERMANY	WHITE	MALE	62	Parathyroid tumour benign	良性副甲状腺腫瘍			MODERATE	YES	7	10	NO	RESOLVED
Rivaroxaban	100323002	YES	GERMANY	WHITE	MALE	56	B-cell lymphoma	Ｂ細胞性リンパ腫	20 mg	.	SEVERE	YES	135		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	100343008	YES	GERMANY	WHITE	MALE	66	Metastases to peritoneum	腹膜転移			SEVERE	YES			NO	UNCHANGED
Rivaroxaban	100343008	YES	GERMANY	WHITE	MALE	66	Malignant ascites	悪性腹水	20 mg	.	SEVERE	YES	65		NO	UNCHANGED
Enoxaparin/VKA	100343009	YES	GERMANY	WHITE	MALE	52	Osteoarthritis	変形性関節症			MODERATE	YES	41	7	NO	RESOLVED
Enoxaparin/VKA	100343014	YES	GERMANY	WHITE	MALE	72	Muscle haemorrhage	筋肉内出血			SEVERE	YES	88	32	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	100343017	YES	GERMANY	WHITE	FEMALE	61	Metastases to liver	肝転移			SEVERE	YES	1		NO	UNCHANGED
Enoxaparin/VKA	100343017	YES	GERMANY	WHITE	FEMALE	61	Lung adenocarcinoma	肺腺癌			SEVERE	YES	9	27	NO	DEATH
Enoxaparin/VKA	100343017	YES	GERMANY	WHITE	FEMALE	61	Metastases to pleura	胸膜転移			SEVERE	YES	9		NO	UNCHANGED
Enoxaparin/VKA	100343017	YES	GERMANY	WHITE	FEMALE	61	Cerebral infarction	脳梗塞			MILD	YES	9	9	NO	RESOLVED
Enoxaparin/VKA	100343018	YES	GERMANY	WHITE	FEMALE	89	Cardiac failure	心不全			SEVERE	YES	165	12	NO	RESOLVED
Enoxaparin/VKA	100343021	YES	GERMANY	WHITE	MALE	77	Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪			SEVERE	YES	18	5	NO	DEATH
Rivaroxaban	100363006	YES	GERMANY	WHITE	MALE	56	Cardiac failure acute	急性心不全	20 mg	.	SEVERE	YES	333	5	YES	RESOLVED
Rivaroxaban	100363006	YES	GERMANY	WHITE	MALE	56	Tracheobronchitis	気管気管支炎	20 mg	F	MODERATE	NO	379	7	NO	RESOLVED
Enoxaparin/VKA	100363012	YES	GERMANY	WHITE	MALE	64	Skin necrosis	皮膚壊死			MILD	YES	8	16	YES	RESOLVED
Rivaroxaban	100393003	YES	GERMANY	WHITE	MALE	77	Prostatic specific antigen increased	前立腺特異性抗原増加	20 mg	I	MILD	YES	326	2	NO	RESOLVED
Rivaroxaban	100393034	YES	GERMANY	WHITE	MALE	72	Prostate cancer	前立腺癌	20 mg	I	MILD	YES	154		NO	UNCHANGED
Enoxaparin/VKA	100393042	YES	GERMANY	WHITE	MALE	72	Ventricular tachycardia	心室性頻脈			MODERATE	YES	23	8	NO	RESOLVED
Enoxaparin/VKA	100393042	YES	GERMANY	WHITE	MALE	72	Coronary artery stenosis	冠動脈狭窄			MODERATE	YES	23	8	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	100393042	YES	GERMANY	WHITE	MALE	72	Atrial fibrillation	心房細動			MODERATE	YES	41	3	NO	RESOLVED
Enoxaparin/VKA	100393044	YES	GERMANY	WHITE	MALE	71	International normalised ratio increased	ＩＮＲ増加			MODERATE	YES	144	2	YES	RESOLVED
Enoxaparin/VKA	100393044	YES	GERMANY	WHITE	MALE	71	Neoplasm malignant	悪性新生物			SEVERE	YES	201	1	NO	DEATH
Rivaroxaban	100393046	YES	GERMANY	WHITE	FEMALE	78	Osteoarthritis	変形性関節症	20 mg	I	MODERATE	YES	219	9	NO	RESOLVED
Enoxaparin/VKA	100393047	YES	GERMANY	WHITE	FEMALE	32	Cervical polyp	子宮頚管ポリープ			MILD	YES	300	1	NO	RESOLVED
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Metastases to pleura	胸膜転移			MODERATE	YES			NO	DEATH
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Pneumonia	肺炎			SEVERE	YES	49	11	NO	RESOLVED
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Pleural effusion	胸水			MODERATE	YES	328	3	NO	RESOLVED
Enoxaparin/VKA	100393053	YES	GERMANY	WHITE	MALE	65	Pleural effusion	胸水			MODERATE	YES	337	38	NO	DEATH
Enoxaparin/VKA	100393057	YES	GERMANY	WHITE	FEMALE	68	Leukopenia	白血球減少症			MODERATE	YES	60	3	NO	RESOLVED
Enoxaparin/VKA	100393057	YES	GERMANY	WHITE	FEMALE	68	Subileus	亜イレウス			MODERATE	YES	110	5	NO	RESOLVED
Rivaroxaban	100393061	YES	GERMANY	WHITE	MALE	84	Pancreatic carcinoma	膵癌	20 mg	F	SEVERE	YES	60		NO	UNCHANGED
Rivaroxaban	100393069	YES	GERMANY	WHITE	FEMALE	76	Subileus	亜イレウス			SEVERE	YES			NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	100393069	YES	GERMANY	WHITE	FEMALE	76	Colon cancer	結腸癌	15 mg	I	MODERATE	YES	18	13	NO	RESOLVED
Enoxaparin/VKA	100393072	YES	GERMANY	WHITE	MALE	34	Bone pain	骨痛			MODERATE	YES	173	2	NO	RESOLVED
Rivaroxaban	100403004	YES	GERMANY	WHITE	MALE	86	Epistaxis	鼻出血	20 mg	.	MILD	YES	112	4	YES	RESOLVED
Rivaroxaban	100403004	YES	GERMANY	WHITE	MALE	86	Rib fracture	肋骨骨折	20 mg	.	MILD	YES	271	2	NO	RESOLVED
Enoxaparin/VKA	100403007	YES	GERMANY	WHITE	FEMALE	48	Menorrhagia	月経過多			MODERATE	YES	156	5	YES	RESOLVED
Enoxaparin/VKA	100403011	YES	GERMANY	WHITE	MALE	45	Presyncope	失神寸前の状態			MILD	YES	6	3	NO	RESOLVED
Rivaroxaban	100403018	YES	GERMANY	WHITE	MALE	56	Sudden hearing loss	突発難聴	20 mg	.	MODERATE	YES	225	148	NO	RESOLVED
Enoxaparin/VKA	100403021	YES	GERMANY	WHITE	MALE	73	Basal cell carcinoma	基底細胞癌			MODERATE	YES	120	1	NO	RESOLVED
Enoxaparin/VKA	100403024	YES	GERMANY	WHITE	MALE	57	Ejection fraction decreased	駆出率減少			MILD	YES	64	3	NO	RESOLVED
Enoxaparin/VKA	100423003	YES	GERMANY	WHITE	MALE	66	Vascular pseudoaneurysm	血管偽動脈瘤			MILD	YES	6	3	YES	RESOLVED
Enoxaparin/VKA	100423003	YES	GERMANY	WHITE	MALE	66	Haematoma	血腫			MODERATE	YES	20	2	YES	IMPROVED
Enoxaparin/VKA	100423005	YES	GERMANY	WHITE	FEMALE	64	Vertigo	回転性めまい			MILD	YES	8	8	NO	RESOLVED
Enoxaparin/VKA	100433001	YES	GERMANY	WHITE	FEMALE	53	Hepatitis	肝炎			MODERATE	YES	4	20	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

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Enoxaparin/VKA	100433003	YES	GERMANY	WHITE	MALE	67	Osteonecrosis	骨壊死			MODERATE	YES	294	2	NO	RESOLVED
Enoxaparin/VKA	100433005	YES	GERMANY	WHITE	MALE	83	Gastrointestinal haemorrhage	胃腸出血			SEVERE	YES	7	2	YES	RESOLVED
Rivaroxaban	100433006	YES	GERMANY	WHITE	MALE	73	Rectal cancer	直腸癌			SEVERE	YES			NO	DEATH
Rivaroxaban	100433006	YES	GERMANY	WHITE	MALE	73	Hepatic pain	肝臓痛	20 mg	.	MODERATE	YES	179		NO	IMPROVED
Rivaroxaban	100433006	YES	GERMANY	WHITE	MALE	73	Cardiac arrest	心停止	20 mg	F	SEVERE	NO	203	1	NO	DEATH
Enoxaparin/VKA	100433008	YES	GERMANY	WHITE	FEMALE	77	Vertigo	回転性めまい			MODERATE	YES	336	9	NO	RESOLVED
Rivaroxaban	100433011	YES	GERMANY	WHITE	MALE	49	Syncope	失神			MODERATE	YES	275	12	NO	RESOLVED
Rivaroxaban	100433013	YES	GERMANY	WHITE	MALE	60	Clumsiness	不器用	20 mg	.	MODERATE	YES	27	68	YES	RESOLVED
Rivaroxaban	100433014	YES	GERMANY	WHITE	MALE	46	Inflammatory pseudotumour	炎症性偽腫瘍	20 mg	.	MILD	YES	189	10	NO	RESOLVED
Rivaroxaban	100433016	YES	GERMANY	WHITE	MALE	83	Haematuria	血尿	15 mg	.	MODERATE	YES	5	8	YES	RESOLVED
Rivaroxaban	100433017	YES	GERMANY	WHITE	MALE	61	Acute myocardial infarction	急性心筋梗塞	20 mg	F	SEVERE	NO	218	9	NO	RESOLVED
Enoxaparin/VKA	100473005	YES	GERMANY	WHITE	MALE	73	Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪			MODERATE	YES	191	10	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	100473005	YES	GERMANY	WHITE	MALE	73	Pneumonia	肺炎			MODERATE	YES	216	12	YES	RESOLVED
Rivaroxaban	100473007	YES	GERMANY	WHITE	FEMALE	81	Hepatic enzyme increased	肝酵素上昇	20 mg	.	SEVERE	YES	95	27	YES	RESOLVED
Enoxaparin/VKA	100473011	YES	GERMANY	WHITE	FEMALE	69	Hypertension	高血圧			MODERATE	YES	59	14	YES	RESOLVED
Rivaroxaban	120023005	YES	UNITED KINGDOM	WHITE	MALE	74	Emphysema	肺気腫	15 mg	I	MODERATE	YES	14		NO	UNCHANGED
Enoxaparin/VKA	120023007	YES	UNITED KINGDOM	BLACK	MALE	63	Chest pain	胸痛			SEVERE	YES	248	2	NO	RESOLVED
Rivaroxaban	120023013	YES	UNITED KINGDOM	WHITE	MALE	57	Syncope	失神	15 mg	.	SEVERE	YES	20	5	NO	RESOLVED
Rivaroxaban	120023013	YES	UNITED KINGDOM	WHITE	MALE	57	Operative haemorrhage	術中出血	15 mg	.	MODERATE	YES	24	1	YES	RESOLVED
Rivaroxaban	120023013	YES	UNITED KINGDOM	WHITE	MALE	57	Cardiac failure	心不全	20 mg	.	SEVERE	YES	81	4	NO	RESOLVED
Enoxaparin/VKA	120023014	YES	UNITED KINGDOM	BLACK	MALE	81	Pleuritic pain	胸膜痛			MODERATE	YES	23	10	NO	RESOLVED
Enoxaparin/VKA	120023014	YES	UNITED KINGDOM	BLACK	MALE	81	Acute coronary syndrome	急性冠動脈症候群			MODERATE	YES	28	1	NO	RESOLVED
Enoxaparin/VKA	120023018	YES	UNITED KINGDOM	WHITE	MALE	64	Granuloma	肉芽腫			SEVERE	YES	10	117	NO	RESOLVED
Enoxaparin/VKA	120023018	YES	UNITED KINGDOM	WHITE	MALE	64	Upper gastrointestinal haemorrhage	上部消化管出血			SEVERE	YES	87		NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	120023019	YES	UNITED KINGDOM	WHITE	FEMALE	35	Upper limb fracture	上肢骨折			SEVERE	YES	134	30	NO	RESOLVED
Enoxaparin/VKA	120023019	YES	UNITED KINGDOM	WHITE	FEMALE	35	Subcutaneous haematoma	皮下血腫			SEVERE	YES	134	45	YES	RESOLVED
Enoxaparin/VKA	120033002	YES	UNITED KINGDOM	BLACK	MALE	80	Gastric ulcer haemorrhage	出血性胃潰瘍			MODERATE	YES	1	84	YES	RESOLVED
Enoxaparin/VKA	120033002	YES	UNITED KINGDOM	BLACK	MALE	80	Subdural haemorrhage	硬膜下出血			SEVERE	YES	179	79	NO	RESOLVED
Enoxaparin/VKA	120033003	YES	UNITED KINGDOM	WHITE	FEMALE	65	Cervix carcinoma	子宮頚部癌			MODERATE	NO	63	16	NO	DEATH
Enoxaparin/VKA	140153001	YES	UNITED STATES	WHITE	MALE	24	Haemoptysis	喀血			SEVERE	YES	1	3	NO	RESOLVED
Enoxaparin/VKA	140153001	YES	UNITED STATES	WHITE	MALE	24	Abscess limb	四肢膿瘍			MODERATE	YES	30		NO	IMPROVED
Enoxaparin/VKA	140153009	YES	UNITED STATES	WHITE	FEMALE	31	Pleuritic pain	胸膜痛			MODERATE	YES	6	5	NO	RESOLVED
Enoxaparin/VKA	140153009	YES	UNITED STATES	WHITE	FEMALE	31	Chest pain	胸痛			SEVERE	YES	19	4	NO	RESOLVED
Rivaroxaban	140153012	YES	UNITED STATES	WHITE	FEMALE	67	Pain in extremity	四肢痛	20 mg	.	SEVERE	YES	56	4	NO	RESOLVED
Rivaroxaban	140163030	YES	UNITED STATES	WHITE	FEMALE	86	Gastrointestinal haemorrhage	胃腸出血	20 mg	F	SEVERE	YES	67	8	YES	RESOLVED
Rivaroxaban	140163046	YES	UNITED STATES	WHITE	FEMALE	57	Osteonecrosis	骨壊死			SEVERE	YES			NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

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Enoxaparin/VKA	140173001	YES	UNITED STATES	WHITE	FEMALE	57	Small intestinal obstruction	小腸閉塞			SEVERE	YES	28	5	NO	RESOLVED
Enoxaparin/VKA	140173001	YES	UNITED STATES	WHITE	FEMALE	57	Osteomyelitis	骨髄炎			SEVERE	YES	119	14	NO	RESOLVED
Enoxaparin/VKA	140173001	YES	UNITED STATES	WHITE	FEMALE	57	Cellulitis	蜂巣炎			MODERATE	YES	119	56	NO	RESOLVED
Rivaroxaban	140173016	YES	UNITED STATES	WHITE	FEMALE	65	Uterine prolapse	子宮脱	20 mg	I	SEVERE	YES	218	2	NO	RESOLVED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Intra-abdominal haemorrhage	腹腔内出血			SEVERE	YES	5	1	NO	RESOLVED
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Malignant ascites	悪性腹水			SEVERE	YES	5	9	NO	DEATH
Enoxaparin/VKA	140203001	YES	UNITED STATES	WHITE	FEMALE	66	Renal failure acute	急性腎不全			MODERATE	YES	5		NO	UNCHANGED
Enoxaparin/VKA	140203016	YES	UNITED STATES	WHITE	FEMALE	54	Non-cardiac chest pain	非心臓性胸痛			MODERATE	YES	31	3	NO	RESOLVED
Enoxaparin/VKA	140203016	YES	UNITED STATES	WHITE	FEMALE	54	Pneumonia	肺炎			MODERATE	YES	31	42	NO	RESOLVED
Enoxaparin/VKA	140203016	YES	UNITED STATES	WHITE	FEMALE	54	Non-cardiac chest pain	非心臓性胸痛			MODERATE	YES	94	101	NO	RESOLVED
Enoxaparin/VKA	140203023	YES	UNITED STATES	WHITE	FEMALE	64	Dyspnoea	呼吸困難			MODERATE	YES	54	11	NO	RESOLVED
Enoxaparin/VKA	140203029	YES	UNITED STATES	WHITE	MALE	79	Lung neoplasm malignant	肺の悪性新生物			SEVERE	YES	3		NO	UNCHANGED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	140203055	YES	UNITED STATES	WHITE	FEMALE	83	Pneumonia	肺炎	20 mg	.	MODERATE	YES	38	3	NO	RESOLVED
Rivaroxaban	140203057	YES	UNITED STATES	BLACK	FEMALE	43	Chest pain	胸痛	15 mg	.	MODERATE	YES	10	3	NO	RESOLVED
Rivaroxaban	140203057	YES	UNITED STATES	BLACK	FEMALE	43	Non-cardiac chest pain	非心臓性胸痛	20 mg	F	MODERATE	NO	193	3	NO	RESOLVED
Enoxaparin/VKA	140203058	YES	UNITED STATES	WHITE	FEMALE	36	Nephrolithiasis	腎結石症			MODERATE	YES	36	21	NO	RESOLVED
Enoxaparin/VKA	140203061	YES	UNITED STATES	WHITE	FEMALE	44	Pleural effusion	胸水			SEVERE	YES	2	21	NO	RESOLVED
Enoxaparin/VKA	140313014	YES	UNITED STATES	WHITE	FEMALE	68	Lung cancer metastatic	転移性肺癌			SEVERE	YES	4	74	NO	DEATH
Rivaroxaban	140313019	YES	UNITED STATES	WHITE	MALE	58	Angina unstable	不安定狭心症	20 mg	.	MODERATE	YES	43	1	NO	RESOLVED
Enoxaparin/VKA	140313022	YES	UNITED STATES	WHITE	FEMALE	37	Groin abscess	鼠径部膿瘍			MILD	YES	14	3	NO	RESOLVED
Rivaroxaban	140313044	YES	UNITED STATES	WHITE	FEMALE	37	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	15 mg	.	MODERATE	YES	15	7	YES	RESOLVED
Enoxaparin/VKA	140313051	YES	UNITED STATES	BLACK	FEMALE	78	Failure to thrive	成長障害			SEVERE	YES	3	24	NO	DEATH
Enoxaparin/VKA	140313052	YES	UNITED STATES	WHITE	MALE	59	Intervertebral disc degeneration	椎間板変性症			MODERATE	YES	238	7	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	140313060	YES	UNITED STATES	WHITE	FEMALE	79	Retroperitoneal haematoma	後腹膜血腫			SEVERE	YES	8	7	YES	RESOLVED
Rivaroxaban	140313066	YES	UNITED STATES	WHITE	FEMALE	46	Dysfunctional uterine bleeding	機能障害性子宮出血	15 mg	.	MODERATE	YES	3	11	YES	RESOLVED
Rivaroxaban	140313072	YES	UNITED STATES	WHITE	MALE	51	Acute myocardial infarction	急性心筋梗塞	20 mg	I	MODERATE	YES	100	2	NO	RESOLVED
Rivaroxaban	140323003	YES	UNITED STATES	WHITE	FEMALE	28	Pneumonia	肺炎	15 mg	.	SEVERE	YES	14	5	NO	RESOLVED
Rivaroxaban	140323009	YES	UNITED STATES	WHITE	MALE	77	Non-cardiac chest pain	非心臓性胸痛	20 mg	.	MODERATE	YES	82	6	NO	RESOLVED
Enoxaparin/VKA	140323012	YES	UNITED STATES	BLACK	FEMALE	67	Non-cardiac chest pain	非心臓性胸痛			MILD	YES	26	3	NO	RESOLVED
Enoxaparin/VKA	140323012	YES	UNITED STATES	BLACK	FEMALE	67	Anxiety	不安			MILD	YES	26	3	NO	RESOLVED
Enoxaparin/VKA	140323020	YES	UNITED STATES	WHITE	MALE	22	Pain in extremity	四肢痛			MODERATE	YES	8	4	NO	RESOLVED
Enoxaparin/VKA	140323020	YES	UNITED STATES	WHITE	MALE	22	Haemarthrosis	出血性関節症			MILD	YES	9	1	YES	RESOLVED
Enoxaparin/VKA	140323048	YES	UNITED STATES	WHITE	MALE	39	Coronary artery disease	冠動脈疾患			SEVERE	YES	59	10	NO	RESOLVED
Rivaroxaban	140323054	YES	UNITED STATES	WHITE	FEMALE	68	Sepsis	敗血症	20 mg	.	SEVERE	YES	33		NO	UNCHANGED
Rivaroxaban	140323054	YES	UNITED STATES	WHITE	FEMALE	68	Hepatic failure	肝不全	20 mg	F	SEVERE	YES	41		NO	UNCHANGED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

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Rivaroxaban	140323054	YES	UNITED STATES	WHITE	FEMALE	68	Breast cancer metastatic	転移性乳癌	20 mg	F	SEVERE	YES	41	1	NO	DEATH
Rivaroxaban	140323054	YES	UNITED STATES	WHITE	FEMALE	68	Metastases to liver	肝転移	20 mg	F	SEVERE	YES	41	1	NO	DEATH
Rivaroxaban	140323061	YES	UNITED STATES	BLACK	FEMALE	40	Pleuritic pain	胸膜痛	15 mg	.	MODERATE	YES	6	4	NO	RESOLVED
Enoxaparin/VKA	140323063	YES	UNITED STATES	WHITE	FEMALE	69	Ischaemic stroke	虚血性脳卒中			MILD	YES	65	19	YES	RESOLVED
Rivaroxaban	140323064	YES	UNITED STATES	WHITE	MALE	66	Pneumonia	肺炎			MODERATE	YES	249	20	NO	RESOLVED
Rivaroxaban	140323064	YES	UNITED STATES	WHITE	MALE	66	Urinary tract infection	尿路感染			MODERATE	YES	249	20	NO	RESOLVED
Enoxaparin/VKA	140323065	YES	UNITED STATES	WHITE	FEMALE	80	Pancreatitis	膵炎			MODERATE	YES	67	6	NO	RESOLVED
Enoxaparin/VKA	140323065	YES	UNITED STATES	WHITE	FEMALE	80	Cholelithiasis	胆石症			MODERATE	YES	67	6	NO	RESOLVED
Enoxaparin/VKA	140343003	YES	UNITED STATES	HISPANIC	MALE	78	Lung adenocarcinoma	肺腺癌			MODERATE	YES	337		NO	UNCHANGED
Rivaroxaban	140343004	YES	UNITED STATES	WHITE	MALE	86	Hypoglycaemia	低血糖症	20 mg	.	MODERATE	YES	50	1	NO	RESOLVED
Enoxaparin/VKA	140353001	YES	UNITED STATES	WHITE	FEMALE	60	Subdural haematoma	硬膜下血腫			SEVERE	YES	173	19	YES	RESOLVED
Rivaroxaban	140353005	YES	UNITED STATES	BLACK	FEMALE	20	Overdose	過量投与	15 mg	.	MODERATE	YES	1	1	NO	RESOLVED

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Rivaroxaban	140353005	YES	UNITED STATES	BLACK	FEMALE	20	Pulmonary infarction	肺梗塞	15 mg	.	MODERATE	YES	5	32	NO	RESOLVED
Enoxaparin/VKA	140353008	YES	UNITED STATES	BLACK	FEMALE	67	Drug hypersensitivity	薬物過敏症			MODERATE	YES	3	12	YES	RESOLVED
Enoxaparin/VKA	140353013	YES	UNITED STATES	WHITE	FEMALE	68	Adverse drug reaction	医薬品副作用			MODERATE	YES	13	11	NO	RESOLVED
Enoxaparin/VKA	140353013	YES	UNITED STATES	WHITE	FEMALE	68	Pulmonary oedema	肺水腫			MODERATE	YES	15	9	NO	RESOLVED
Enoxaparin/VKA	140353013	YES	UNITED STATES	WHITE	FEMALE	68	Tachycardia	頻脈			MODERATE	YES	100	14	NO	RESOLVED
Enoxaparin/VKA	140353013	YES	UNITED STATES	WHITE	FEMALE	68	Mental status changes	精神状態変化			MODERATE	YES	100	14	NO	RESOLVED
Enoxaparin/VKA	140353020	YES	UNITED STATES	WHITE	MALE	34	Pulmonary infarction	肺梗塞			SEVERE	YES	4	4	NO	RESOLVED
Enoxaparin/VKA	140353022	YES	UNITED STATES	BLACK	FEMALE	71	Atrial fibrillation	心房細動			MODERATE	YES	1	5	NO	RESOLVED
Rivaroxaban	140353024	YES	UNITED STATES	WHITE	MALE	54	Pericarditis	心膜炎	15 mg	.	MODERATE	YES	11	459	NO	RESOLVED
Enoxaparin/VKA	140353029	YES	UNITED STATES	WHITE	FEMALE	43	Chest pain	胸痛			MODERATE	YES	40	5	NO	RESOLVED
Enoxaparin/VKA	140353033	YES	UNITED STATES	WHITE	FEMALE	21	Pregnancy	妊娠			MODERATE	YES			NO	RESOLVED
Enoxaparin/VKA	140353033	YES	UNITED STATES	WHITE	FEMALE	21	Post abortion haemorrhage	流産後の出血			MODERATE	YES	87	1	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	140363003	YES	UNITED STATES	BLACK	FEMALE	50	Dyspnoea	呼吸困難	15 mg	.	.	YES	4		.	INSUFFICIENT FOLLOW-UP
Rivaroxaban	140363003	YES	UNITED STATES	BLACK	FEMALE	50	Chest pain	胸痛	15 mg	.	.	YES	4		.	INSUFFICIENT FOLLOW-UP
Rivaroxaban	140363003	YES	UNITED STATES	BLACK	FEMALE	50	Cough	咳嗽	15 mg	.	.	YES	4		.	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	140363005	YES	UNITED STATES	WHITE	MALE	62	Supraventricular tachycardia	上室性頻脈			SEVERE	YES	101	6	NO	RESOLVED
Enoxaparin/VKA	140363005	YES	UNITED STATES	WHITE	MALE	62	Coronary artery disease	冠動脈疾患			SEVERE	YES	101	3	NO	RESOLVED
Enoxaparin/VKA	140363005	YES	UNITED STATES	WHITE	MALE	62	Acute myocardial infarction	急性心筋梗塞			SEVERE	YES	102	1	NO	RESOLVED
Rivaroxaban	140373011	YES	UNITED STATES	WHITE	FEMALE	28	Post procedural haemorrhage	処置後出血	15 mg	.	SEVERE	YES	10	4	YES	RESOLVED
Rivaroxaban	140373011	YES	UNITED STATES	WHITE	FEMALE	28	Vaginal haemorrhage	膣出血	15 mg	F	SEVERE	NO	18	14	NO	RESOLVED
Enoxaparin/VKA	140373051	YES	UNITED STATES	WHITE	MALE	62	Respiratory arrest	呼吸停止			SEVERE	YES	3	1	NO	DEATH
Enoxaparin/VKA	140413007	YES	UNITED STATES	WHITE	MALE	49	Embolism arterial	動脈塞栓症			MODERATE	YES	1	3	NO	RESOLVED
Enoxaparin/VKA	140413007	YES	UNITED STATES	WHITE	MALE	49	Ischaemic stroke	虚血性脳卒中			MODERATE	YES	17	8	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	140413007	YES	UNITED STATES	WHITE	MALE	49	Lacunar infarction	ラクナ梗塞			MILD	YES	18	35	NO	RESOLVED
Rivaroxaban	140423008	YES	UNITED STATES	WHITE	MALE	69	Melaena	メレナ	15 mg	.	MODERATE	YES	18	4	NO	RESOLVED
Rivaroxaban	140423008	YES	UNITED STATES	WHITE	MALE	69	Renal cancer	腎癌	20 mg	.	SEVERE	YES	34		NO	UNCHANGED
Rivaroxaban	140423009	YES	UNITED STATES	BLACK	FEMALE	19	Pleural effusion	胸水	15 mg	.	SEVERE	YES	8	3	NO	RESOLVED
Enoxaparin/VKA	140423013	YES	UNITED STATES	WHITE	MALE	70	Atrial fibrillation	心房細動			SEVERE	YES	3	34	NO	RESOLVED
Enoxaparin/VKA	140423013	YES	UNITED STATES	WHITE	MALE	70	Transient ischaemic attack	一過性脳虚血発作			MODERATE	YES	17	2	NO	RESOLVED
Rivaroxaban	140423016	YES	UNITED STATES	BLACK	MALE	42	Alcohol poisoning	アルコール中毒	20 mg	.	SEVERE	YES	111	2	NO	RESOLVED
Rivaroxaban	140423016	YES	UNITED STATES	BLACK	MALE	42	Non-cardiac chest pain	非心臓性胸痛	20 mg	.	SEVERE	YES	144	2	NO	RESOLVED
Rivaroxaban	140423017	YES	UNITED STATES	WHITE	MALE	84	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	MILD	YES	70	4	NO	RESOLVED
Rivaroxaban	140423021	YES	UNITED STATES	WHITE	MALE	53	Cellulitis	蜂巣炎	20 mg	.	SEVERE	YES	54	3	NO	RESOLVED
Rivaroxaban	140423021	YES	UNITED STATES	WHITE	MALE	53	Non-cardiac chest pain	非心臓性胸痛	20 mg	.	MODERATE	YES	146	3	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	140423023	YES	UNITED STATES	WHITE	MALE	62	Colitis ischaemic	虚血性大腸炎	20 mg	.	SEVERE	YES	46	6	NO	RESOLVED
Rivaroxaban	140423030	YES	UNITED STATES	WHITE	FEMALE	66	Gastroenteritis	胃腸炎	15 mg	.	SEVERE	YES	10	4	NO	RESOLVED
Rivaroxaban	140423030	YES	UNITED STATES	WHITE	FEMALE	66	Vomiting	嘔吐	20 mg	.	SEVERE	YES	33	2	NO	RESOLVED
Rivaroxaban	140423032	YES	UNITED STATES	WHITE	FEMALE	55	Non-cardiac chest pain	非心臓性胸痛	15 mg	.	SEVERE	YES	9	4	NO	RESOLVED
Rivaroxaban	140423032	YES	UNITED STATES	WHITE	FEMALE	55	Depressed level of consciousness	意識レベルの低下	20 mg	.	SEVERE	YES	68	5	NO	RESOLVED
Rivaroxaban	140423032	YES	UNITED STATES	WHITE	FEMALE	55	Overdose	過量投与	20 mg	F	SEVERE	NO	192	2	NO	RESOLVED
Rivaroxaban	140423036	YES	UNITED STATES	WHITE	FEMALE	74	Meningioma	髄膜腫	20 mg	I	SEVERE	YES	241	4	NO	RESOLVED
Rivaroxaban	140423036	YES	UNITED STATES	WHITE	FEMALE	74	Sepsis	敗血症	20 mg	.	SEVERE	YES	274	24	NO	RESOLVED
Rivaroxaban	140423036	YES	UNITED STATES	WHITE	FEMALE	74	Gastric perforation	胃穿孔	20 mg	F	SEVERE	YES	276	1	NO	RESOLVED
Rivaroxaban	140423037	YES	UNITED STATES	WHITE	FEMALE	64	Orthostatic hypotension	起立性低血圧	20 mg	.	SEVERE	YES	238	3	NO	RESOLVED
Rivaroxaban	140423043	YES	UNITED STATES	WHITE	FEMALE	76	Atrial fibrillation	心房細動	20 mg	.	MODERATE	YES	94		NO	UNCHANGED
Enoxaparin/VKA	140453002	YES	UNITED STATES	HISPANIC	MALE	64	Coronary artery disease	冠動脈疾患			MODERATE	YES	14		NO	UNCHANGED

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Enoxaparin/VKA	140453002	YES	UNITED STATES	HISPANIC	MALE	64	Oedema peripheral	末梢性浮腫			MODERATE	YES	14	5	NO	RESOLVED
Enoxaparin/VKA	140453002	YES	UNITED STATES	HISPANIC	MALE	64	Chest pain	胸痛			MODERATE	YES	14	5	NO	RESOLVED
Rivaroxaban	140463003	YES	UNITED STATES	BLACK	MALE	50	Chest pain	胸痛	20 mg	I	MODERATE	YES	92	3	NO	RESOLVED
Rivaroxaban	140463003	YES	UNITED STATES	BLACK	MALE	50	Muscular weakness	筋力低下	20 mg	.	MODERATE	YES	97	2	NO	RESOLVED
Rivaroxaban	140463003	YES	UNITED STATES	BLACK	MALE	50	Chest pain	胸痛	20 mg	.	MODERATE	YES	219	3	NO	RESOLVED
Enoxaparin/VKA	140473002	YES	UNITED STATES	WHITE	FEMALE	23	Sinus tachycardia	洞性頻脈			MODERATE	YES	18		NO	UNCHANGED
Enoxaparin/VKA	140473002	YES	UNITED STATES	WHITE	FEMALE	23	Hypokalaemia	低カリウム血症			MILD	YES	18	70	NO	RESOLVED
Enoxaparin/VKA	140473002	YES	UNITED STATES	WHITE	FEMALE	23	Hypertension	高血圧			MILD	YES	18		NO	UNCHANGED
Enoxaparin/VKA	140473002	YES	UNITED STATES	WHITE	FEMALE	23	Dyspnoea	呼吸困難			MODERATE	YES	18	1	NO	RESOLVED
Enoxaparin/VKA	140473002	YES	UNITED STATES	WHITE	FEMALE	23	Chest pain	胸痛			MODERATE	YES	18	2	NO	RESOLVED
Enoxaparin/VKA	140473002	YES	UNITED STATES	WHITE	FEMALE	23	Anxiety	不安			MODERATE	YES	18	2	NO	RESOLVED
Enoxaparin/VKA	140473012	YES	UNITED STATES	WHITE	FEMALE	37	Anaemia	貧血			SEVERE	YES	31	4	NO	RESOLVED

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Enoxaparin/VKA	140473012	YES	UNITED STATES	WHITE	FEMALE	37	Abdominal pain	腹痛			SEVERE	YES	177	9	NO	RESOLVED
Enoxaparin/VKA	160013012	YES	FRANCE	N.A.	MALE	49	Retroperitoneal haematoma	後腹膜血腫			MILD	YES	134	14	YES	RESOLVED
Enoxaparin/VKA	160013021	YES	FRANCE	N.A.	FEMALE	74	Haematuria	血尿			MODERATE	YES	4	4	YES	RESOLVED
Enoxaparin/VKA	160013023	YES	FRANCE	N.A.	MALE	81	Eye haemorrhage	眼出血			MODERATE	YES	142	62	YES	RESOLVED
Rivaroxaban	160013031	YES	FRANCE	N.A.	FEMALE	72	Vulval disorder	外陰部障害	20 mg	I	MODERATE	YES	152	8	NO	RESOLVED
Rivaroxaban	160013063	YES	FRANCE	N.A.	MALE	84	Chest pain	胸痛	15 mg	.	SEVERE	YES	9	2	NO	RESOLVED
Rivaroxaban	160013071	YES	FRANCE	N.A.	FEMALE	90	Fall	転倒	20 mg	.	MILD	YES	34	1	NO	RESOLVED
Rivaroxaban	160013071	YES	FRANCE	N.A.	FEMALE	90	Back pain	背部痛	20 mg	I	SEVERE	YES	35	9	NO	RESOLVED
Rivaroxaban	160013078	YES	FRANCE	N.A.	MALE	51	Epilepsy	てんかん	20 mg	.	MODERATE	YES	160	9	NO	RESOLVED
Enoxaparin/VKA	160013088	YES	FRANCE	N.A.	MALE	56	Joint stiffness	関節硬直			MODERATE	YES	26	40	NO	RESOLVED
Enoxaparin/VKA	160013092	YES	FRANCE	N.A.	MALE	87	Atrioventricular block	房室ブロック			SEVERE	YES	6	2	NO	DEATH
Enoxaparin/VKA	160013093	YES	FRANCE	N.A.	FEMALE	18	Chest pain	胸痛			MODERATE	YES	35	23	NO	RESOLVED
Rivaroxaban	160013107	YES	FRANCE	N.A.	FEMALE	82	Pulmonary embolism	肺塞栓症	20 mg	.	SEVERE	YES	36	1	YES	DEATH
Rivaroxaban	160023005	YES	FRANCE	N.A.	MALE	52	Haematoma	血腫	20 mg	.	SEVERE	YES	177	33	YES	RESOLVED
Rivaroxaban	160023013	YES	FRANCE	N.A.	FEMALE	72	Osteoarthritis	変形性関節症	20 mg	.	SEVERE	YES	330	32	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	160023018	YES	FRANCE	N.A.	FEMALE	70	Cardiac valve replacement complication	心臓弁置換合併症			SEVERE	YES	141	2	NO	RESOLVED
Enoxaparin/VKA	160023018	YES	FRANCE	N.A.	FEMALE	70	Cardiac valve replacement complication	心臓弁置換合併症			SEVERE	YES	161	53	NO	RESOLVED
Rivaroxaban	160023020	YES	FRANCE	N.A.	FEMALE	92	Upper limb fracture	上肢骨折	20 mg	I	SEVERE	YES	95	10	NO	RESOLVED
Enoxaparin/VKA	160023023	YES	FRANCE	N.A.	FEMALE	61	Nephrolithiasis	腎結石症			SEVERE	YES	20	13	NO	RESOLVED
Enoxaparin/VKA	160023029	YES	FRANCE	N.A.	FEMALE	63	Haematuria	血尿			SEVERE	YES	16	6	YES	RESOLVED
Enoxaparin/VKA	160033008	YES	FRANCE	N.A.	MALE	58	Myocardial ischaemia	心筋虚血			SEVERE	YES	21		NO	UNCHANGED
Rivaroxaban	160033013	YES	FRANCE	N.A.	FEMALE	60	Malaise	倦怠感	15 mg	.	MODERATE	YES	4	11	YES	RESOLVED
Rivaroxaban	160053004	YES	FRANCE	N.A.	FEMALE	18	Haemothorax	血胸	20 mg	.	SEVERE	YES	44	19	YES	RESOLVED
Enoxaparin/VKA	160053006	YES	FRANCE	N.A.	FEMALE	95	Arthralgia	関節痛			MILD	YES	169	10	NO	RESOLVED
Rivaroxaban	160053008	YES	FRANCE	N.A.	FEMALE	18	Non-cardiac chest pain	非心臓性胸痛	15 mg	.	MILD	YES	5	4	NO	RESOLVED
Rivaroxaban	160053009	YES	FRANCE	N.A.	MALE	70	Lung adenocarcinoma	肺腺癌	20 mg	.	SEVERE	YES	62	114	NO	DEATH
Enoxaparin/VKA	160063002	YES	FRANCE	N.A.	FEMALE	92	Cholelithiasis	胆石症			MILD	YES	46	4	NO	RESOLVED
Enoxaparin/VKA	160063004	YES	FRANCE	N.A.	MALE	69	Haemoptysis	喀血			MODERATE	YES	78	17	YES	RESOLVED
Rivaroxaban	160063006	YES	FRANCE	N.A.	MALE	56	Cardiac failure	心不全	20 mg	.	SEVERE	YES	29	6	NO	RESOLVED

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Rivaroxaban	160063006	YES	FRANCE	N.A.	MALE	56	Cardiac failure	心不全	20 mg	.	MODERATE	YES	180	5	NO	IMPROVED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Ischaemic stroke	虚血性脳卒中	15 mg	.	MODERATE	YES	11		NO	RESOLVED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Metastases to spine	脊椎転移	20 mg	.	SEVERE	YES	45	127	NO	WORSENED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Lung cancer metastatic	転移性肺癌	20 mg	.	SEVERE	YES	45		NO	UNCHANGED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Metastases to spine	脊椎転移	20 mg	.	SEVERE	YES	171		NO	WORSENED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Pneumonia	肺炎	20 mg	F	SEVERE	NO	191		NO	UNCHANGED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Cardiac failure acute	急性心不全	20 mg	F	SEVERE	NO	191		NO	UNCHANGED
Rivaroxaban	160063010	YES	FRANCE	N.A.	FEMALE	82	Coma	昏睡	20 mg	F	SEVERE	NO	197	3	NO	DEATH
Rivaroxaban	160063014	YES	FRANCE	N.A.	MALE	81	Intervertebral disc disorder	椎間板障害	20 mg	.	MODERATE	YES	91	20	NO	RESOLVED
Rivaroxaban	160063014	YES	FRANCE	N.A.	MALE	81	Intervertebral discitis	椎間板炎	20 mg	.	SEVERE	YES	101	10	NO	RESOLVED
Enoxaparin/VKA	160063018	YES	FRANCE	N.A.	MALE	39	Pleural effusion	胸水			MODERATE	YES	4	5	NO	RESOLVED
Enoxaparin/VKA	160063030	YES	FRANCE	N.A.	MALE	62	Subcutaneous haematoma	皮下血腫			MODERATE	YES	6	25	YES	RESOLVED
Rivaroxaban	160083003	YES	FRANCE	N.A.	MALE	25	Pleuritic pain	胸膜痛	15 mg	.	MILD	YES	5	4	NO	RESOLVED
Rivaroxaban	160083004	YES	FRANCE	N.A.	MALE	27	Traumatic fracture	外傷性骨折			MODERATE	NO	101	9	NO	RESOLVED
Enoxaparin/V	160083005	YES	FRANCE	N.A.	FEMALE	85	Tachycardia	頻脈			MILD	YES	33	2	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

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KA																
Enoxaparin/VKA	160083005	YES	FRANCE	N.A.	FEMALE	85	Tachycardia	頻脈			MILD	YES	69	2	NO	RESOLVED
Rivaroxaban	160083010	YES	FRANCE	N.A.	MALE	81	Epilepsy	てんかん	15 mg	.	MILD	YES	14	3	NO	RESOLVED
Rivaroxaban	160083010	YES	FRANCE	N.A.	MALE	81	Cerebral haemorrhage traumatic	外傷性脳出血	20 mg	.	SEVERE	YES	110	6	YES	DEATH
Enoxaparin/VKA	160083025	YES	FRANCE	N.A.	MALE	76	Prostatic adenoma	前立腺腺腫			MODERATE	YES	153	7	NO	RESOLVED
Enoxaparin/VKA	160083030	YES	FRANCE	N.A.	FEMALE	87	Death	死亡			SEVERE	YES	117	1	YES	DEATH
Rivaroxaban	160083034	YES	FRANCE	N.A.	MALE	78	Dyspnoea	呼吸困難	20 mg	.	MODERATE	YES	25	5	NO	RESOLVED
Rivaroxaban	160083034	YES	FRANCE	N.A.	MALE	78	Respiratory failure	呼吸不全	20 mg	.	MODERATE	YES	76	2	NO	RESOLVED
Rivaroxaban	160083038	YES	FRANCE	N.A.	MALE	76	Arrhythmia	不整脈	15 mg	.	MILD	YES	3	1	NO	RESOLVED
Enoxaparin/VKA	160083040	YES	FRANCE	N.A.	FEMALE	75	Respiratory failure	呼吸不全			SEVERE	YES	56	2	NO	DEATH
Enoxaparin/VKA	160083042	YES	FRANCE	N.A.	FEMALE	72	International normalised ratio increased	ＩＮＲ増加			SEVERE	YES	66	1	YES	RESOLVED
Enoxaparin/VKA	160083043	YES	FRANCE	N.A.	MALE	76	Respiratory failure	呼吸不全			SEVERE	YES	4	3	NO	DEATH
Rivaroxaban	160083053	YES	FRANCE	N.A.	MALE	73	Ankle fracture	足関節部骨折	20 mg	.	MILD	YES	99	7	NO	RESOLVED
Rivaroxaban	160083056	YES	FRANCE	N.A.	MALE	68	Ankle fracture	足関節部骨折	20 mg	.	MILD	YES	97	9	NO	RESOLVED

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Rivaroxaban	160083059	YES	FRANCE	N.A.	MALE	79	Rectal haemorrhage	直腸出血	20 mg	.	MODERATE	YES	120	12	YES	RESOLVED
Enoxaparin/VKA	160083061	YES	FRANCE	N.A.	MALE	54	Bipolar I disorder	双極 1 型障害			SEVERE	YES	100	21	NO	RESOLVED
Enoxaparin/VKA	160083061	YES	FRANCE	N.A.	MALE	54	Depression	うつ病			SEVERE	NO	159	36	NO	RESOLVED
Enoxaparin/VKA	160083083	YES	FRANCE	N.A.	FEMALE	80	Back pain	背部痛			MODERATE	NO	181	48	NO	RESOLVED
Rivaroxaban	160083084	YES	FRANCE	N.A.	FEMALE	80	Breast cancer recurrent	再発乳癌	20 mg	I	MODERATE	YES	104	5	NO	RESOLVED
Rivaroxaban	160083086	YES	FRANCE	N.A.	MALE	68	Anxiety	不安	15 mg	.	MILD	YES	5	2	NO	RESOLVED
Rivaroxaban	160083088	YES	FRANCE	N.A.	MALE	60	Delusion	妄想	20 mg	.	MODERATE	YES	23	27	NO	RESOLVED
Rivaroxaban	160083091	YES	FRANCE	N.A.	MALE	72	Haemorrhoidal haemorrhage	痔出血	20 mg	.	MILD	YES	105	8	YES	RESOLVED
Enoxaparin/VKA	160083125	YES	FRANCE	N.A.	FEMALE	78	Anaemia	貧血			MILD	YES	3	14	NO	RESOLVED
Enoxaparin/VKA	160083125	YES	FRANCE	N.A.	FEMALE	78	Myelodysplastic syndrome	骨髄異形成症候群			SEVERE	YES	13	6	NO	DEATH
Enoxaparin/VKA	160083130	YES	FRANCE	N.A.	MALE	68	Renal cancer	腎癌			SEVERE	NO	24	82	NO	RESOLVED
Enoxaparin/VKA	160083136	YES	FRANCE	N.A.	MALE	85	Lung disorder	肺障害			MODERATE	YES	45	65	NO	RESOLVED
Rivaroxaban	160103012	YES	FRANCE	N.A.	MALE	70	Brain neoplasm	脳新生物	15 mg	.	SEVERE	YES	2	20	NO	DEATH
Rivaroxaban	160103012	YES	FRANCE	N.A.	MALE	70	Tumour haemorrhage	腫瘍出血	15 mg	F	SEVERE	NO	16	6	NO	DEATH
Rivaroxaban	160103021	YES	FRANCE	N.A.	MALE	82	Chest pain	胸痛	15 mg	I	MILD	YES	21	3	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160103024	YES	FRANCE	N.A.	FEMALE	48	Ovarian germ cell teratoma benign	卵巣胚細胞良性奇形腫	20 mg	I	MILD	YES	113	1	NO	RESOLVED
Rivaroxaban	160103026	YES	FRANCE	N.A.	MALE	80	Bronchitis	気管支炎	20 mg	.	MILD	YES	64	37	NO	RESOLVED
Enoxaparin/VKA	160113001	YES	FRANCE	N.A.	FEMALE	70	Abdominal pain	腹痛			MODERATE	YES	132	27	NO	RESOLVED
Enoxaparin/VKA	160113006	YES	FRANCE	N.A.	MALE	52	Hepatitis	肝炎			SEVERE	NO	1	28	NO	RESOLVED
Enoxaparin/VKA	160113012	YES	FRANCE	N.A.	MALE	37	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MODERATE	YES	14	14	NO	RESOLVED
Rivaroxaban	160123003	YES	FRANCE	N.A.	MALE	78	Cardiac failure	心不全	20 mg	.	SEVERE	YES	41	11	NO	RESOLVED
Rivaroxaban	160123003	YES	FRANCE	N.A.	MALE	78	Melaena	メレナ	20 mg	I	MODERATE	YES	44	1	YES	RESOLVED
Rivaroxaban	160123003	YES	FRANCE	N.A.	MALE	78	Gastrointestinal dysplasia	胃腸異形成	20 mg	.	MODERATE	YES	64	3	NO	IMPROVED
Rivaroxaban	160123003	YES	FRANCE	N.A.	MALE	78	Cardiac failure	心不全	20 mg	.	MODERATE	YES	80	7	NO	RESOLVED
Rivaroxaban	160123003	YES	FRANCE	N.A.	MALE	78	Cardiac failure	心不全	20 mg	F	SEVERE	NO	196	1	NO	DEATH
Enoxaparin/VKA	160123005	YES	FRANCE	N.A.	MALE	79	Pleurisy	胸膜炎			MODERATE	YES	50	14	NO	RESOLVED
Rivaroxaban	160123010	YES	FRANCE	N.A.	MALE	82	Adenocarcinoma	腺癌	15 mg	.	SEVERE	YES	6		NO	UNCHANGED
Rivaroxaban	160123010	YES	FRANCE	N.A.	MALE	82	Ischaemic stroke	虚血性脳卒中	15 mg	.	SEVERE	YES	11	41	NO	DEATH
Enoxaparin/V	160123011	YES	FRANCE	N.A.	FEMALE	67	Pericardial	心嚢内出血			SEVERE	YES	89	34	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA							haemorrhage									
Rivaroxaban	160123021	YES	FRANCE	N.A.	FEMALE	32	Benign oesophageal neoplasm	食道の良性新生物	20 mg	I	MODERATE	YES	272	3	NO	RESOLVED
Rivaroxaban	160123024	YES	FRANCE	N.A.	FEMALE	70	Pericarditis	心膜炎	15 mg	.	MODERATE	YES	10	16	NO	RESOLVED
Enoxaparin/VKA	160123025	YES	FRANCE	N.A.	MALE	64	Urethral stenosis	尿道狭窄			MODERATE	NO	363	3	NO	RESOLVED
Rivaroxaban	160133002	YES	FRANCE	N.A.	MALE	74	Prostate cancer	前立腺癌	15 mg	I	MODERATE	YES	24		NO	UNCHANGED
Rivaroxaban	160133002	YES	FRANCE	N.A.	MALE	74	Sudden death	突然死	20 mg	.	SEVERE	YES	260	1	YES	DEATH
Rivaroxaban	160133002	YES	FRANCE	N.A.	MALE	74	Haematemesis	吐血	20 mg	.	SEVERE	YES	260	1	NO	RESOLVED
Rivaroxaban	160143013	YES	FRANCE	N.A.	MALE	72	Parkinsonism	パーキンソニズム			SEVERE	YES			NO	UNCHANGED
Enoxaparin/VKA	160143020	YES	FRANCE	N.A.	FEMALE	82	Amaurosis	黒内障			MODERATE	YES			NO	RESOLVED
Rivaroxaban	160143032	YES	FRANCE	N.A.	MALE	55	Chest pain	胸痛	15 mg	.	MILD	YES	6	22	NO	RESOLVED
Rivaroxaban	160143039	YES	FRANCE	N.A.	MALE	77	Sudden death	突然死	20 mg	.	SEVERE	YES	120	1	NO	DEATH
Rivaroxaban	160143040	YES	FRANCE	N.A.	MALE	83	Diverticulum oesophageal	食道憩室	20 mg	F	MILD	NO	193	2	NO	RESOLVED
Enoxaparin/VKA	160143041	YES	FRANCE	N.A.	MALE	32	Chest pain	胸痛			MILD	YES	111	2	NO	RESOLVED
Enoxaparin/VKA	160143041	YES	FRANCE	N.A.	MALE	32	Toxicity to various agents	各種物質毒性			MODERATE	YES	117	3	NO	RESOLVED
Enoxaparin/VKA	160153002	YES	FRANCE	N.A.	MALE	49	Kidney rupture	腎臓破裂			MILD	YES	16	8	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患			SEVERE	YES	15	24	NO	DEATH
Enoxaparin/VKA	160153015	YES	FRANCE	N.A.	FEMALE	65	Melaena	メレナ			MODERATE	YES	17	2	YES	RESOLVED
Rivaroxaban	160153030	YES	FRANCE	N.A.	FEMALE	80	Mitral valve incompetence	僧帽弁閉鎖不全症	20 mg	F	MODERATE	YES	357		NO	UNCHANGED
Rivaroxaban	160153030	YES	FRANCE	N.A.	FEMALE	80	Pericardial haemorrhage	心嚢内出血	20 mg	F	SEVERE	NO	358		NO	UNCHANGED
Rivaroxaban	160153030	YES	FRANCE	N.A.	FEMALE	80	Cardiogenic shock	心原性ショック	20 mg	F	SEVERE	NO	358	1	NO	DEATH
Rivaroxaban	160153034	YES	FRANCE	N.A.	FEMALE	82	Lung adenocarcinoma	肺腺癌	20 mg	.	SEVERE	YES	50		NO	IMPROVED
Rivaroxaban	160153040	YES	FRANCE	N.A.	MALE	63	Renal cell carcinoma	腎細胞癌	20 mg	.	MODERATE	YES	82		NO	IMPROVED
Enoxaparin/VKA	160153043	YES	FRANCE	N.A.	FEMALE	77	Temporal arteritis	側頭動脈炎			MILD	YES	95	8	NO	RESOLVED
Enoxaparin/VKA	160153053	YES	FRANCE	N.A.	FEMALE	83	Myocarditis	心筋炎			MODERATE	YES	136	36	NO	RESOLVED
Enoxaparin/VKA	160153053	YES	FRANCE	N.A.	FEMALE	83	Cardiac failure congestive	うっ血性心不全			MILD	YES	136	14	NO	RESOLVED
Enoxaparin/VKA	160153053	YES	FRANCE	N.A.	FEMALE	83	Transient ischaemic attack	一過性脳虚血発作			MILD	YES	315	9	NO	RESOLVED
Rivaroxaban	160153062	YES	FRANCE	N.A.	FEMALE	73	Transaminases increased	トランスアミナーゼ上昇	20 mg	.	MILD	YES	180	50	YES	RESOLVED
Rivaroxaban	160153065	YES	FRANCE	N.A.	FEMALE	78	Transient	一過性脳虚	20 mg	.	SEVERE	YES	64	8	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							ischaemic attack	血発作								
Rivaroxaban	160153065	YES	FRANCE	N.A.	FEMALE	78	Parkinson's disease	パーキンソン病	20 mg	.	MODERATE	YES	89	3	NO	RESOLVED
Enoxaparin/VKA	160153077	YES	FRANCE	N.A.	FEMALE	53	Depression	うつ病			MILD	YES	43	27	NO	RESOLVED
Enoxaparin/VKA	160153077	YES	FRANCE	N.A.	FEMALE	53	Depression	うつ病			MILD	YES	111	25	NO	RESOLVED
Enoxaparin/VKA	160153077	YES	FRANCE	N.A.	FEMALE	53	Alcohol abuse	アルコール乱用			MILD	YES	317	15	NO	RESOLVED
Enoxaparin/VKA	160153089	YES	FRANCE	N.A.	MALE	68	VIIth nerve paralysis	第７脳神経麻痺			MILD	YES	57	15	NO	RESOLVED
Rivaroxaban	160173002	YES	FRANCE	N.A.	MALE	77	Haematuria	血尿	20 mg	.	MODERATE	YES	39	6	YES	RESOLVED
Rivaroxaban	160173002	YES	FRANCE	N.A.	MALE	77	Haematuria	血尿	20 mg	.	MODERATE	YES	47	6	YES	RESOLVED
Enoxaparin/VKA	160173006	YES	FRANCE	N.A.	FEMALE	78	Intra-abdominal haematoma	腹腔内血腫			SEVERE	YES	7	35	YES	IMPROVED
Enoxaparin/VKA	160173006	YES	FRANCE	N.A.	FEMALE	78	Anaemia	貧血			SEVERE	YES	8	4	YES	IMPROVED
Enoxaparin/VKA	160173006	YES	FRANCE	N.A.	FEMALE	78	Hypovolaemia	血液量減少症			SEVERE	YES	8	1	YES	RESOLVED
Enoxaparin/VKA	160173006	YES	FRANCE	N.A.	FEMALE	78	Renal failure acute	急性腎不全			SEVERE	YES	8	5	YES	RESOLVED
Rivaroxaban	160173013	YES	FRANCE	N.A.	MALE	75	Amyotrophic lateral sclerosis	筋萎縮性側索硬化症	20 mg	F	MILD	NO	210	6	NO	RESOLVED
Rivaroxaban	160173014	YES	FRANCE	N.A.	FEMALE	49	Menorrhagia	月経過多	20 mg	.	MODERATE	YES	58	12	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	160173015	YES	FRANCE	N.A.	MALE	75	Prostate cancer	前立腺癌			MILD	YES	7	3	NO	RESOLVED
Enoxaparin/VKA	160173015	YES	FRANCE	N.A.	MALE	75	Haematuria	血尿			MODERATE	YES	9	6	YES	RESOLVED
Enoxaparin/VKA	160173015	YES	FRANCE	N.A.	MALE	75	Anuria	無尿			MODERATE	YES	9	6	NO	RESOLVED
Enoxaparin/VKA	160173015	YES	FRANCE	N.A.	MALE	75	Prostate cancer	前立腺癌			SEVERE	YES	14		NO	UNCHANGED
Enoxaparin/VKA	160173015	YES	FRANCE	N.A.	MALE	75	Appendiceal abscess	虫垂膿瘍			SEVERE	YES	54	17	NO	RESOLVED
Enoxaparin/VKA	160173029	YES	FRANCE	N.A.	MALE	84	Prostate infection	前立腺感染			MODERATE	YES	18	33	NO	RESOLVED
Enoxaparin/VKA	160173029	YES	FRANCE	N.A.	MALE	84	Aortic thrombosis	大動脈血栓症			SEVERE	YES	153	16	NO	RESOLVED
Enoxaparin/VKA	160173029	YES	FRANCE	N.A.	MALE	84	Aortic aneurysm	大動脈瘤			SEVERE	YES	153	16	NO	RESOLVED
Enoxaparin/VKA	160173029	YES	FRANCE	N.A.	MALE	84	Haemoptysis	喀血			SEVERE	YES	231	7	YES	RESOLVED
Enoxaparin/VKA	160173029	YES	FRANCE	N.A.	MALE	84	Lung squamous cell carcinoma stage unspecified	肺扁平上皮癌、病期不明			SEVERE	YES	236		NO	UNCHANGED
Enoxaparin/VKA	160173029	YES	FRANCE	N.A.	MALE	84	Arterial haemorrhage	動脈出血			MILD	NO	240	4	YES	RESOLVED
Rivaroxaban	160173033	YES	FRANCE	N.A.	MALE	71	Lymphocele	リンパ嚢腫	15 mg	.	MODERATE	YES	16	82	NO	RESOLVED
Enoxaparin/VKA	160173042	YES	FRANCE	N.A.	FEMALE	21	Pneumonia	肺炎			MODERATE	YES	9	12	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	160173043	YES	FRANCE	N.A.	MALE	77	Hypertension	高血圧			SEVERE	YES	148	3	NO	RESOLVED
Rivaroxaban	160173045	YES	FRANCE	N.A.	MALE	72	Acute respiratory failure	急性呼吸不全	20 mg	.	MODERATE	YES	107	14	NO	RESOLVED
Rivaroxaban	160173045	YES	FRANCE	N.A.	MALE	72	Acute respiratory failure	急性呼吸不全	20 mg	.	MODERATE	YES	291	9	NO	RESOLVED
Rivaroxaban	160173045	YES	FRANCE	N.A.	MALE	72	Acute respiratory failure	急性呼吸不全	20 mg	.	SEVERE	YES	313	28	NO	RESOLVED
Rivaroxaban	160173047	YES	FRANCE	N.A.	MALE	32	Joint injury	関節損傷	20 mg	.	MODERATE	YES	69	7	NO	RESOLVED
Rivaroxaban	160173047	YES	FRANCE	N.A.	MALE	32	Wound infection staphylococcal	ブドウ球菌性創感染	20 mg	I	MODERATE	YES	80	37	NO	RESOLVED
Rivaroxaban	160173057	YES	FRANCE	N.A.	FEMALE	87	Lung infection	肺感染	20 mg	.	MODERATE	YES	181	15	NO	RESOLVED
Rivaroxaban	160173058	YES	FRANCE	N.A.	FEMALE	71	Pyelonephritis	腎盂腎炎	20 mg	.	MODERATE	YES	49	10	NO	RESOLVED
Rivaroxaban	160173061	YES	FRANCE	N.A.	MALE	64	Anaemia	貧血	20 mg	.	MODERATE	YES	35	17	YES	RESOLVED
Rivaroxaban	160173061	YES	FRANCE	N.A.	MALE	64	Colorectal cancer	結腸直腸癌	20 mg	.	SEVERE	YES	42		NO	UNCHANGED
Rivaroxaban	160173063	YES	FRANCE	N.A.	MALE	60	Panic attack	パニック発作	20 mg	.	MILD	YES	24	2	NO	RESOLVED
Rivaroxaban	160183005	YES	FRANCE	N.A.	FEMALE	63	Hepatitis acute	急性肝炎	15 mg	.	SEVERE	YES	18		YES	WORSENED
Rivaroxaban	160183005	YES	FRANCE	N.A.	FEMALE	63	Cardiac failure	心不全	15 mg	F	SEVERE	NO	21	6	NO	DEATH

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

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Enoxaparin/VKA	160193002	YES	FRANCE	N.A.	MALE	82	Prostate cancer	前立腺癌			SEVERE	YES	36	2	NO	IMPROVED
Enoxaparin/VKA	160193002	YES	FRANCE	N.A.	MALE	82	Cataract	白内障			MODERATE	YES	177	3	NO	RESOLVED
Rivaroxaban	160193004	YES	FRANCE	N.A.	FEMALE	73	Haemoptysis	喀血	20 mg	.	MODERATE	YES	93	1	YES	RESOLVED
Enoxaparin/VKA	160193009	YES	FRANCE	N.A.	FEMALE	57	Angioedema	血管浮腫			MODERATE	YES	143	2	NO	RESOLVED
Enoxaparin/VKA	160193014	YES	FRANCE	N.A.	MALE	85	Haematuria	血尿			MILD	YES	5	7	YES	RESOLVED
Enoxaparin/VKA	160193014	YES	FRANCE	N.A.	MALE	85	Overdose	過量投与			MILD	YES	30	1	YES	RESOLVED
Enoxaparin/VKA	160193032	YES	FRANCE	N.A.	MALE	73	Abdominal pain upper	上腹部痛			MILD	YES	340	2	NO	RESOLVED
Rivaroxaban	160193035	YES	FRANCE	N.A.	MALE	56	Malignant melanoma	悪性黒色腫	15 mg	.	SEVERE	YES	6	47	NO	WORSENED
Rivaroxaban	160193035	YES	FRANCE	N.A.	MALE	56	Malignant melanoma	悪性黒色腫	20 mg	.	MODERATE	YES	52	5	NO	IMPROVED
Rivaroxaban	160193035	YES	FRANCE	N.A.	MALE	56	Urinary retention	尿閉	20 mg	.	MODERATE	YES	54	4	NO	RESOLVED
Rivaroxaban	160193035	YES	FRANCE	N.A.	MALE	56	Malignant melanoma	悪性黒色腫	20 mg	.	MODERATE	YES	101	2	NO	RESOLVED
Enoxaparin/VKA	160193042	YES	FRANCE	N.A.	MALE	47	Pharyngeal cyst	咽頭嚢腫			MODERATE	YES	112	3	NO	RESOLVED
Enoxaparin/VKA	160193048	YES	FRANCE	N.A.	FEMALE	20	Haemothorax	血胸			SEVERE	YES	14	7	NO	RESOLVED
Rivaroxaban	160203003	YES	FRANCE	N.A.	FEMALE	71	Acute left	急性左室不	20 mg	.	SEVERE	YES	253	2	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							ventricular failure	全								
Rivaroxaban	160203003	YES	FRANCE	N.A.	FEMALE	71	Angina unstable	不安定狭心症	20 mg	F	SEVERE	NO	290	2	NO	RESOLVED
Rivaroxaban	160203006	YES	FRANCE	N.A.	FEMALE	77	Extranodal marginal zone B-cell lymphoma (MALT type)	節外周辺帯Ｂ細胞リンパ腫（ＭＡＬＴ型）	20 mg	.	MILD	YES	103		NO	IMPROVED
Enoxaparin/VKA	160203009	YES	FRANCE	N.A.	MALE	82	Ileus	イレウス			MODERATE	YES	4		NO	INSUFFICIENT FOLLOW-UP
Enoxaparin/VKA	160203010	YES	FRANCE	N.A.	FEMALE	66	Complex regional pain syndrome	複合性局所疼痛症候群			MODERATE	YES	70	54	NO	RESOLVED
Enoxaparin/VKA	160203012	YES	FRANCE	N.A.	FEMALE	86	Melaena	メレナ			SEVERE	YES	42	2	YES	RESOLVED
Enoxaparin/VKA	160203012	YES	FRANCE	N.A.	FEMALE	86	Muscle haemorrhage	筋肉内出血			SEVERE	YES	95	8	YES	RESOLVED
Enoxaparin/VKA	160203012	YES	FRANCE	N.A.	FEMALE	86	Bronchopneumonia	気管支肺炎			SEVERE	YES	203	11	NO	RESOLVED
Rivaroxaban	160203019	YES	FRANCE	N.A.	FEMALE	67	Sepsis	敗血症	15 mg	.	SEVERE	YES	4	4	NO	RESOLVED
Rivaroxaban	160203019	YES	FRANCE	N.A.	FEMALE	67	Rectal cancer	直腸癌	15 mg	.	SEVERE	YES	7	10	NO	RESOLVED
Enoxaparin/VKA	160203024	YES	FRANCE	N.A.	MALE	80	Prostate cancer recurrent	再発前立腺癌			SEVERE	YES	76		NO	UNCHANGED
Rivaroxaban	160203026	YES	FRANCE	N.A.	MALE	76	Inguinal hernia	鼠径ヘルニア	20 mg	I	MODERATE	YES	98	4	NO	RESOLVED
Enoxaparin/VKA	160203028	YES	FRANCE	N.A.	FEMALE	36	Chest pain	胸痛			MODERATE	YES	86	6	NO	RESOLVED
Enoxaparin/V	160203028	YES	FRANCE	N.A.	FEMALE	36	Thyroid cancer	甲状腺癌			SEVERE	YES	175	5	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA																
Enoxaparin/VKA	160203028	YES	FRANCE	N.A.	FEMALE	36	Hypercalcaemia	高カルシウム血症			SEVERE	YES	190	3	NO	RESOLVED
Enoxaparin/VKA	160203028	YES	FRANCE	N.A.	FEMALE	36	Thyroid cancer	甲状腺癌			MILD	YES	223	4	NO	RESOLVED
Enoxaparin/VKA	160213006	YES	FRANCE	N.A.	FEMALE	93	Bladder dilatation	膀胱拡大			SEVERE	YES	14	23	NO	RESOLVED
Enoxaparin/VKA	160213008	YES	FRANCE	N.A.	FEMALE	74	Anorectal disorder	肛門直腸障害			MILD	YES	73	5	NO	RESOLVED
Enoxaparin/VKA	160213008	YES	FRANCE	N.A.	FEMALE	74	Anaemia	貧血			SEVERE	NO	208	24	YES	RESOLVED
Enoxaparin/VKA	160213014	YES	FRANCE	N.A.	FEMALE	79	Bladder neoplasm	膀胱新生物			MODERATE	YES	88	4	NO	RESOLVED
Enoxaparin/VKA	160213014	YES	FRANCE	N.A.	FEMALE	79	Joint dislocation	関節脱臼			SEVERE	YES	106	18	NO	RESOLVED
Enoxaparin/VKA	160213021	YES	FRANCE	N.A.	FEMALE	89	Hyperthyroidism	甲状腺機能亢進症			MODERATE	YES	97		NO	IMPROVED
Enoxaparin/VKA	160213029	YES	FRANCE	N.A.	FEMALE	40	Abortion induced	人工流産			MODERATE	YES	71	1	NO	RESOLVED
Rivaroxaban	160213031	YES	FRANCE	N.A.	FEMALE	47	Angina unstable	不安定狭心症			SEVERE	YES			NO	RESOLVED
Rivaroxaban	160213031	YES	FRANCE	N.A.	FEMALE	47	Chest pain	胸痛	20 mg	.	MILD	YES	92	4	NO	RESOLVED
Rivaroxaban	160213031	YES	FRANCE	N.A.	FEMALE	47	Anaemia	貧血	20 mg	.	MODERATE	YES	134	3	YES	RESOLVED
Rivaroxaban	160213035	YES	FRANCE	N.A.	FEMALE	50	Ischaemic stroke	虚血性脳卒中	15 mg	F	MODERATE	YES	3	1	NO	IMPROVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

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Enoxaparin/VKA	160213036	YES	FRANCE	N.A.	FEMALE	81	Bronchitis	気管支炎			MODERATE	YES	89	6	NO	RESOLVED
Enoxaparin/VKA	160213037	YES	FRANCE	N.A.	FEMALE	67	Renal colic	腎仙痛			MODERATE	YES	289	4	NO	RESOLVED
Enoxaparin/VKA	160213041	YES	FRANCE	N.A.	MALE	62	Prostate cancer	前立腺癌			SEVERE	YES	128		NO	UNCHANGED
Rivaroxaban	160213042	YES	FRANCE	N.A.	FEMALE	90	Haematemesis	吐血	15 mg	.	SEVERE	YES	21	1	YES	RESOLVED
Rivaroxaban	160223001	YES	FRANCE	N.A.	MALE	48	Gastroenteritis salmonella	サルモネラ菌性胃腸炎	20 mg	.	MODERATE	YES	26	7	NO	RESOLVED
Enoxaparin/VKA	160223006	YES	FRANCE	N.A.	MALE	23	Transaminases increased	トランスアミナーゼ上昇			MILD	YES	15	27	YES	RESOLVED
Rivaroxaban	160223007	YES	FRANCE	N.A.	MALE	48	Depression	うつ病	20 mg	.	SEVERE	YES	338	7	NO	IMPROVED
Rivaroxaban	160223018	YES	FRANCE	N.A.	FEMALE	84	Sciatica	坐骨神経痛	20 mg	.	MILD	YES	195	10	NO	RESOLVED
Rivaroxaban	160223020	YES	FRANCE	N.A.	MALE	65	Lung disorder	肺障害	20 mg	F	MODERATE	NO	295	10	NO	RESOLVED
Enoxaparin/VKA	160233003	YES	FRANCE	N.A.	MALE	79	Pneumonia	肺炎			MODERATE	YES	24	14	NO	RESOLVED
Enoxaparin/VKA	160233003	YES	FRANCE	N.A.	MALE	79	Bronchitis	気管支炎			MODERATE	YES	216	13	NO	RESOLVED
Enoxaparin/VKA	160233003	YES	FRANCE	N.A.	MALE	79	Transient ischaemic attack	一過性脳虚血発作			MODERATE	YES	277	1	NO	RESOLVED
Rivaroxaban	160233009	YES	FRANCE	N.A.	MALE	67	Hyperglycaemia	高血糖	20 mg	.	MILD	YES	208	10	NO	RESOLVED
Rivaroxaban	160233010	YES	FRANCE	N.A.	FEMALE	78	Urinary tract infection	尿路感染	20 mg	.	MILD	YES	49	5	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160233010	YES	FRANCE	N.A.	FEMALE	78	Intestinal haemorrhage	腸出血	20 mg	.	MODERATE	YES	237	8	YES	RESOLVED
Rivaroxaban	160233013	YES	FRANCE	N.A.	FEMALE	71	Infectious peritonitis	感染性腹膜炎	15 mg	.	SEVERE	YES	7	19	NO	RESOLVED
Enoxaparin/VKA	160233017	YES	FRANCE	N.A.	MALE	44	Device deposit issue	医療機器沈着物の問題			MODERATE	YES	91	16	NO	RESOLVED
Rivaroxaban	160233020	YES	FRANCE	N.A.	FEMALE	71	Breast neoplasm	乳房新生物	20 mg	I	MODERATE	YES	60	11	NO	RESOLVED
Rivaroxaban	160233022	YES	FRANCE	N.A.	FEMALE	74	Epistaxis	鼻出血	15 mg	.	MILD	YES	10	1	YES	RESOLVED
Enoxaparin/VKA	160233027	YES	FRANCE	N.A.	MALE	68	Priapism	持続勃起症			MODERATE	YES	69	3	YES	RESOLVED
Enoxaparin/VKA	160233027	YES	FRANCE	N.A.	MALE	68	International normalised ratio increased	ＩＮＲ増加			MODERATE	YES	69	4	YES	RESOLVED
Enoxaparin/VKA	160233027	YES	FRANCE	N.A.	MALE	68	Pyelonephritis acute	急性腎盂腎炎			MODERATE	YES	149	14	NO	RESOLVED
Enoxaparin/VKA	160233027	YES	FRANCE	N.A.	MALE	68	Arthralgia	関節痛			MODERATE	YES	171	10	NO	RESOLVED
Enoxaparin/VKA	160233027	YES	FRANCE	N.A.	MALE	68	Cardiac failure acute	急性心不全			MILD	YES	289	6	NO	RESOLVED
Enoxaparin/VKA	160233027	YES	FRANCE	N.A.	MALE	68	Lung infection	肺感染			MODERATE	YES	312	7	NO	RESOLVED
Enoxaparin/VKA	160233027	YES	FRANCE	N.A.	MALE	68	Arrhythmia	不整脈			MODERATE	YES	343	11	NO	RESOLVED
Rivaroxaban	160233028	YES	FRANCE	N.A.	MALE	65	Ischaemic stroke	虚血性脳卒中	20 mg	.	MODERATE	YES	231	15	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160233031	YES	FRANCE	N.A.	MALE	90	Dental caries	齲歯	20 mg	.	MILD	YES	51	4	NO	RESOLVED
Enoxaparin/VKA	160233036	YES	FRANCE	N.A.	FEMALE	87	Muscle haemorrhage	筋肉内出血			MODERATE	YES	19	8	YES	RESOLVED
Enoxaparin/VKA	160233064	YES	FRANCE	N.A.	MALE	31	Depression	うつ病			MODERATE	YES	286		NO	UNCHANGED
Enoxaparin/VKA	160233070	YES	FRANCE	N.A.	FEMALE	57	Pyelonephritis	腎盂腎炎			MODERATE	YES	317	7	NO	RESOLVED
Enoxaparin/VKA	160233075	YES	FRANCE	N.A.	MALE	62	Amyotrophic lateral sclerosis	筋萎縮性側索硬化症			SEVERE	NO	106	76	NO	DEATH
Rivaroxaban	160233078	YES	FRANCE	N.A.	MALE	73	Right ventricular failure	右室不全	20 mg	.	MODERATE	YES	197	16	NO	RESOLVED
Enoxaparin/VKA	160233079	YES	FRANCE	N.A.	MALE	63	Benign prostatic hyperplasia	良性前立腺肥大症			MODERATE	NO	373	6	NO	RESOLVED
Enoxaparin/VKA	160233083	YES	FRANCE	N.A.	MALE	53	Hepatic enzyme increased	肝酵素上昇			MODERATE	YES	6	28	YES	RESOLVED
Enoxaparin/VKA	160233085	YES	FRANCE	N.A.	FEMALE	85	Large intestine perforation	大腸穿孔			MODERATE	YES	220	18	NO	RESOLVED
Rivaroxaban	160233086	YES	FRANCE	N.A.	MALE	60	Vertigo	回転性めまい	20 mg	.	MILD	YES	147	2	NO	RESOLVED
Enoxaparin/VKA	160233089	YES	FRANCE	N.A.	FEMALE	83	Muscle haemorrhage	筋肉内出血			SEVERE	YES	12	37	YES	RESOLVED
Rivaroxaban	160233093	YES	FRANCE	N.A.	MALE	25	Hepatic enzyme increased	肝酵素上昇	15 mg	.	MILD	YES	4	7	NO	RESOLVED
Rivaroxaban	160233099	YES	FRANCE	N.A.	MALE	77	Prostatic adenoma	前立腺腺腫	20 mg	.	MODERATE	YES	120	5	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160233104	YES	FRANCE	N.A.	FEMALE	83	Cytolytic hepatitis	肝細胞融解性肝炎	15 mg	.	MODERATE	YES	9	9	YES	RESOLVED
Enoxaparin/VKA	160233107	YES	FRANCE	N.A.	MALE	55	Lung neoplasm	肺新生物			MILD	YES	60	3	NO	RESOLVED
Rivaroxaban	160243009	YES	FRANCE	N.A.	MALE	35	Mania	躁病	20 mg	.	MODERATE	YES	64	10	NO	RESOLVED
Enoxaparin/VKA	160243015	YES	FRANCE	N.A.	FEMALE	82	Eye haemorrhage	眼出血			SEVERE	YES	38		NO	UNCHANGED
Enoxaparin/VKA	160243015	YES	FRANCE	N.A.	FEMALE	82	Age-related macular degeneration	加齢黄斑変性			SEVERE	YES	38		NO	UNCHANGED
Enoxaparin/VKA	160243015	YES	FRANCE	N.A.	FEMALE	82	Retinal haemorrhage	網膜出血			SEVERE	YES	154	6	YES	RESOLVED
Enoxaparin/VKA	160243026	YES	FRANCE	N.A.	FEMALE	61	Lung neoplasm malignant	肺の悪性新生物			SEVERE	YES	135		NO	UNCHANGED
Rivaroxaban	160243028	YES	FRANCE	N.A.	FEMALE	87	Death	死亡	20 mg	.	SEVERE	YES	136	1	YES	DEATH
Enoxaparin/VKA	160243029	YES	FRANCE	N.A.	MALE	84	Dementia Alzheimer's type	アルツハイマー型認知症			SEVERE	YES	142		NO	UNCHANGED
Enoxaparin/VKA	160243029	YES	FRANCE	N.A.	MALE	84	Pneumothorax	気胸			MODERATE	YES	148	2	NO	RESOLVED
Enoxaparin/VKA	160243029	YES	FRANCE	N.A.	MALE	84	Haemorrhage intracranial	頭蓋内出血			SEVERE	YES	166	4	YES	DEATH
Rivaroxaban	160243030	YES	FRANCE	N.A.	MALE	54	Cardiac failure acute	急性心不全	20 mg	.	MODERATE	YES	53	75	NO	DEATH
Rivaroxaban	160243030	YES	FRANCE	N.A.	MALE	54	Cardiac failure	心不全	20 mg	F	SEVERE	YES	127	1	NO	DEATH
Rivaroxaban	160263007	YES	FRANCE	N.A.	MALE	39	Anaemia	貧血	20 mg	.	SEVERE	YES	32	4	NO	RESOLVED

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Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160263007	YES	FRANCE	N.A.	MALE	39	Acute respiratory distress syndrome	急性呼吸窮迫症候群	20 mg	.	SEVERE	YES	40	1	NO	DEATH
Enoxaparin/VKA	160263012	YES	FRANCE	N.A.	MALE	85	Pancreatitis acute	急性膵炎			SEVERE	YES	26	23	NO	RESOLVED
Enoxaparin/VKA	160263012	YES	FRANCE	N.A.	MALE	85	Carotid artery stenosis	頚動脈狭窄			MILD	YES	41	31	NO	RESOLVED
Enoxaparin/VKA	160263018	YES	FRANCE	N.A.	MALE	68	Muscle haemorrhage	筋肉内出血			SEVERE	YES	4		YES	UNCHANGED
Enoxaparin/VKA	160263018	YES	FRANCE	N.A.	MALE	68	Haemothorax	血胸			SEVERE	YES	8	4	YES	RESOLVED
Enoxaparin/VKA	160263018	YES	FRANCE	N.A.	MALE	68	Muscle haemorrhage	筋肉内出血			SEVERE	YES	100		YES	IMPROVED
Rivaroxaban	160273006	YES	FRANCE	N.A.	FEMALE	69	Sciatica	坐骨神経痛	20 mg	.	SEVERE	YES	100	11	NO	RESOLVED
Enoxaparin/VKA	160273009	YES	FRANCE	N.A.	FEMALE	77	Dyspnoea	呼吸困難			MODERATE	YES	227	7	NO	RESOLVED
Enoxaparin/VKA	160273009	YES	FRANCE	N.A.	FEMALE	77	Pulmonary arterial hypertension	肺動脈高血圧症			SEVERE	NO	358		NO	UNCHANGED
Enoxaparin/VKA	160273024	YES	FRANCE	N.A.	FEMALE	72	Chest pain	胸痛			MODERATE	YES	335	2	NO	RESOLVED
Enoxaparin/VKA	160273024	YES	FRANCE	N.A.	FEMALE	72	Dizziness	浮動性めまい			MODERATE	NO	357	4	NO	RESOLVED
Enoxaparin/VKA	160273026	YES	FRANCE	N.A.	MALE	77	Atrial fibrillation	心房細動			MODERATE	YES	57	3	NO	RESOLVED
Rivaroxaban	160273027	YES	FRANCE	N.A.	MALE	40	Diabetes mellitus	糖尿病			MILD	YES	149	4	NO	RESOLVED

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Enoxaparin/VKA	160273041	YES	FRANCE	N.A.	MALE	70	Spinal cord compression	脊髄圧迫			SEVERE	YES	51		NO	UNCHANGED
Enoxaparin/VKA	160273041	YES	FRANCE	N.A.	MALE	70	Metastatic neoplasm	転移性新生物			SEVERE	YES	51	52	NO	DEATH
Rivaroxaban	160283004	YES	FRANCE	N.A.	MALE	34	Tachycardia	頻脈	20 mg	.	MILD	YES	23	2	NO	RESOLVED
Enoxaparin/VKA	160283008	YES	FRANCE	N.A.	FEMALE	36	Oedema peripheral	末梢性浮腫			MILD	YES	145	7	NO	RESOLVED
Rivaroxaban	160293004	YES	FRANCE	N.A.	MALE	81	Ventricular tachycardia	心室性頻脈	20 mg	.	SEVERE	YES	136	11	NO	RESOLVED
Rivaroxaban	160293022	YES	FRANCE	N.A.	FEMALE	69	Intra-abdominal haemorrhage	腹腔内出血	15 mg	.	SEVERE	YES	3	12	YES	RESOLVED
Rivaroxaban	160293025	YES	FRANCE	N.A.	FEMALE	63	Urinary tract infection	尿路感染	20 mg	F	MODERATE	NO	190	9	NO	RESOLVED
Rivaroxaban	160293030	YES	FRANCE	N.A.	FEMALE	63	Ischaemic stroke	虚血性脳卒中	20 mg	F	SEVERE	NO	187	32	NO	RESOLVED
Rivaroxaban	160293044	YES	FRANCE	N.A.	FEMALE	57	Metrorrhagia	不正子宮出血	15 mg	.	MODERATE	YES	7	69	YES	RESOLVED
Enoxaparin/VKA	160293045	YES	FRANCE	N.A.	FEMALE	71	Osteoarthritis	変形性関節症			MODERATE	YES	166	4	NO	RESOLVED
Enoxaparin/VKA	160293045	YES	FRANCE	N.A.	FEMALE	71	Musculoskeletal chest pain	筋骨格系胸痛			MODERATE	YES	200	5	NO	RESOLVED
Enoxaparin/VKA	160293045	YES	FRANCE	N.A.	FEMALE	71	Lung infection	肺感染			MODERATE	YES	277	19	NO	RESOLVED
Rivaroxaban	160293054	YES	FRANCE	N.A.	MALE	58	Gait disturbance	歩行障害	15 mg	.	MODERATE	YES	16	5	NO	RESOLVED
Rivaroxaban	160293054	YES	FRANCE	N.A.	MALE	58	Balance disorder	平衡障害	15 mg	.	MILD	YES	16	5	NO	RESOLVED

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Enoxaparin/VKA	160293055	YES	FRANCE	N.A.	MALE	59	Gastric haemorrhage	胃出血			SEVERE	YES	21	6	YES	RESOLVED
Enoxaparin/VKA	160293055	YES	FRANCE	N.A.	MALE	59	Haematuria	血尿			SEVERE	YES	21	6	YES	RESOLVED
Enoxaparin/VKA	160293055	YES	FRANCE	N.A.	MALE	59	Gastrointestinal haemorrhage	胃腸出血			SEVERE	NO	360	12	NO	RESOLVED
Rivaroxaban	160293056	YES	FRANCE	N.A.	FEMALE	84	Femoral neck fracture	大腿骨頚部骨折	20 mg	.	SEVERE	YES	304		NO	IMPROVED
Enoxaparin/VKA	160293058	YES	FRANCE	N.A.	FEMALE	85	Haemorrhoidal haemorrhage	痔出血			MILD	YES	39	2	NO	RESOLVED
Rivaroxaban	160293064	YES	FRANCE	N.A.	FEMALE	87	Joint abscess	関節膿瘍	15 mg	I	SEVERE	YES	3	11	NO	RESOLVED
Rivaroxaban	160293076	YES	FRANCE	N.A.	FEMALE	73	Cardiac failure	心不全	20 mg	.	MODERATE	YES	72	11	NO	RESOLVED
Enoxaparin/VKA	160293078	YES	FRANCE	N.A.	MALE	87	Cerebral haemorrhage	脳出血			SEVERE	YES	135	1	YES	DEATH
Rivaroxaban	160293080	YES	FRANCE	N.A.	FEMALE	51	Ischaemic stroke	虚血性脳卒中	15 mg	.	SEVERE	YES	7		NO	UNCHANGED
Rivaroxaban	160293080	YES	FRANCE	N.A.	FEMALE	51	Endocarditis	心内膜炎	15 mg	.	MODERATE	YES	7	11	NO	DEATH
Rivaroxaban	160293080	YES	FRANCE	N.A.	FEMALE	51	Sepsis	敗血症	15 mg	.	SEVERE	YES	7	11	NO	DEATH
Rivaroxaban	160293083	YES	FRANCE	N.A.	FEMALE	46	Infectious peritonitis	感染性腹膜炎	20 mg	I	SEVERE	YES	45	15	NO	RESOLVED
Rivaroxaban	160293083	YES	FRANCE	N.A.	FEMALE	46	Lung disorder	肺障害	20 mg	I	MODERATE	YES	52	8	NO	RESOLVED
Rivaroxaban	160293083	YES	FRANCE	N.A.	FEMALE	46	Large intestine perforation	大腸穿孔	20 mg	.	MILD	YES	135	8	NO	RESOLVED
Rivaroxaban	160293084	YES	FRANCE	N.A.	FEMALE	84	Haematoma	血腫	20 mg	F	MODERATE	NO	368	11	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160293099	YES	FRANCE	N.A.	MALE	85	Prostatic adenoma	前立腺腺腫	20 mg	.	MODERATE	YES	78	9	NO	RESOLVED
Enoxaparin/VKA	160293102	YES	FRANCE	N.A.	MALE	74	Prostate cancer	前立腺癌			MODERATE	YES	8		NO	UNCHANGED
Enoxaparin/VKA	160293102	YES	FRANCE	N.A.	MALE	74	Aortic aneurysm rupture	大動脈瘤破裂			SEVERE	NO	30	14	NO	RESOLVED
Rivaroxaban	160293103	YES	FRANCE	N.A.	FEMALE	80	Acute myocardial infarction	急性心筋梗塞	15 mg	.	SEVERE	YES	17	6	NO	DEATH
Enoxaparin/VKA	160293107	YES	FRANCE	N.A.	FEMALE	79	Cerebral haemorrhage	脳出血			MODERATE	YES	27	18	YES	RESOLVED
Rivaroxaban	160293110	YES	FRANCE	N.A.	FEMALE	67	Pneumonia	肺炎	15 mg	.	MODERATE	YES	19		NO	IMPROVED
Rivaroxaban	160293113	YES	FRANCE	N.A.	FEMALE	81	Cardiac failure acute	急性心不全	20 mg	F	MODERATE	NO	206		NO	UNCHANGED
Rivaroxaban	160303003	YES	FRANCE	N.A.	MALE	57	General physical health deterioration	全身健康状態低下	20 mg	.	MILD	YES	72	4	NO	RESOLVED
Enoxaparin/VKA	160303009	YES	FRANCE	N.A.	FEMALE	46	Liver function test abnormal	肝機能検査異常			MILD	YES	5	52	YES	RESOLVED
Rivaroxaban	160303010	YES	FRANCE	N.A.	FEMALE	53	Uterine leiomyoma	子宮平滑筋腫	20 mg	I	MODERATE	YES	178	6	NO	RESOLVED
Rivaroxaban	160303011	YES	FRANCE	N.A.	FEMALE	36	Paradoxical embolism	奇異性塞栓症	15 mg	.	SEVERE	YES	3	16	NO	IMPROVED
Enoxaparin/VKA	160303012	YES	FRANCE	N.A.	FEMALE	76	Ovarian cyst	卵巣嚢胞			SEVERE	YES	28	78	NO	RESOLVED
Rivaroxaban	160303014	YES	FRANCE	N.A.	MALE	81	Anaemia	貧血	20 mg	.	SEVERE	YES	221	17	YES	RESOLVED
Enoxaparin/V	160303016	YES	FRANCE	N.A.	MALE	61	Aortic aneurysm	大動脈瘤			SEVERE	YES	338	12	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA																
Enoxaparin/VKA	160303016	YES	FRANCE	N.A.	MALE	61	Abdominal pain upper	上腹部痛			SEVERE	NO	361	24	NO	RESOLVED
Rivaroxaban	160303021	YES	FRANCE	N.A.	FEMALE	72	Pulmonary hypertension	肺高血圧症	20 mg	F	MILD	NO	377		NO	UNCHANGED
Enoxaparin/VKA	160303024	YES	FRANCE	N.A.	MALE	48	Renal cyst	腎嚢胞			SEVERE	YES	199	8	NO	RESOLVED
Rivaroxaban	160303025	YES	FRANCE	N.A.	MALE	46	Chest pain	胸痛	15 mg	.	MILD	YES	18	2	NO	RESOLVED
Rivaroxaban	160303027	YES	FRANCE	N.A.	MALE	59	Bronchopulmonary aspergillosis	気管支肺アスペルギルス症	20 mg	.	SEVERE	YES	44	55	NO	DEATH
Rivaroxaban	160303027	YES	FRANCE	N.A.	MALE	59	Pulmonary haemorrhage	肺出血	20 mg	.	SEVERE	YES	76	23	NO	DEATH
Enoxaparin/VKA	160303031	YES	FRANCE	N.A.	FEMALE	49	Abdominal pain upper	上腹部痛			MILD	YES	7	2	NO	RESOLVED
Enoxaparin/VKA	160303031	YES	FRANCE	N.A.	FEMALE	49	Splenic haematoma	脾血腫			SEVERE	YES	105		YES	IMPROVED
Enoxaparin/VKA	160303036	YES	FRANCE	N.A.	FEMALE	35	Colon cancer	結腸癌			MILD	NO	383	2	NO	RESOLVED
Rivaroxaban	160303041	YES	FRANCE	N.A.	FEMALE	64	Glomerulonephritis membranous	膜性糸球体腎炎	20 mg	I	SEVERE	YES	28	2	NO	IMPROVED
Rivaroxaban	160303041	YES	FRANCE	N.A.	FEMALE	64	Glomerulonephritis membranous	膜性糸球体腎炎	20 mg	.	MODERATE	YES	45	2	NO	IMPROVED
Rivaroxaban	160303044	YES	FRANCE	N.A.	MALE	75	Atrial flutter	心房粗動	20 mg	.	MODERATE	YES	196	4	NO	RESOLVED
Rivaroxaban	160303044	YES	FRANCE	N.A.	MALE	75	Ischaemic stroke	虚血性脳卒中	20 mg	.	MODERATE	YES	261	9	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	160303047	YES	FRANCE	N.A.	FEMALE	35	Chest pain	胸痛	20 mg	.	MILD	YES	177	2	NO	RESOLVED
Rivaroxaban	160303047	YES	FRANCE	N.A.	FEMALE	35	Atrial septal defect	心房中隔欠損症	20 mg	.	MILD	YES	210	5	NO	RESOLVED
Rivaroxaban	160303047	YES	FRANCE	N.A.	FEMALE	35	Atrial septal defect	心房中隔欠損症	20 mg	.	MILD	YES	231	2	NO	RESOLVED
Rivaroxaban	160303047	YES	FRANCE	N.A.	FEMALE	35	Atrial septal defect	心房中隔欠損症	20 mg	.	MILD	YES	247	3	NO	RESOLVED
Rivaroxaban	160303048	YES	FRANCE	N.A.	MALE	55	Depression	うつ病	20 mg	.	MODERATE	YES	112	45	NO	RESOLVED
Rivaroxaban	160303048	YES	FRANCE	N.A.	MALE	55	Depression	うつ病	20 mg	F	MILD	NO	316	15	NO	RESOLVED
Enoxaparin/VKA	160303051	YES	FRANCE	N.A.	FEMALE	20	Lung disorder	肺障害			MILD	YES	9	3	NO	RESOLVED
Enoxaparin/VKA	160303051	YES	FRANCE	N.A.	FEMALE	20	Chest pain	胸痛			MILD	YES	29	3	NO	RESOLVED
Enoxaparin/VKA	160303051	YES	FRANCE	N.A.	FEMALE	20	International normalised ratio abnormal	ＩＮＲ異常			MILD	YES	50	10	YES	RESOLVED
Enoxaparin/VKA	160303051	YES	FRANCE	N.A.	FEMALE	20	Thoracic vertebral fracture	胸椎骨折			MODERATE	YES	324	57	NO	IMPROVED
Rivaroxaban	160323002	YES	FRANCE	N.A.	FEMALE	87	Syncope	失神	15 mg	.	SEVERE	YES	4	5	YES	RESOLVED
Rivaroxaban	160323002	YES	FRANCE	N.A.	FEMALE	87	Anaemia	貧血	20 mg	.	SEVERE	YES	22	4	NO	RESOLVED
Rivaroxaban	160323002	YES	FRANCE	N.A.	FEMALE	87	Syncope	失神	20 mg	.	SEVERE	YES	22	10	YES	RESOLVED
Rivaroxaban	160323014	YES	FRANCE	N.A.	FEMALE	27	Suicide attempt	自殺企図	20 mg	.	MODERATE	YES	53	5	NO	RESOLVED
Rivaroxaban	160323014	YES	FRANCE	N.A.	FEMALE	27	Sarcoidosis	サルコイドーシス	20 mg	.	MODERATE	YES	145	3	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

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Enoxaparin/VKA	160323020	YES	FRANCE	N.A.	MALE	78	Haematuria	血尿			MODERATE	YES	18	10	YES	RESOLVED
Enoxaparin/VKA	160323020	YES	FRANCE	N.A.	MALE	78	Renal cancer	腎癌			SEVERE	NO	42	7	NO	RESOLVED
Rivaroxaban	160323023	YES	FRANCE	N.A.	MALE	37	Pulmonary infarction	肺梗塞	15 mg	.	SEVERE	YES	10	10	NO	RESOLVED
Rivaroxaban	160323023	YES	FRANCE	N.A.	MALE	37	Colitis	大腸炎	20 mg	.	SEVERE	YES	104	8	NO	IMPROVED
Enoxaparin/VKA	160323026	YES	FRANCE	N.A.	FEMALE	43	Lung infection	肺感染			MODERATE	YES	19	2	NO	RESOLVED
Rivaroxaban	160323035	YES	FRANCE	N.A.	FEMALE	36	Asthma	喘息	20 mg	F	SEVERE	YES	183	4	NO	RESOLVED
Rivaroxaban	160323036	YES	FRANCE	N.A.	FEMALE	80	Metrorrhagia	不正子宮出血	20 mg	.	MILD	YES	119	6	YES	RESOLVED
Rivaroxaban	160323036	YES	FRANCE	N.A.	FEMALE	80	Pneumonia	肺炎	20 mg	F	MODERATE	NO	205	5	NO	RESOLVED
Rivaroxaban	160333001	YES	FRANCE	N.A.	FEMALE	83	Syncope	失神	15 mg	.	SEVERE	YES	22	5	NO	RESOLVED
Rivaroxaban	160333004	YES	FRANCE	N.A.	FEMALE	85	Acute respiratory distress syndrome	急性呼吸窮迫症候群	15 mg	F	SEVERE	NO	25	1	NO	DEATH
Enoxaparin/VKA	160333009	YES	FRANCE	N.A.	MALE	74	Pleurisy	胸膜炎			MODERATE	YES	104	9	NO	DEATH
Enoxaparin/VKA	160333012	YES	FRANCE	N.A.	MALE	83	Haemoptysis	喀血			MODERATE	YES	22	23	YES	RESOLVED
Rivaroxaban	160333014	YES	FRANCE	N.A.	MALE	57	Rectal haemorrhage	直腸出血	20 mg	F	MODERATE	YES	140	6	YES	RESOLVED
Rivaroxaban	160333014	YES	FRANCE	N.A.	MALE	57	Colon cancer	結腸癌	20 mg	F	SEVERE	NO	146	22	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	160333023	YES	FRANCE	N.A.	FEMALE	28	Hepatitis A	A型肝炎			MODERATE	YES	164	75	NO	RESOLVED
Enoxaparin/VKA	160333035	YES	FRANCE	N.A.	MALE	65	Mental disorder	精神障害			MILD	YES	42	5	NO	IMPROVED
Enoxaparin/VKA	160333035	YES	FRANCE	N.A.	MALE	65	Back pain	背部痛			SEVERE	YES	151		NO	UNCHANGED
Enoxaparin/VKA	160333035	YES	FRANCE	N.A.	MALE	65	Acute respiratory failure	急性呼吸不全			SEVERE	NO	155	1	NO	DEATH
Enoxaparin/VKA	160333039	YES	FRANCE	N.A.	MALE	65	Coronary artery disease	冠動脈疾患			MILD	YES	160	3	NO	IMPROVED
Enoxaparin/VKA	160333049	YES	FRANCE	N.A.	FEMALE	78	Melaena	メレナ			SEVERE	YES	34	6	YES	RESOLVED
Rivaroxaban	160333058	YES	FRANCE	N.A.	MALE	85	Urinary bladder polyp	膀胱ポリープ	20 mg	I	MODERATE	YES	143	7	NO	RESOLVED
Enoxaparin/VKA	160333068	YES	FRANCE	N.A.	MALE	77	Multiple injuries	多発性外傷			SEVERE	YES	19	1	NO	DEATH
Enoxaparin/VKA	160343004	YES	FRANCE	N.A.	MALE	61	Osteomyelitis	骨髄炎			MODERATE	YES	117	10	NO	RESOLVED
Rivaroxaban	160343007	YES	FRANCE	N.A.	MALE	58	Dyspepsia	消化不良	20 mg	I	MILD	YES	201	3	NO	RESOLVED
Enoxaparin/VKA	160363004	YES	FRANCE	N.A.	MALE	77	Intestinal obstruction	腸閉塞			MODERATE	YES	30	3	NO	IMPROVED
Rivaroxaban	160363005	YES	FRANCE	N.A.	FEMALE	68	Anxiety	不安	20 mg	.	MODERATE	YES	243	4	NO	RESOLVED
Enoxaparin/VKA	160363006	YES	FRANCE	N.A.	MALE	85	Prostatic adenoma	前立腺腺腫			SEVERE	YES	258	4	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

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Enoxaparin/VKA	160363006	YES	FRANCE	N.A.	MALE	85	Prostatic adenoma	前立腺腺腫			MODERATE	YES	263	3	NO	RESOLVED
Enoxaparin/VKA	160373001	YES	FRANCE	N.A.	FEMALE	84	Haematuria	血尿			MODERATE	YES	95	7	YES	IMPROVED
Enoxaparin/VKA	160373001	YES	FRANCE	N.A.	FEMALE	84	Renal colic	腎仙痛			MODERATE	YES	95	7	NO	RESOLVED
Rivaroxaban	160373003	YES	FRANCE	N.A.	MALE	87	Lung infection	肺感染	20 mg	.	MODERATE	YES	72	15	NO	RESOLVED
Enoxaparin/VKA	160373005	YES	FRANCE	N.A.	FEMALE	76	Abdominal wall haematoma	腹壁血腫			SEVERE	YES	9	15	YES	RESOLVED
Enoxaparin/VKA	160373005	YES	FRANCE	N.A.	FEMALE	76	Renal failure acute	急性腎不全			SEVERE	YES	11	4	NO	RESOLVED
Enoxaparin/VKA	160373007	YES	FRANCE	N.A.	FEMALE	69	Intervertebral disc compression	椎間板圧迫			MILD	YES	66	2	NO	RESOLVED
Enoxaparin/VKA	160373007	YES	FRANCE	N.A.	FEMALE	69	Dizziness	浮動性めまい			MILD	YES	146	2	NO	RESOLVED
Rivaroxaban	160373015	YES	FRANCE	N.A.	MALE	60	Haemorrhoids	痔核	20 mg	I	MODERATE	YES	179	2	NO	RESOLVED
Enoxaparin/VKA	160373017	YES	FRANCE	N.A.	FEMALE	41	Dyspnoea	呼吸困難			MILD	YES	13	2	NO	RESOLVED
Enoxaparin/VKA	160373017	YES	FRANCE	N.A.	FEMALE	41	Uterine leiomyoma	子宮平滑筋腫			MODERATE	YES	247	7	NO	RESOLVED
Rivaroxaban	160383002	YES	FRANCE	N.A.	FEMALE	61	Rectal haemorrhage	直腸出血	20 mg	.	MILD	YES	30	243	YES	RESOLVED
Rivaroxaban	160383002	YES	FRANCE	N.A.	FEMALE	61	Angina unstable	不安定狭心症	20 mg	.	MILD	YES	78	20	NO	RESOLVED
Rivaroxaban	160383002	YES	FRANCE	N.A.	FEMALE	61	Anaemia	貧血	20 mg	.	SEVERE	YES	91	3	YES	RESOLVED

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Rivaroxaban	160383002	YES	FRANCE	N.A.	FEMALE	61	Anaemia	貧血	20 mg	.	SEVERE	YES	148	7	YES	RESOLVED
Enoxaparin/VKA	160383003	YES	FRANCE	N.A.	MALE	54	Atrial fibrillation	心房細動			SEVERE	YES	238	45	NO	RESOLVED
Rivaroxaban	160383004	YES	FRANCE	N.A.	FEMALE	40	Cholelithiasis	胆石症	20 mg	.	MODERATE	YES	329	2	NO	RESOLVED
Rivaroxaban	160383009	YES	FRANCE	N.A.	FEMALE	76	Syncope	失神	20 mg	F	SEVERE	NO	376	1	NO	RESOLVED
Enoxaparin/VKA	160383010	YES	FRANCE	N.A.	FEMALE	26	Pyelonephritis	腎盂腎炎			SEVERE	YES	15	4	NO	RESOLVED
Enoxaparin/VKA	160383010	YES	FRANCE	N.A.	FEMALE	26	Pregnancy	妊娠			MODERATE	YES	50	15	NO	RESOLVED
Enoxaparin/VKA	160383010	YES	FRANCE	N.A.	FEMALE	26	Abortion induced	人工流産			SEVERE	YES	62	3	NO	RESOLVED
Enoxaparin/VKA	160383010	YES	FRANCE	N.A.	FEMALE	26	Metrorrhagia	不正子宮出血			SEVERE	YES	87	12	YES	RESOLVED
Rivaroxaban	160403001	YES	FRANCE	N.A.	FEMALE	79	Right ventricular failure	右室不全	20 mg	.	MODERATE	YES	176	40	YES	RESOLVED
Rivaroxaban	160403002	YES	FRANCE	N.A.	FEMALE	83	International normalised ratio increased	ＩＮＲ増加	15 mg	.	MODERATE	YES	2	1	YES	RESOLVED
Enoxaparin/VKA	160403003	YES	FRANCE	N.A.	MALE	58	Skin lesion	皮膚病変			MILD	YES	55	3	NO	RESOLVED
Rivaroxaban	160403006	YES	FRANCE	N.A.	MALE	60	Urticaria	蕁麻疹	15 mg	.	MODERATE	YES	7	21	YES	RESOLVED
Enoxaparin/VKA	180053001	YES	POLAND	WHITE	FEMALE	80	Rectal haemorrhage	直腸出血			SEVERE	YES	104	9	YES	IMPROVED
Enoxaparin/VKA	180053001	YES	POLAND	WHITE	FEMALE	80	Rectal cancer	直腸癌			SEVERE	NO	117	190	NO	WORSENED

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Enoxaparin/VKA	180053001	YES	POLAND	WHITE	FEMALE	80	Rectal cancer	直腸癌			SEVERE	NO	307	9	NO	RESOLVED
Enoxaparin/VKA	180053004	YES	POLAND	WHITE	MALE	31	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			SEVERE	YES	7	22	NO	RESOLVED
Enoxaparin/VKA	180053004	YES	POLAND	WHITE	MALE	31	Systemic lupus erythematosus	全身性エリテマトーデス			SEVERE	YES	74	8	NO	IMPROVED
Enoxaparin/VKA	180053004	YES	POLAND	WHITE	MALE	31	Antiphospholipid syndrome	抗リン脂質抗体症候群			SEVERE	YES	74	8	NO	IMPROVED
Rivaroxaban	180053011	YES	POLAND	WHITE	FEMALE	71	Angina unstable	不安定狭心症	15 mg	.	SEVERE	YES	12	8	NO	RESOLVED
Rivaroxaban	180053011	YES	POLAND	WHITE	FEMALE	71	Abdominal pain	腹痛	20 mg	.	SEVERE	YES	89	2	NO	IMPROVED
Rivaroxaban	180053011	YES	POLAND	WHITE	FEMALE	71	Ultrasound liver abnormal	肝超音波検査異常	20 mg	.	SEVERE	YES	92	50	YES	RESOLVED
Rivaroxaban	180053011	YES	POLAND	WHITE	FEMALE	71	Hepatitis chronic active	慢性活動性肝炎	20 mg	I	SEVERE	YES	94		YES	UNCHANGED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Pelvic neoplasm	骨盤新生物			SEVERE	YES	9	90	NO	DEATH
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Anaemia	貧血			SEVERE	YES	19	3	YES	IMPROVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Pneumonia	肺炎			SEVERE	YES	21	23	NO	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Coagulopathy	凝血異常			SEVERE	YES	59	11	YES	RESOLVED
Enoxaparin/VKA	180053014	YES	POLAND	WHITE	FEMALE	67	Ischaemic stroke	虚血性脳卒中			SEVERE	NO	80	6	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Respiratory tract infection	気道感染	20 mg	.	SEVERE	YES	30	7	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Circulatory collapse	循環虚脱	20 mg	.	SEVERE	YES	68	11	NO	IMPROVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Cerebrovascular insufficiency	脳血管不全	20 mg	F	SEVERE	NO	231	9	NO	RESOLVED
Rivaroxaban	180053017	YES	POLAND	WHITE	FEMALE	80	Circulatory collapse	循環虚脱	20 mg	F	SEVERE	NO	282	3	NO	DEATH
Rivaroxaban	180053018	YES	POLAND	WHITE	MALE	35	Hypercoagulation	凝固亢進	20 mg	.	SEVERE	YES	181	4	NO	IMPROVED
Rivaroxaban	180053023	YES	POLAND	WHITE	FEMALE	68	Lung carcinoma cell type unspecified recurrent	再発肺癌、細胞タイプ不明	20 mg	.	SEVERE	YES	133		NO	UNCHANGED
Rivaroxaban	180053023	YES	POLAND	WHITE	FEMALE	68	Anaemia	貧血	20 mg	F	SEVERE	NO	228	14	NO	RESOLVED
Enoxaparin/VKA	180053026	YES	POLAND	WHITE	FEMALE	49	Spinal osteoarthritis	変形性脊椎症			SEVERE	YES	119	22	NO	RESOLVED
Rivaroxaban	180053029	YES	POLAND	WHITE	FEMALE	74	Purpura	紫斑	15 mg	I	SEVERE	YES	12	5	YES	RESOLVED
Rivaroxaban	180053029	YES	POLAND	WHITE	FEMALE	74	Osteolysis	骨溶解	20 mg	.	SEVERE	YES	77	14	NO	RESOLVED
Rivaroxaban	180053032	YES	POLAND	WHITE	FEMALE	52	Syncope	失神	15 mg	.	SEVERE	YES	2	1	NO	RESOLVED
Rivaroxaban	180053032	YES	POLAND	WHITE	FEMALE	52	Respiratory arrest	呼吸停止	15 mg	.	SEVERE	YES	2	1	NO	RESOLVED
Enoxaparin/VKA	180063008	YES	POLAND	WHITE	FEMALE	23	Syncope	失神			MILD	YES	111	8	NO	RESOLVED
Rivaroxaban	180063009	YES	POLAND	WHITE	MALE	71	Lung adenocarcinoma	肺腺癌	15 mg	.	SEVERE	YES	7		NO	UNCHANGED
Rivaroxaban	180063009	YES	POLAND	WHITE	MALE	71	Urosepsis	尿路性敗血症	20 mg	.	SEVERE	YES	43	13	NO	RESOLVED
Enoxaparin/VKA	180103004	YES	POLAND	WHITE	MALE	76	Vertigo	回転性めまい			MILD	YES	266	6	NO	IMPROVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	180103007	YES	POLAND	WHITE	FEMALE	72	Chest pain	胸痛			MODERATE	YES	109	3	NO	RESOLVED
Rivaroxaban	220013020	YES	ITALY	WHITE	FEMALE	76	Ovarian cancer	卵巣癌	20 mg	.	SEVERE	YES	31	1	NO	DEATH
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Cardiac failure	心不全			MODERATE	YES	2	6	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Cerebral haemorrhage	脳出血			SEVERE	YES	3	10	NO	RESOLVED
Enoxaparin/VKA	220013035	YES	ITALY	WHITE	FEMALE	74	Respiratory failure	呼吸不全			SEVERE	NO	27	47	NO	DEATH
Enoxaparin/VKA	220013048	YES	ITALY	WHITE	MALE	69	Muscle haemorrhage	筋肉内出血			SEVERE	YES	5	8	YES	RESOLVED
Rivaroxaban	220033014	YES	ITALY	WHITE	MALE	88	Abdominal pain upper	上腹部痛	20 mg	.	MODERATE	YES	122	7	NO	RESOLVED
Rivaroxaban	220043004	YES	ITALY	WHITE	MALE	76	Fatigue	疲労	20 mg	.	MILD	YES	92	2	NO	RESOLVED
Enoxaparin/VKA	220053010	YES	ITALY	WHITE	FEMALE	84	Supraventricular tachycardia	上室性頻脈			SEVERE	YES	19	6	NO	RESOLVED
Enoxaparin/VKA	220053010	YES	ITALY	WHITE	FEMALE	84	Supraventricular tachycardia	上室性頻脈			MODERATE	YES	72	6	NO	RESOLVED
Enoxaparin/VKA	220053010	YES	ITALY	WHITE	FEMALE	84	Pleural effusion	胸水			MODERATE	YES	96	8	NO	RESOLVED
Enoxaparin/VKA	220053010	YES	ITALY	WHITE	FEMALE	84	Supraventricular tachycardia	上室性頻脈			MODERATE	YES	98	8	NO	RESOLVED
Enoxaparin/VKA	220053010	YES	ITALY	WHITE	FEMALE	84	Pleural effusion	胸水			MODERATE	YES	141	41	NO	RESOLVED
Enoxaparin/VKA	220053010	YES	ITALY	WHITE	FEMALE	84	Cardiac failure	心不全			MODERATE	YES	141	41	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

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Rivaroxaban	220093011	YES	ITALY	WHITE	FEMALE	77	Sudden death	突然死	15 mg	F	SEVERE	YES	13	1	YES	DEATH
Enoxaparin/VKA	220093038	YES	ITALY	WHITE	MALE	76	Chest injury	胸部損傷			MODERATE	YES	83	8	NO	IMPROVED
Enoxaparin/VKA	220093038	YES	ITALY	WHITE	MALE	76	Mediastinal haemorrhage	縦隔出血			MILD	YES	83	8	NO	RESOLVED
Enoxaparin/VKA	220093038	YES	ITALY	WHITE	MALE	76	Sternal fracture	胸骨骨折			MODERATE	YES	83	8	NO	RESOLVED
Rivaroxaban	220133003	YES	ITALY	WHITE	FEMALE	72	Dyspnoea	呼吸困難	15 mg	.	MODERATE	YES	17	11	NO	RESOLVED
Enoxaparin/VKA	220133007	YES	ITALY	WHITE	MALE	67	International normalised ratio increased	ＩＮＲ増加			MILD	YES	169	3	YES	RESOLVED
Rivaroxaban	220133013	YES	ITALY	WHITE	MALE	67	Pleural effusion	胸水	15 mg	.	MODERATE	YES	18	3	NO	RESOLVED
Rivaroxaban	220143017	YES	ITALY	WHITE	MALE	74	Pyrexia	発熱	15 mg	.	MILD	YES	16	5	NO	RESOLVED
Rivaroxaban	220143017	YES	ITALY	WHITE	MALE	74	Blood amylase increased	血中アミラーゼ増加	15 mg	.	MILD	YES	16	3	NO	RESOLVED
Enoxaparin/VKA	220143042	YES	ITALY	WHITE	MALE	60	Metastasis	転移			SEVERE	YES	5		NO	UNCHANGED
Enoxaparin/VKA	220143042	YES	ITALY	WHITE	MALE	60	Syncope	失神			MODERATE	YES	12	1	NO	RESOLVED
Enoxaparin/VKA	220143042	YES	ITALY	WHITE	MALE	60	Renal cancer	腎癌			SEVERE	NO	26	30	NO	RESOLVED
Enoxaparin/VKA	220143044	YES	ITALY	WHITE	MALE	83	Lung neoplasm malignant	肺の悪性新生物			SEVERE	YES	22		NO	UNCHANGED
Enoxaparin/VKA	220143044	YES	ITALY	WHITE	MALE	83	Pericardial haemorrhage	心嚢内出血			SEVERE	YES	34	25	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	220143050	YES	ITALY	WHITE	FEMALE	60	Abdominal hernia	腹部ヘルニア	20 mg	.	MODERATE	YES	156		NO	UNCHANGED
Enoxaparin/VKA	220143054	YES	ITALY	WHITE	FEMALE	82	Metastases to lymph nodes	リンパ節転移			SEVERE	YES	14		NO	UNCHANGED
Enoxaparin/VKA	220143055	YES	ITALY	WHITE	FEMALE	78	Gastrointestinal stromal tumour	消化管間質性腫瘍			SEVERE	YES	28	7	NO	RESOLVED
Enoxaparin/VKA	220143059	YES	ITALY	WHITE	FEMALE	75	Breast cancer	乳癌			SEVERE	NO	81		NO	UNCHANGED
Enoxaparin/VKA	220153004	YES	ITALY	WHITE	FEMALE	61	Headache	頭痛			MODERATE	YES	55	10	NO	RESOLVED
Enoxaparin/VKA	220153004	YES	ITALY	WHITE	FEMALE	61	Back pain	背部痛			MODERATE	YES	55	12	NO	RESOLVED
Enoxaparin/VKA	220153007	YES	ITALY	WHITE	FEMALE	72	Cholangitis	胆管炎			MODERATE	NO	191	9	NO	RESOLVED
Rivaroxaban	220153014	YES	ITALY	WHITE	MALE	71	Angina pectoris	狭心症	20 mg	.	MILD	YES	46	3	NO	RESOLVED
Enoxaparin/VKA	220153015	YES	ITALY	WHITE	MALE	82	Post procedural haemorrhage	処置後出血			MODERATE	NO	24	1	YES	RESOLVED
Enoxaparin/VKA	240023015	YES	SPAIN	WHITE	MALE	66	Haematuria	血尿			MODERATE	YES	3	6	YES	RESOLVED
Enoxaparin/VKA	240023015	YES	SPAIN	WHITE	MALE	66	Transaminases increased	トランスアミナーゼ上昇			MODERATE	YES	7	25	NO	RESOLVED
Rivaroxaban	240023016	YES	SPAIN	WHITE	FEMALE	55	Pneumonia	肺炎	15 mg	.	SEVERE	YES	1	18	NO	RESOLVED
Rivaroxaban	240023016	YES	SPAIN	WHITE	FEMALE	55	Lung infection	肺感染	20 mg	I	SEVERE	YES	116	5	NO	IMPROVED
Rivaroxaban	240023017	YES	SPAIN	WHITE	MALE	78	Chronic obstructive	慢性閉塞性肺疾患	15 mg	.	SEVERE	YES	15	11	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							pulmonary disease									
Rivaroxaban	240043018	YES	SPAIN	WHITE	FEMALE	78	Type 2 diabetes mellitus	２型糖尿病	20 mg	.	SEVERE	YES	75	24	NO	IMPROVED
Rivaroxaban	240043021	YES	SPAIN	WHITE	FEMALE	75	Femur fracture	大腿骨骨折	20 mg	.	MODERATE	YES	56	8	NO	RESOLVED
Rivaroxaban	240073010	YES	SPAIN	WHITE	FEMALE	83	Anaemia	貧血	20 mg	.	SEVERE	YES	142	37	YES	RESOLVED
Enoxaparin/VKA	240073026	YES	SPAIN	WHITE	MALE	77	Bacteraemia	菌血症			SEVERE	YES	93	4	NO	RESOLVED
Enoxaparin/VKA	240073028	YES	SPAIN	WHITE	FEMALE	72	Incision site haemorrhage	切開部位出血			SEVERE	YES	3	2	NO	RESOLVED
Rivaroxaban	240073029	YES	SPAIN	WHITE	MALE	65	Asthenia	無力症	20 mg	.	SEVERE	YES	134	13	YES	IMPROVED
Rivaroxaban	240073038	YES	SPAIN	WHITE	FEMALE	65	Colorectal cancer	結腸直腸癌	20 mg	I	SEVERE	YES	37		NO	IMPROVED
Rivaroxaban	240073041	YES	SPAIN	WHITE	FEMALE	80	Pulmonary embolism	肺塞栓症	15 mg	.	SEVERE	YES	5	2	NO	DEATH
Rivaroxaban	240103001	YES	SPAIN	WHITE	FEMALE	31	Pneumonia	肺炎	20 mg	.	MODERATE	YES	74	20	NO	RESOLVED
Rivaroxaban	240103003	YES	SPAIN	WHITE	FEMALE	62	Antiphospholipid syndrome	抗リン脂質抗体症候群	20 mg	.	MILD	YES	143		NO	UNCHANGED
Rivaroxaban	240113002	YES	SPAIN	WHITE	MALE	61	Anaemia folate deficiency	葉酸欠乏性貧血	20 mg	.	SEVERE	YES	241	143	NO	RESOLVED
Rivaroxaban	240113002	YES	SPAIN	WHITE	MALE	61	Endocarditis bacterial	細菌性心内膜炎	20 mg	.	SEVERE	YES	293	57	NO	RESOLVED
Enoxaparin/VKA	240113003	YES	SPAIN	WHITE	FEMALE	74	Skin infection	皮膚感染			SEVERE	YES	209	39	NO	RESOLVED
Enoxaparin/VKA	240113003	YES	SPAIN	WHITE	FEMALE	74	Subcutaneous haematoma	皮下血腫			SEVERE	YES	214	34	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	260053012	YES	CANADA	WHITE	FEMALE	56	Ischaemic stroke	虚血性脳卒中			SEVERE	YES			NO	UNCHANGED
Enoxaparin/VKA	260053012	YES	CANADA	WHITE	FEMALE	56	Non-cardiac chest pain	非心臓性胸痛			SEVERE	YES	29	3	NO	RESOLVED
Enoxaparin/VKA	260053012	YES	CANADA	WHITE	FEMALE	56	Humerus fracture	上腕骨骨折			SEVERE	YES	51		NO	UNCHANGED
Enoxaparin/VKA	260053012	YES	CANADA	WHITE	FEMALE	56	Fall	転倒			SEVERE	YES	51	1	NO	RESOLVED
Enoxaparin/VKA	260053012	YES	CANADA	WHITE	FEMALE	56	Hyponatraemia	低ナトリウム血症			SEVERE	YES	90	30	NO	RESOLVED
Enoxaparin/VKA	260053012	YES	CANADA	WHITE	FEMALE	56	Acute respiratory failure	急性呼吸不全			SEVERE	NO	100	15	NO	RESOLVED
Enoxaparin/VKA	260053012	YES	CANADA	WHITE	FEMALE	56	Cardiac failure congestive	うっ血性心不全			MODERATE	NO	100	30	NO	RESOLVED
Enoxaparin/VKA	260053020	YES	CANADA	WHITE	MALE	68	Cholelithiasis	胆石症			MILD	YES	69	45	NO	RESOLVED
Enoxaparin/VKA	260053092	YES	CANADA	WHITE	MALE	43	Haematoma	血腫			MILD	YES	3	4	YES	RESOLVED
Rivaroxaban	260053098	YES	CANADA	WHITE	FEMALE	80	Musculoskeletal chest pain	筋骨格系胸痛	20 mg	.	SEVERE	YES	53	49	NO	RESOLVED
Rivaroxaban	260053119	YES	CANADA	WHITE	FEMALE	57	Pneumonia	肺炎	15 mg	.	SEVERE	YES	6	40	NO	RESOLVED
Enoxaparin/VKA	260053127	YES	CANADA	WHITE	FEMALE	80	Death	死亡			SEVERE	YES	21	1	YES	DEATH
Rivaroxaban	260123067	YES	CANADA	WHITE	MALE	53	Muscle haemorrhage	筋肉内出血	15 mg	.	SEVERE	YES	19	6	YES	RESOLVED
Enoxaparin/VKA	260123075	YES	CANADA	WHITE	FEMALE	57	Cholelithiasis	胆石症			SEVERE	YES	86	5	NO	RESOLVED
Enoxaparin/V	260123080	YES	CANADA	WHITE	MALE	62	Pneumonia	肺炎			SEVERE	YES	178	4	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

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KA																
Rivaroxaban	280013003	YES	BELGIUM	WHITE	FEMALE	68	Arthralgia	関節痛	20 mg	I	SEVERE	YES	289	10	NO	RESOLVED
Enoxaparin/VKA	280013004	YES	BELGIUM	WHITE	FEMALE	78	Muscle haemorrhage	筋肉内出血			MODERATE	YES	7	9	YES	RESOLVED
Enoxaparin/VKA	280013007	YES	BELGIUM	WHITE	FEMALE	78	Osteoarthritis	変形性関節症			MODERATE	YES	309	12	NO	RESOLVED
Rivaroxaban	280013009	YES	BELGIUM	WHITE	FEMALE	66	Headache	頭痛	15 mg	.	MILD	YES	9	2	NO	RESOLVED
Rivaroxaban	280013009	YES	BELGIUM	WHITE	FEMALE	66	Back pain	背部痛	15 mg	.	MODERATE	YES	9	39	NO	RESOLVED
Rivaroxaban	280013009	YES	BELGIUM	WHITE	FEMALE	66	Dizziness	浮動性めまい	15 mg	.	MILD	YES	11	7	NO	RESOLVED
Enoxaparin/VKA	280013022	YES	BELGIUM	WHITE	FEMALE	57	Dyspnoea	呼吸困難			MILD	YES	11	5	NO	RESOLVED
Enoxaparin/VKA	280013023	YES	BELGIUM	WHITE	FEMALE	76	Squamous cell carcinoma of skin	皮膚有棘細胞癌			MODERATE	YES	72	25	NO	RESOLVED
Enoxaparin/VKA	280013026	YES	BELGIUM	WHITE	MALE	69	Rectal haemorrhage	直腸出血			MILD	YES	25	4	YES	RESOLVED
Enoxaparin/VKA	280013026	YES	BELGIUM	WHITE	MALE	69	Rectal haemorrhage	直腸出血			MILD	YES	35	16	YES	IMPROVED
Enoxaparin/VKA	280013026	YES	BELGIUM	WHITE	MALE	69	Abdominal pain	腹痛			MODERATE	YES	176	8	NO	RESOLVED
Enoxaparin/VKA	280013026	YES	BELGIUM	WHITE	MALE	69	Angina pectoris	狭心症			MODERATE	YES	176	8	NO	RESOLVED
Enoxaparin/VKA	280013026	YES	BELGIUM	WHITE	MALE	69	Acute myocardial infarction	急性心筋梗塞			MODERATE	YES	181	1	NO	RESOLVED

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Enoxaparin/VKA	280013026	YES	BELGIUM	WHITE	MALE	69	Angina pectoris	狭心症			MODERATE	YES	187	11	NO	RESOLVED
Enoxaparin/VKA	280013026	YES	BELGIUM	WHITE	MALE	69	Gastrooesophageal reflux disease	胃食道逆流性疾患			MODERATE	YES	331	6	NO	IMPROVED
Enoxaparin/VKA	280013027	YES	BELGIUM	WHITE	FEMALE	77	Bronchitis	気管支炎			MILD	YES	335	3	NO	IMPROVED
Rivaroxaban	280013038	YES	BELGIUM	WHITE	MALE	29	Bipolar I disorder	双極 1 型障害	20 mg	.	MODERATE	YES	56	63	NO	RESOLVED
Rivaroxaban	280013039	YES	BELGIUM	WHITE	FEMALE	74	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	MODERATE	YES	25	13	NO	RESOLVED
Rivaroxaban	280013039	YES	BELGIUM	WHITE	FEMALE	74	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	MODERATE	YES	129	11	NO	RESOLVED
Rivaroxaban	280013039	YES	BELGIUM	WHITE	FEMALE	74	Gastroenteritis	胃腸炎	20 mg	.	MODERATE	YES	175	7	NO	RESOLVED
Rivaroxaban	280013039	YES	BELGIUM	WHITE	FEMALE	74	General physical health deterioration	全身健康状態低下	20 mg	.	MILD	YES	242	5	NO	RESOLVED
Enoxaparin/VKA	280013044	YES	BELGIUM	WHITE	FEMALE	49	Temporomandibular joint syndrome	顎関節症候群			MILD	NO	144	4	NO	RESOLVED
Enoxaparin/VKA	280013045	YES	BELGIUM	WHITE	FEMALE	88	Epilepsy	てんかん			MILD	YES	52	2	NO	IMPROVED
Enoxaparin/VKA	280013045	YES	BELGIUM	WHITE	FEMALE	88	Epilepsy	てんかん			MODERATE	YES	134		NO	UNCHANGED

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Enoxaparin/VKA	280013045	YES	BELGIUM	WHITE	FEMALE	88	General physical health deterioration	全身健康状態低下			SEVERE	YES	134	11	NO	DEATH
Enoxaparin/VKA	280013051	YES	BELGIUM	WHITE	FEMALE	77	Dyspnoea	呼吸困難			MODERATE	YES	244	5	NO	IMPROVED
Enoxaparin/VKA	280013059	YES	BELGIUM	WHITE	MALE	76	Chest pain	胸痛			MILD	YES	46	3	NO	RESOLVED
Enoxaparin/VKA	280013059	YES	BELGIUM	WHITE	MALE	76	Chest pain	胸痛			MILD	YES	348	2	NO	RESOLVED
Enoxaparin/VKA	280013061	YES	BELGIUM	WHITE	MALE	61	Pulmonary hypertension	肺高血圧症			SEVERE	YES	71	72	NO	RESOLVED
Enoxaparin/VKA	280013061	YES	BELGIUM	WHITE	MALE	61	Sleep apnoea syndrome	睡眠時無呼吸症候群			MILD	YES	88	2	NO	RESOLVED
Enoxaparin/VKA	280013070	YES	BELGIUM	WHITE	MALE	57	Chest pain	胸痛			MILD	YES	3	5	NO	RESOLVED
Rivaroxaban	280013071	YES	BELGIUM	WHITE	FEMALE	48	Menorrhagia	月経過多	15 mg	.	MODERATE	YES	6	4	YES	IMPROVED
Rivaroxaban	280013071	YES	BELGIUM	WHITE	FEMALE	48	Menorrhagia	月経過多	20 mg	.	MODERATE	YES	25	9	YES	IMPROVED
Rivaroxaban	280013071	YES	BELGIUM	WHITE	FEMALE	48	Concussion	脳振盪	20 mg	.	MILD	YES	212	2	NO	RESOLVED
Rivaroxaban	280013076	YES	BELGIUM	WHITE	FEMALE	37	Acute prerenal failure	急性腎前性腎不全	15 mg	.	SEVERE	YES	2	5	NO	RESOLVED
Rivaroxaban	280013076	YES	BELGIUM	WHITE	FEMALE	37	Pneumonia necrotising	壊死性肺炎	20 mg	.	MODERATE	YES	22	10	NO	RESOLVED
Rivaroxaban	280013076	YES	BELGIUM	WHITE	FEMALE	37	Vena cava thrombosis	大静脈血栓症	20 mg	.	MODERATE	YES	121	57	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	280013077	YES	BELGIUM	WHITE	FEMALE	68	Anaemia	貧血	20 mg	F	MODERATE	YES	128	10	YES	IMPROVED
Rivaroxaban	280013077	YES	BELGIUM	WHITE	FEMALE	68	Colon neoplasm	結腸新生物	20 mg	F	MILD	NO	134		NO	UNCHANGED
Enoxaparin/VKA	280013078	YES	BELGIUM	WHITE	MALE	56	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患			MILD	YES	8	4	NO	IMPROVED
Rivaroxaban	280033002	YES	BELGIUM	WHITE	MALE	82	Neoplasm prostate	前立腺新生物	20 mg	.	SEVERE	YES	123	18	NO	DEATH
Rivaroxaban	280033002	YES	BELGIUM	WHITE	MALE	82	Decreased appetite	食欲減退	20 mg	.	SEVERE	YES	123		NO	UNCHANGED
Rivaroxaban	280033002	YES	BELGIUM	WHITE	MALE	82	Pneumonia	肺炎	20 mg	.	SEVERE	YES	123		NO	UNCHANGED
Enoxaparin/VKA	280073008	YES	BELGIUM	WHITE	FEMALE	77	Intra-abdominal haemorrhage	腹腔内出血			SEVERE	YES	3	19	NO	RESOLVED
Enoxaparin/VKA	280073008	YES	BELGIUM	WHITE	FEMALE	77	Renal failure acute	急性腎不全			MODERATE	YES	6	4	NO	RESOLVED
Enoxaparin/VKA	280073010	YES	BELGIUM	WHITE	MALE	70	Bronchitis	気管支炎			SEVERE	YES	46	4	NO	IMPROVED
Enoxaparin/VKA	280073010	YES	BELGIUM	WHITE	MALE	70	Bronchitis	気管支炎			SEVERE	NO	191	11	NO	RESOLVED
Rivaroxaban	280073021	YES	BELGIUM	WHITE	MALE	54	Nephritis	腎炎	20 mg	.	MODERATE	YES	117	11	NO	RESOLVED
Enoxaparin/VKA	280073034	YES	BELGIUM	WHITE	FEMALE	60	Rectal haemorrhage	直腸出血			SEVERE	YES	220	6	YES	RESOLVED
Rivaroxaban	280073042	YES	BELGIUM	WHITE	MALE	81	Colon cancer	結腸癌	20 mg	.	SEVERE	YES	235		NO	IMPROVED
Rivaroxaban	280073042	YES	BELGIUM	WHITE	MALE	81	Postoperative ileus	術後イレウス	20 mg	I	MODERATE	YES	280	8	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	280083006	YES	BELGIUM	WHITE	FEMALE	78	Muscle haemorrhage	筋肉内出血			MODERATE	YES	79	5	YES	IMPROVED
Enoxaparin/VKA	280083006	YES	BELGIUM	WHITE	FEMALE	78	Chest pain	胸痛			MODERATE	YES	85	4	NO	RESOLVED
Rivaroxaban	280083010	YES	BELGIUM	WHITE	FEMALE	86	Haematuria	血尿	15 mg	.	MILD	YES	3	5	YES	RESOLVED
Enoxaparin/VKA	280083018	YES	BELGIUM	WHITE	FEMALE	83	Sudden death	突然死			SEVERE	YES	3	1	NO	DEATH
Enoxaparin/VKA	280083023	YES	BELGIUM	WHITE	FEMALE	60	Angina unstable	不安定狭心症			MODERATE	YES	5	47	NO	RESOLVED
Enoxaparin/VKA	280083023	YES	BELGIUM	WHITE	FEMALE	60	Coronary artery disease	冠動脈疾患			SEVERE	YES	35	27	NO	RESOLVED
Enoxaparin/VKA	280083023	YES	BELGIUM	WHITE	FEMALE	60	Anaemia postoperative	術後貧血			MODERATE	YES	51		NO	IMPROVED
Rivaroxaban	280083024	YES	BELGIUM	WHITE	FEMALE	68	Pulmonary hypertension	肺高血圧症	15 mg	.	SEVERE	YES	5	11	NO	RESOLVED
Rivaroxaban	280083024	YES	BELGIUM	WHITE	FEMALE	68	Sepsis	敗血症	15 mg	.	SEVERE	YES	17	11	NO	RESOLVED
Rivaroxaban	280083024	YES	BELGIUM	WHITE	FEMALE	68	Ovarian epithelial cancer	卵巣上皮癌	20 mg	I	SEVERE	YES	28	1	NO	RESOLVED
Rivaroxaban	280083024	YES	BELGIUM	WHITE	FEMALE	68	Diverticulum intestinal	腸憩室	20 mg	I	SEVERE	YES	28	1	NO	RESOLVED
Rivaroxaban	280083024	YES	BELGIUM	WHITE	FEMALE	68	Colonic stenosis	結腸狭窄	20 mg	I	SEVERE	YES	129	2	NO	RESOLVED
Rivaroxaban	280083025	YES	BELGIUM	WHITE	MALE	69	Back pain	背部痛	20 mg	.	MODERATE	YES	84	2	NO	RESOLVED
Rivaroxaban	280083028	YES	BELGIUM	WHITE	MALE	40	Depression	うつ病	15 mg	.	SEVERE	YES	12	50	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	280083028	YES	BELGIUM	WHITE	MALE	40	Pneumonia	肺炎	20 mg	.	MODERATE	YES	87	13	NO	RESOLVED
Rivaroxaban	280083029	YES	BELGIUM	WHITE	FEMALE	80	Fall	転倒	20 mg	.	MODERATE	YES	48	20	NO	RESOLVED
Rivaroxaban	280083029	YES	BELGIUM	WHITE	FEMALE	80	General physical health deterioration	全身健康状態低下	20 mg	.	MODERATE	YES	98	5	NO	RESOLVED
Rivaroxaban	280083029	YES	BELGIUM	WHITE	FEMALE	80	General physical health deterioration	全身健康状態低下	20 mg	.	MODERATE	YES	181	6	NO	RESOLVED
Enoxaparin/VKA	280083031	YES	BELGIUM	WHITE	FEMALE	59	Breast cancer recurrent	再発乳癌			SEVERE	YES	4		NO	IMPROVED
Enoxaparin/VKA	280083031	YES	BELGIUM	WHITE	FEMALE	59	Lung infection	肺感染			MODERATE	NO	40	11	NO	RESOLVED
Rivaroxaban	280083032	YES	BELGIUM	WHITE	FEMALE	73	Subdural haematoma	硬膜下血腫	15 mg	.	SEVERE	YES	3	61	YES	DEATH
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Metrorrhagia	不正子宮出血	15 mg	.	SEVERE	YES	6	3	YES	RESOLVED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Dizziness	浮動性めまい	15 mg	.	MODERATE	YES	10	11	NO	RESOLVED
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Gallbladder cancer	胆嚢癌	20 mg	I	SEVERE	YES	57	68	NO	DEATH
Rivaroxaban	280083033	YES	BELGIUM	WHITE	FEMALE	89	Cholelithiasis	胆石症	20 mg	I	SEVERE	YES	57	7	NO	RESOLVED
Rivaroxaban	280083041	YES	BELGIUM	WHITE	FEMALE	43	Cholelithiasis	胆石症	20 mg	.	MODERATE	YES	45	17	NO	RESOLVED
Rivaroxaban	280083042	YES	BELGIUM	WHITE	FEMALE	73	Respiratory failure	呼吸不全	15 mg	.	SEVERE	YES	3	3	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	280083043	YES	BELGIUM	WHITE	FEMALE	33	Suicide attempt	自殺企図			MODERATE	YES	82	1	NO	RESOLVED
Enoxaparin/VKA	280123002	YES	BELGIUM	WHITE	FEMALE	25	Intestinal haemorrhage	腸出血			SEVERE	YES	114	4	YES	RESOLVED
Enoxaparin/VKA	280123002	YES	BELGIUM	WHITE	FEMALE	25	Intestinal haemorrhage	腸出血			SEVERE	NO	133	21	NO	RESOLVED
Rivaroxaban	280133003	YES	BELGIUM	WHITE	MALE	55	Pneumothorax	気胸	20 mg	.	MODERATE	YES	32	1	NO	RESOLVED
Rivaroxaban	280133003	YES	BELGIUM	WHITE	MALE	55	Lobar pneumonia	大葉性肺炎	20 mg	F	MODERATE	NO	198	9	NO	RESOLVED
Enoxaparin/VKA	280173001	YES	BELGIUM	WHITE	FEMALE	71	Respiratory failure	呼吸不全			SEVERE	YES	12	1	NO	DEATH
Rivaroxaban	280173002	YES	BELGIUM	WHITE	MALE	79	Interstitial lung disease	間質性肺疾患	15 mg	.	SEVERE	YES	1	30	NO	DEATH
Enoxaparin/VKA	280173006	YES	BELGIUM	WHITE	MALE	39	Lung neoplasm	肺新生物			MILD	YES	106	5	YES	RESOLVED
Rivaroxaban	280173022	YES	BELGIUM	WHITE	MALE	67	Pneumonia	肺炎	20 mg	.	MODERATE	YES	133	23	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Cardiac failure	心不全	20 mg	.	SEVERE	YES	55	7	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Cardiac failure	心不全	20 mg	.	SEVERE	YES	98	7	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Bronchopneumonia	気管支肺炎	20 mg	.	MODERATE	YES	330	15	NO	RESOLVED
Rivaroxaban	280193001	YES	BELGIUM	WHITE	MALE	31	Arrhythmia	不整脈	20 mg	F	SEVERE	NO	364	1	NO	DEATH
Enoxaparin/VKA	280193002	YES	BELGIUM	WHITE	MALE	83	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患			MODERATE	YES	124	15	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	280193004	YES	BELGIUM	WHITE	MALE	77	Lung carcinoma cell type unspecified recurrent	再発肺癌、細胞タイプ不明			MODERATE	YES	295		NO	UNCHANGED
Rivaroxaban	280193009	YES	BELGIUM	WHITE	MALE	62	Back pain	背部痛	20 mg	.	SEVERE	YES	34		NO	UNCHANGED
Rivaroxaban	280193009	YES	BELGIUM	WHITE	MALE	62	Non-small cell lung cancer	非小細胞肺癌	20 mg	.	SEVERE	YES	42		NO	UNCHANGED
Rivaroxaban	280193009	YES	BELGIUM	WHITE	MALE	62	Pleural effusion	胸水	20 mg	.	SEVERE	YES	54	6	NO	RESOLVED
Rivaroxaban	280193009	YES	BELGIUM	WHITE	MALE	62	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	SEVERE	YES	80	40	NO	RESOLVED
Rivaroxaban	280193009	YES	BELGIUM	WHITE	MALE	62	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	F	MODERATE	YES	187	19	NO	RESOLVED
Enoxaparin/VKA	300063030	YES	NETHERLANDS	WHITE	MALE	56	Diabetes insipidus	尿崩症			SEVERE	YES	4	5	NO	RESOLVED
Rivaroxaban	300063073	YES	NETHERLANDS	WHITE	FEMALE	20	Headache	頭痛	20 mg	F	SEVERE	NO	190	4	NO	IMPROVED
Enoxaparin/VKA	300063096	YES	NETHERLANDS	WHITE	MALE	72	Pneumonia	肺炎			MODERATE	YES	1	9	NO	IMPROVED
Rivaroxaban	300063097	YES	NETHERLANDS	WHITE	FEMALE	75	Vaginal haemorrhage	膣出血	20 mg	.	MODERATE	YES	185	4	YES	RESOLVED
Enoxaparin/VKA	300073001	YES	NETHERLANDS	WHITE	FEMALE	45	Subdural haemorrhage	硬膜下出血			SEVERE	NO	204	4	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	300073013	YES	NETHERLANDS	WHITE	MALE	68	Malnutrition	栄養障害			SEVERE	YES	15	8	NO	RESOLVED
Rivaroxaban	300073051	YES	NETHERLANDS	WHITE	MALE	79	Death	死亡	15 mg	.	SEVERE	YES	3	1	NO	DEATH
Enoxaparin/VKA	300073058	YES	NETHERLANDS	WHITE	MALE	48	Pneumonia	肺炎			MODERATE	YES	102	5	NO	RESOLVED
Rivaroxaban	300073079	YES	NETHERLANDS	WHITE	FEMALE	59	Pleural effusion	胸水	20 mg	.	SEVERE	YES	137	13	NO	RESOLVED
Rivaroxaban	300073079	YES	NETHERLANDS	WHITE	FEMALE	59	Pyrexia	発熱	20 mg	.	MODERATE	YES	165	14	NO	RESOLVED
Rivaroxaban	300073104	YES	NETHERLANDS	WHITE	MALE	71	Device related infection	医療機器関連感染	20 mg	F	MILD	NO	186	8	NO	RESOLVED
Enoxaparin/VKA	300073108	YES	NETHERLANDS	WHITE	FEMALE	75	Pneumonia	肺炎			SEVERE	YES	54	6	NO	RESOLVED
Enoxaparin/VKA	300073113	YES	NETHERLANDS	WHITE	MALE	57	Acute myocardial infarction	急性心筋梗塞			SEVERE	YES	88	14	NO	DEATH
Rivaroxaban	300073125	YES	NETHERLANDS	WHITE	FEMALE	31	Death	死亡	20 mg	.	SEVERE	YES	165	1	NO	DEATH
Rivaroxaban	300073134	YES	NETHERLANDS	WHITE	FEMALE	26	Dehydration	脱水	20 mg	.	MILD	YES	25	4	NO	RESOLVED
Enoxaparin/VKA	300073144	YES	NETHERLANDS	WHITE	FEMALE	78	Atrial fibrillation	心房細動			MODERATE	YES	152	2	NO	RESOLVED
Rivaroxaban	300073151	YES	NETHERLANDS	WHITE	FEMALE	52	Pyrexia	発熱	20 mg	.	MILD	YES	139	3	NO	RESOLVED

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Rivaroxaban	300073190	YES	NETHERLANDS	WHITE	MALE	79	Lung disorder	肺障害	15 mg	.	MODERATE	YES	22	16	NO	RESOLVED
Enoxaparin/VKA	300073198	YES	NETHERLANDS	WHITE	MALE	67	Aortic aneurysm rupture	大動脈瘤破裂			SEVERE	YES	122	2	NO	RESOLVED
Enoxaparin/VKA	300073213	YES	NETHERLANDS	WHITE	MALE	57	Rectal cancer metastatic	転移性直腸癌			SEVERE	YES	36	93	NO	DEATH
Enoxaparin/VKA	300073216	YES	NETHERLANDS	WHITE	FEMALE	49	Asthma	喘息			MODERATE	NO	125	4	NO	RESOLVED
Enoxaparin/VKA	300073217	YES	NETHERLANDS	WHITE	MALE	49	Pleural effusion	胸水			MODERATE	YES	14	14	NO	RESOLVED
Rivaroxaban	300073219	YES	NETHERLANDS	WHITE	MALE	78	Myelofibrosis	骨髄線維症	20 mg	F	MILD	NO	206		NO	UNCHANGED
Enoxaparin/VKA	300073246	YES	NETHERLANDS	WHITE	FEMALE	45	Pulmonary congestion	肺うっ血			MODERATE	YES	54	2	YES	RESOLVED
Rivaroxaban	300073282	YES	NETHERLANDS	WHITE	FEMALE	44	Pulmonary embolism	肺塞栓症	15 mg	.	SEVERE	YES	1	2	NO	DEATH
Enoxaparin/VKA	300073283	YES	NETHERLANDS	WHITE	MALE	75	Acute myocardial infarction	急性心筋梗塞			SEVERE	YES	55	5	NO	RESOLVED
Enoxaparin/VKA	300073283	YES	NETHERLANDS	WHITE	MALE	75	Oesophageal ulcer haemorrhage	食道潰瘍出血			SEVERE	YES	59	7	YES	RESOLVED
Rivaroxaban	300073296	YES	NETHERLANDS	WHITE	MALE	50	Tooth loss	歯の脱落			SEVERE	YES			NO	RESOLVED
Enoxaparin/VKA	300073298	YES	NETHERLANDS	WHITE	FEMALE	21	Muscle haemorrhage	筋肉内出血			MODERATE	YES	7	7	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	300073298	YES	NETHERLANDS	WHITE	FEMALE	21	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MODERATE	YES	14	10	YES	RESOLVED
Rivaroxaban	300073299	YES	NETHERLANDS	WHITE	MALE	62	Cauda equina syndrome	馬尾症候群	15 mg	.	SEVERE	YES	15	8	NO	RESOLVED
Enoxaparin/VKA	300073321	YES	NETHERLANDS	WHITE	MALE	71	Haematoma	血腫			SEVERE	YES	14		YES	RESOLVED
Enoxaparin/VKA	300073327	YES	NETHERLANDS	WHITE	FEMALE	73	Cardiac failure congestive	うっ血性心不全			MODERATE	YES	96	11	NO	IMPROVED
Enoxaparin/VKA	300073328	YES	NETHERLANDS	WHITE	FEMALE	64	Bronchial obstruction	気管支閉塞			MODERATE	YES	58	13	NO	RESOLVED
Enoxaparin/VKA	300073328	YES	NETHERLANDS	WHITE	FEMALE	64	Bronchial obstruction	気管支閉塞			MODERATE	YES	104	19	NO	RESOLVED
Enoxaparin/VKA	300073335	YES	NETHERLANDS	WHITE	MALE	59	Pneumothorax	気胸			MODERATE	YES	176	4	NO	RESOLVED
Rivaroxaban	300073338	YES	NETHERLANDS	WHITE	MALE	63	Rectal haemorrhage	直腸出血	20 mg	.	MODERATE	YES	106	3	YES	RESOLVED
Rivaroxaban	300073351	YES	NETHERLANDS	WHITE	MALE	61	Gastric cancer	胃癌			SEVERE	YES			NO	UNCHANGED
Rivaroxaban	300073351	YES	NETHERLANDS	WHITE	MALE	61	Renal impairment	腎機能障害	20 mg	.	SEVERE	YES	176	11	NO	IMPROVED
Enoxaparin/VKA	300073353	YES	NETHERLANDS	WHITE	FEMALE	79	Respiratory tract infection	気道感染			MODERATE	YES	67	6	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	300083044	YES	NETHERLANDS	WHITE	MALE	62	Post procedural haemorrhage	処置後出血			MODERATE	YES	7	2	YES	RESOLVED
Enoxaparin/VKA	300083044	YES	NETHERLANDS	WHITE	MALE	62	Iliac artery thrombosis	腸骨動脈血栓症			SEVERE	YES	23	2	NO	RESOLVED
Enoxaparin/VKA	300083044	YES	NETHERLANDS	WHITE	MALE	62	Urinary tract infection	尿路感染			MODERATE	NO	51	8	NO	RESOLVED
Rivaroxaban	300083048	YES	NETHERLANDS	BLACK	FEMALE	51	Haemoptysis	喀血	20 mg	.	MILD	YES	25	1	YES	RESOLVED
Rivaroxaban	300083049	YES	NETHERLANDS	WHITE	MALE	74	Medical observation	医学的観察	15 mg	.	MODERATE	YES	17	2	NO	RESOLVED
Rivaroxaban	300083049	YES	NETHERLANDS	WHITE	MALE	74	Pneumonia	肺炎	20 mg	.	MODERATE	YES	33	12	NO	RESOLVED
Rivaroxaban	300083049	YES	NETHERLANDS	WHITE	MALE	74	Rectal haemorrhage	直腸出血	20 mg	.	SEVERE	YES	41	2	YES	RESOLVED
Rivaroxaban	300103003	YES	NETHERLANDS	WHITE	MALE	66	Adrenal haemorrhage	副腎出血	20 mg	.	SEVERE	YES	61	10	YES	RESOLVED
Rivaroxaban	300103003	YES	NETHERLANDS	WHITE	MALE	66	Addison's disease	アジソン病	20 mg	F	SEVERE	YES	64		YES	UNCHANGED
Rivaroxaban	340013001	YES	SWEDEN	WHITE	FEMALE	24	Bronchopneumonia	気管支肺炎	20 mg	.	MODERATE	YES	125	18	NO	RESOLVED
Enoxaparin/VKA	340013013	YES	SWEDEN	WHITE	FEMALE	85	Sick sinus syndrome	洞不全症候群			MODERATE	YES	133	5	NO	RESOLVED
Enoxaparin/VKA	340013019	YES	SWEDEN	WHITE	FEMALE	38	Pneumonia mycoplasmal	マイコプラズマ性肺炎			MODERATE	YES	6	4	NO	IMPROVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	340013025	YES	SWEDEN	WHITE	MALE	60	Nephrotic syndrome	ネフローゼ症候群	20 mg	.	SEVERE	YES	194		NO	RESOLVED
Rivaroxaban	340013034	YES	SWEDEN	WHITE	MALE	56	Umbilical hernia	臍ヘルニア	20 mg	I	MODERATE	YES	243	2	NO	RESOLVED
Enoxaparin/VKA	340013037	YES	SWEDEN	WHITE	FEMALE	78	Dyspnoea	呼吸困難			SEVERE	YES	4	3	YES	RESOLVED
Enoxaparin/VKA	340013037	YES	SWEDEN	WHITE	FEMALE	78	Retroperitoneal haemorrhage	後腹膜出血			SEVERE	NO	18	26	YES	RESOLVED
Enoxaparin/VKA	340013037	YES	SWEDEN	WHITE	FEMALE	78	Melaena	メレナ			MODERATE	NO	18	26	YES	RESOLVED
Rivaroxaban	340013040	YES	SWEDEN	WHITE	FEMALE	85	Vertigo	回転性めまい	20 mg	.	SEVERE	YES	25	3	NO	RESOLVED
Rivaroxaban	340013040	YES	SWEDEN	WHITE	FEMALE	85	Atrial fibrillation	心房細動	20 mg	.	MODERATE	YES	35	2	NO	RESOLVED
Enoxaparin/VKA	340013042	YES	SWEDEN	WHITE	MALE	38	Liver function test abnormal	肝機能検査異常			MILD	YES	14	9	YES	RESOLVED
Rivaroxaban	340013047	YES	SWEDEN	WHITE	FEMALE	59	Dyspnoea	呼吸困難	15 mg	.	MODERATE	YES	12	3	NO	RESOLVED
Enoxaparin/VKA	340013048	YES	SWEDEN	WHITE	MALE	64	Pulmonary fibrosis	肺線維症			MODERATE	YES	51	8	NO	RESOLVED
Enoxaparin/VKA	340013048	YES	SWEDEN	WHITE	MALE	64	Headache	頭痛			MODERATE	YES	95	5	NO	RESOLVED
Enoxaparin/VKA	340013048	YES	SWEDEN	WHITE	MALE	64	Atrial fibrillation	心房細動			MODERATE	YES	175	9	NO	RESOLVED
Rivaroxaban	340013051	YES	SWEDEN	WHITE	MALE	65	Cholecystitis	胆嚢炎	15 mg	.	MODERATE	YES	1	5	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	340043003	YES	SWEDEN	WHITE	FEMALE	81	Asthma	喘息			SEVERE	NO	367	5	NO	IMPROVED
Rivaroxaban	340043009	YES	SWEDEN	WHITE	FEMALE	36	Brain neoplasm	脳新生物	20 mg	.	SEVERE	YES	340		NO	IMPROVED
Rivaroxaban	340043017	YES	SWEDEN	WHITE	MALE	59	Thrombocytopenia	血小板減少症	15 mg	.	SEVERE	YES	18	99	YES	RESOLVED
Enoxaparin/VKA	340043020	YES	SWEDEN	WHITE	MALE	64	Hyperparathyroidism primary	原発性副甲状腺機能亢進症			MODERATE	NO	384	2	NO	RESOLVED
Enoxaparin/VKA	340043024	YES	SWEDEN	WHITE	FEMALE	66	Retinal degeneration	網膜変性			SEVERE	YES	274	3	NO	RESOLVED
Rivaroxaban	340043027	YES	SWEDEN	WHITE	FEMALE	72	Renal neoplasm	腎新生物	20 mg	.	SEVERE	YES	59		NO	IMPROVED
Rivaroxaban	340043028	YES	SWEDEN	WHITE	FEMALE	55	Nausea	悪心	20 mg	I	SEVERE	YES	35	3	YES	RESOLVED
Enoxaparin/VKA	340053006	YES	SWEDEN	WHITE	MALE	56	Urosepsis	尿路性敗血症			MODERATE	NO	17	4	NO	RESOLVED
Rivaroxaban	340083002	YES	SWEDEN	WHITE	FEMALE	65	Liver function test abnormal	肝機能検査異常	20 mg	.	MILD	YES	55	42	NO	RESOLVED
Enoxaparin/VKA	360013001	YES	NORWAY	WHITE	MALE	24	Pyrexia	発熱			MODERATE	YES	8	6	NO	RESOLVED
Enoxaparin/VKA	360013001	YES	NORWAY	WHITE	MALE	24	Respiratory tract infection	気道感染			MODERATE	YES	8	6	NO	RESOLVED
Rivaroxaban	360013017	YES	NORWAY	WHITE	MALE	61	Dyspnoea	呼吸困難	15 mg	.	MODERATE	YES	19	5	NO	RESOLVED
Enoxaparin/VKA	360013029	YES	NORWAY	WHITE	MALE	57	Chest pain	胸痛			MODERATE	YES	158	6	NO	RESOLVED
Enoxaparin/VKA	360013035	YES	NORWAY	WHITE	FEMALE	74	Humerus fracture	上腕骨骨折			MODERATE	YES	109	6	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	360023007	YES	NORWAY	WHITE	MALE	33	Chest pain	胸痛	15 mg	.	MODERATE	YES	3	2	NO	RESOLVED
Rivaroxaban	360023007	YES	NORWAY	WHITE	MALE	33	Syncope	失神	15 mg	.	MODERATE	YES	3	2	NO	RESOLVED
Rivaroxaban	360023010	YES	NORWAY	WHITE	FEMALE	71	Haematemesis	吐血	15 mg	.	MODERATE	YES	7	6	YES	RESOLVED
Rivaroxaban	360023010	YES	NORWAY	WHITE	FEMALE	71	Myalgia	筋肉痛	15 mg	.	SEVERE	YES	7	6	NO	RESOLVED
Rivaroxaban	360023010	YES	NORWAY	WHITE	FEMALE	71	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	15 mg	F	SEVERE	YES	23	70	YES	RESOLVED
Rivaroxaban	360023010	YES	NORWAY	WHITE	FEMALE	71	Chest pain	胸痛	15 mg	F	SEVERE	YES	23	5	NO	RESOLVED
Rivaroxaban	360043003	YES	NORWAY	WHITE	FEMALE	78	Bladder cancer	膀胱癌	15 mg	F	SEVERE	NO	21		NO	UNCHANGED
Rivaroxaban	360043005	YES	NORWAY	WHITE	FEMALE	83	Colon cancer	結腸癌	20 mg	.	SEVERE	YES	134	34	NO	RESOLVED
Enoxaparin/VKA	360043010	YES	NORWAY	WHITE	MALE	65	Bladder cancer	膀胱癌			MODERATE	YES			NO	RESOLVED
Enoxaparin/VKA	360043019	YES	NORWAY	WHITE	FEMALE	54	Syncope	失神			MODERATE	YES	9	2	NO	RESOLVED
Enoxaparin/VKA	370013005	YES	SOUTH AFRICA	WHITE	MALE	88	Pneumonia	肺炎			SEVERE	YES	8	10	NO	RESOLVED
Enoxaparin/VKA	370013005	YES	SOUTH AFRICA	WHITE	MALE	88	Subdural haemorrhage	硬膜下出血			SEVERE	YES	108	9	YES	RESOLVED
Enoxaparin/VKA	370013005	YES	SOUTH AFRICA	WHITE	MALE	88	Hyperkeratosis	過角化			MODERATE	NO	158	2	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Large intestinal obstruction	大腸閉塞	15 mg	.	SEVERE	YES	10		NO	UNCHANGED
Rivaroxaban	370013010	YES	SOUTH AFRICA	WHITE	MALE	70	Ventricular fibrillation	心室細動	15 mg	F	SEVERE	NO	19	1	NO	DEATH
Enoxaparin/VKA	370023029	YES	SOUTH AFRICA	WHITE	FEMALE	74	Abdominal wall haematoma	腹壁血腫			SEVERE	YES	23	1	YES	DEATH
Enoxaparin/VKA	370023031	YES	SOUTH AFRICA	WHITE	FEMALE	75	Haemorrhagic anaemia	出血性貧血			MODERATE	YES	3		YES	UNCHANGED
Enoxaparin/VKA	370023031	YES	SOUTH AFRICA	WHITE	FEMALE	75	Coagulopathy	凝血異常			SEVERE	YES	4		YES	UNCHANGED
Enoxaparin/VKA	370023031	YES	SOUTH AFRICA	WHITE	FEMALE	75	Respiratory failure	呼吸不全			SEVERE	NO	10	1	NO	DEATH
Enoxaparin/VKA	370043004	YES	SOUTH AFRICA	WHITE	FEMALE	71	Haemorrhage subcutaneous	皮下出血			MODERATE	YES	128	5	YES	RESOLVED
Enoxaparin/VKA	370043007	YES	SOUTH AFRICA	UNCODABLE	MALE	60	Cardiac failure	心不全			MILD	YES	22	2	NO	RESOLVED
Enoxaparin/VKA	370043007	YES	SOUTH AFRICA	UNCODABLE	MALE	60	Cardiac failure	心不全			MILD	YES	209	14	NO	RESOLVED
Rivaroxaban	370043011	YES	SOUTH AFRICA	WHITE	FEMALE	68	Cellulitis	蜂巣炎	20 mg	.	MODERATE	YES	84	4	NO	RESOLVED
Enoxaparin/VKA	370043026	YES	SOUTH AFRICA	WHITE	FEMALE	79	Lung adenocarcinoma	肺腺癌			MODERATE	YES	112	326	NO	DEATH
Rivaroxaban	370043027	YES	SOUTH AFRICA	WHITE	FEMALE	62	Hyponatraemia	低ナトリウム血症	20 mg	.	SEVERE	YES	62	16	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	370043027	YES	SOUTH AFRICA	WHITE	FEMALE	62	Pericardial effusion	心嚢液貯留	20 mg	.	MODERATE	YES	96	3	NO	RESOLVED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Haemoptysis	喀血	15 mg	.	MILD	YES	3	1	NO	RESOLVED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	T-cell lymphoma	Ｔ細胞性リンパ腫	15 mg	.	SEVERE	YES	15		NO	UNCHANGED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Spinal compression fracture	脊椎圧迫骨折	15 mg	.	SEVERE	YES	16	10	NO	RESOLVED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Histiocytosis haematophagic	貪食細胞性組織球症	20 mg	.	SEVERE	YES	83		NO	UNCHANGED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Guillain-Barre syndrome	ギラン・バレー症候群	20 mg	.	SEVERE	YES	121		NO	UNCHANGED
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Multi-organ failure	多臓器不全	20 mg	F	SEVERE	NO	184	1	NO	DEATH
Rivaroxaban	370053012	YES	SOUTH AFRICA	WHITE	MALE	62	Neutropenic sepsis	好中球減少性敗血症	20 mg	F	SEVERE	NO	184		NO	UNCHANGED
Enoxaparin/VKA	370053015	YES	SOUTH AFRICA	BLACK	FEMALE	41	Epistaxis	鼻出血			MILD	YES	2	1	NO	RESOLVED
Enoxaparin/VKA	370053016	YES	SOUTH AFRICA	WHITE	FEMALE	63	Haematemesis	吐血			MODERATE	YES	11	2	YES	RESOLVED
Rivaroxaban	370053017	YES	SOUTH AFRICA	WHITE	FEMALE	74	Hypersensitivity	過敏症	15 mg	.	MODERATE	YES	16	2	NO	RESOLVED
Rivaroxaban	370053020	YES	SOUTH AFRICA	BLACK	FEMALE	41	Syncope	失神			MILD	YES			NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370053023	YES	SOUTH AFRICA	WHITE	FEMALE	56	Haematuria	血尿			MODERATE	YES	84	3	YES	RESOLVED
Enoxaparin/VKA	370053023	YES	SOUTH AFRICA	WHITE	FEMALE	56	Bronchitis	気管支炎			MODERATE	YES	84	3	NO	RESOLVED
Rivaroxaban	370053024	YES	SOUTH AFRICA	WHITE	FEMALE	80	Cor pulmonale	肺性心	20 mg	.	MILD	YES	53		NO	UNCHANGED
Rivaroxaban	370053028	YES	SOUTH AFRICA	WHITE	FEMALE	26	Menorrhagia	月経過多	20 mg	.	MODERATE	YES	38	36	YES	RESOLVED
Rivaroxaban	370053028	YES	SOUTH AFRICA	WHITE	FEMALE	26	Cholelithiasis	胆石症	20 mg	.	MODERATE	YES	113	12	NO	RESOLVED
Enoxaparin/VKA	370053030	YES	SOUTH AFRICA	WHITE	MALE	61	Melaena	メレナ			MODERATE	YES	58	2	YES	RESOLVED
Enoxaparin/VKA	370053030	YES	SOUTH AFRICA	WHITE	MALE	61	Chest pain	胸痛			SEVERE	YES	176	2	NO	RESOLVED
Rivaroxaban	370053041	YES	SOUTH AFRICA	WHITE	MALE	37	Chest pain	胸痛	15 mg	.	SEVERE	YES	5	4	NO	RESOLVED
Rivaroxaban	370053041	YES	SOUTH AFRICA	WHITE	MALE	37	Dyspnoea	呼吸困難	15 mg	.	SEVERE	YES	5	4	NO	RESOLVED
Rivaroxaban	370053046	YES	SOUTH AFRICA	WHITE	FEMALE	65	Death	死亡	20 mg	.	SEVERE	YES	56	1	NO	DEATH
Rivaroxaban	370053049	YES	SOUTH AFRICA	BLACK	FEMALE	74	Gastritis	胃炎	20 mg	.	MILD	YES	128	4	NO	RESOLVED
Rivaroxaban	370053049	YES	SOUTH AFRICA	BLACK	FEMALE	74	Pleural effusion	胸水	20 mg	.	MODERATE	YES	193	11	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	370053049	YES	SOUTH AFRICA	BLACK	FEMALE	74	Tuberculosis	結核	20 mg	F	MODERATE	NO	202		NO	IMPROVED
Enoxaparin/VKA	370053055	YES	SOUTH AFRICA	WHITE	MALE	45	Chest pain	胸痛			MILD	YES	342	14	NO	RESOLVED
Enoxaparin/VKA	370053058	YES	SOUTH AFRICA	WHITE	MALE	77	Dyspnoea	呼吸困難			MILD	YES	7	3	NO	RESOLVED
Enoxaparin/VKA	370053058	YES	SOUTH AFRICA	WHITE	MALE	77	Anxiety	不安			MILD	YES	7		NO	IMPROVED
Enoxaparin/VKA	370053058	YES	SOUTH AFRICA	WHITE	MALE	77	Perirenal haematoma	腎周囲血腫			MODERATE	YES	49	20	YES	RESOLVED
Enoxaparin/VKA	370053059	YES	SOUTH AFRICA	WHITE	FEMALE	82	Angina unstable	不安定狭心症			MILD	YES	65	6	NO	RESOLVED
Rivaroxaban	370053061	YES	SOUTH AFRICA	WHITE	FEMALE	46	Subcutaneous haematoma	皮下血腫	15 mg	.	MODERATE	YES	7	4	YES	RESOLVED
Rivaroxaban	370053066	YES	SOUTH AFRICA	WHITE	FEMALE	25	Depression	うつ病	20 mg	.	MILD	YES	153	10	NO	RESOLVED
Rivaroxaban	370053070	YES	SOUTH AFRICA	WHITE	MALE	71	Hypotension	低血圧	15 mg	.	MILD	YES	16	2	NO	RESOLVED
Enoxaparin/VKA	370053073	YES	SOUTH AFRICA	WHITE	MALE	97	Pneumonia	肺炎			SEVERE	YES	17		NO	UNCHANGED
Enoxaparin/VKA	370053073	YES	SOUTH AFRICA	WHITE	MALE	97	Acute respiratory distress syndrome	急性呼吸窮迫症候群			SEVERE	YES	33	1	NO	DEATH

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370053079	YES	SOUTH AFRICA	WHITE	MALE	65	Angina pectoris	狭心症			MILD	YES	169	10	NO	RESOLVED
Enoxaparin/VKA	370053081	YES	SOUTH AFRICA	WHITE	FEMALE	34	Haematemesis	吐血			MILD	YES	6	1	YES	RESOLVED
Enoxaparin/VKA	370053081	YES	SOUTH AFRICA	WHITE	FEMALE	34	Bronchospasm	気管支痙攣			MILD	YES	11	7	NO	RESOLVED
Enoxaparin/VKA	370053081	YES	SOUTH AFRICA	WHITE	FEMALE	34	Vomiting	嘔吐			MILD	YES	78	5	NO	RESOLVED
Enoxaparin/VKA	370053081	YES	SOUTH AFRICA	WHITE	FEMALE	34	Migraine	片頭痛			MODERATE	YES	110	4	NO	RESOLVED
Enoxaparin/VKA	370053081	YES	SOUTH AFRICA	WHITE	FEMALE	34	Bronchopneumonia	気管支肺炎			MODERATE	YES	132	6	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Arthralgia	関節痛	15 mg	.	MODERATE	YES	18	23	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Diarrhoea	下痢	20 mg	.	MILD	YES	35	2	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Supraventricular tachycardia	上室性頻脈	20 mg	.	MODERATE	YES	37	2	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Diarrhoea	下痢	20 mg	.	SEVERE	YES	81	11	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Vomiting	嘔吐	20 mg	.	SEVERE	YES	81	11	NO	RESOLVED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Hiatus hernia	裂孔ヘルニア	20 mg	.	SEVERE	YES	89		NO	UNCHANGED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Gastrooesophageal reflux disease	胃食道逆流性疾患	20 mg	.	SEVERE	YES	89		NO	UNCHANGED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Thrombocytopenia	血小板減少症	20 mg	.	SEVERE	YES	111		NO	UNCHANGED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Gastroenteritis	胃腸炎	20 mg	.	SEVERE	YES	111		NO	UNCHANGED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Infectious peritonitis	感染性腹膜炎	20 mg	.	MODERATE	YES	116		NO	UNCHANGED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Acidosis	アシドーシス	20 mg	F	MODERATE	YES	117		NO	UNCHANGED
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Intestinal infarction	腸梗塞	20 mg	F	SEVERE	YES	118	3	NO	DEATH
Rivaroxaban	370053087	YES	SOUTH AFRICA	WHITE	FEMALE	83	Sepsis	敗血症	20 mg	F	SEVERE	NO	120	1	NO	DEATH
Enoxaparin/VKA	370053093	YES	SOUTH AFRICA	WHITE	FEMALE	58	Urinary tract infection	尿路感染			MODERATE	YES	38	3	NO	RESOLVED
Enoxaparin/VKA	370053093	YES	SOUTH AFRICA	WHITE	FEMALE	58	Cor pulmonale	肺性心			MODERATE	YES	164	10	NO	IMPROVED
Enoxaparin/VKA	370053093	YES	SOUTH AFRICA	WHITE	FEMALE	58	Lower respiratory tract infection	下気道感染			MODERATE	YES	164	10	NO	RESOLVED
Enoxaparin/VKA	370053093	YES	SOUTH AFRICA	WHITE	FEMALE	58	Encephalopathy	脳症			MODERATE	YES	182	11	NO	RESOLVED
Enoxaparin/VKA	370053093	YES	SOUTH AFRICA	WHITE	FEMALE	58	Hepatic failure	肝不全			MODERATE	NO	186		NO	UNCHANGED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	370053095	YES	SOUTH AFRICA	ASIAN	FEMALE	24	Pneumonia	肺炎	15 mg	I	MODERATE	YES	4	5	NO	RESOLVED
Rivaroxaban	370053095	YES	SOUTH AFRICA	ASIAN	FEMALE	24	Pleural effusion	胸水	15 mg	I	MODERATE	YES	4	5	NO	RESOLVED
Rivaroxaban	370053097	YES	SOUTH AFRICA	BLACK	FEMALE	42	Chest pain	胸痛	15 mg	.	MODERATE	YES	2	4	NO	RESOLVED
Rivaroxaban	370053097	YES	SOUTH AFRICA	BLACK	FEMALE	42	Mastitis	乳腺炎	15 mg	.	MILD	YES	12	5	NO	RESOLVED
Rivaroxaban	370053097	YES	SOUTH AFRICA	BLACK	FEMALE	42	Menorrhagia	月経過多	20 mg	.	MILD	YES	109	4	YES	RESOLVED
Rivaroxaban	370053097	YES	SOUTH AFRICA	BLACK	FEMALE	42	Haematuria	血尿	20 mg	.	MILD	YES	109	4	YES	RESOLVED
Rivaroxaban	370053097	YES	SOUTH AFRICA	BLACK	FEMALE	42	Type 2 diabetes mellitus	２型糖尿病	20 mg	.	MILD	YES	110	6	NO	RESOLVED
Rivaroxaban	370053097	YES	SOUTH AFRICA	BLACK	FEMALE	42	Fibroadenoma of breast	乳腺線維腺腫	20 mg	.	MODERATE	YES	172	20	NO	RESOLVED
Rivaroxaban	370053097	YES	SOUTH AFRICA	BLACK	FEMALE	42	Rotator cuff syndrome	肩回旋筋腱板症候群	20 mg	.	MILD	YES	172	2	NO	RESOLVED
Rivaroxaban	370053097	YES	SOUTH AFRICA	BLACK	FEMALE	42	Cervical spinal stenosis	頚部脊柱管狭窄症	20 mg	.	MILD	YES	205	18	NO	RESOLVED
Rivaroxaban	370053097	YES	SOUTH AFRICA	BLACK	FEMALE	42	Nausea	悪心	20 mg	.	MILD	YES	205	4	NO	RESOLVED
Enoxaparin/VKA	370053106	YES	SOUTH AFRICA	BLACK	FEMALE	69	Haemorrhoidal haemorrhage	痔出血			MODERATE	YES	16	3	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370053106	YES	SOUTH AFRICA	BLACK	FEMALE	69	Cardiac failure congestive	うっ血性心不全			MODERATE	YES	17	12	NO	RESOLVED
Enoxaparin/VKA	370053106	YES	SOUTH AFRICA	BLACK	FEMALE	69	Renal impairment	腎機能障害			MODERATE	YES	17	12	NO	RESOLVED
Enoxaparin/VKA	370053106	YES	SOUTH AFRICA	BLACK	FEMALE	69	Coagulation time prolonged	凝固時間延長			MODERATE	YES	17	2	YES	RESOLVED
Enoxaparin/VKA	370053106	YES	SOUTH AFRICA	BLACK	FEMALE	69	Gastritis haemorrhagic	出血性胃炎			MILD	YES	19	10	YES	RESOLVED
Enoxaparin/VKA	370053106	YES	SOUTH AFRICA	BLACK	FEMALE	69	Cardiac failure congestive	うっ血性心不全			MODERATE	YES	58	19	NO	RESOLVED
Enoxaparin/VKA	370053106	YES	SOUTH AFRICA	BLACK	FEMALE	69	Hypotension	低血圧			MODERATE	YES	58	3	NO	RESOLVED
Enoxaparin/VKA	370053106	YES	SOUTH AFRICA	BLACK	FEMALE	69	Pleural effusion	胸水			MODERATE	YES	59	18	NO	RESOLVED
Enoxaparin/VKA	370053106	YES	SOUTH AFRICA	BLACK	FEMALE	69	Cardiac failure congestive	うっ血性心不全			MILD	YES	118	21	NO	RESOLVED
Enoxaparin/VKA	370053106	YES	SOUTH AFRICA	BLACK	FEMALE	69	Hypoalbuminaemia	低アルブミン血症			MILD	YES	118	19	NO	RESOLVED
Enoxaparin/VKA	370053106	YES	SOUTH AFRICA	BLACK	FEMALE	69	Cardiac failure congestive	うっ血性心不全			MODERATE	NO	188	3	NO	RESOLVED
Rivaroxaban	370053108	YES	SOUTH AFRICA	WHITE	MALE	68	Cardiac failure congestive	うっ血性心不全	20 mg	I	MODERATE	YES	249	7	NO	RESOLVED
Rivaroxaban	370053108	YES	SOUTH AFRICA	WHITE	MALE	68	Hypotension	低血圧	20 mg	I	MODERATE	YES	251	2	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370053110	YES	SOUTH AFRICA	BLACK	MALE	76	Bronchopneumonia	気管支肺炎			MODERATE	YES	49	9	NO	RESOLVED
Enoxaparin/VKA	370053110	YES	SOUTH AFRICA	BLACK	MALE	76	Cardiac failure congestive	うっ血性心不全			MILD	YES	126		NO	IMPROVED
Enoxaparin/VKA	370053117	YES	SOUTH AFRICA	WHITE	MALE	57	Cellulitis	蜂巣炎			MILD	YES	70	7	NO	RESOLVED
Enoxaparin/VKA	370053122	YES	SOUTH AFRICA	WHITE	FEMALE	64	Diverticulum	憩室			MILD	YES	114	3	NO	RESOLVED
Enoxaparin/VKA	370053122	YES	SOUTH AFRICA	WHITE	FEMALE	64	Anaemia	貧血			MODERATE	YES	114	2	NO	RESOLVED
Rivaroxaban	370053132	YES	SOUTH AFRICA	WHITE	MALE	42	Gastric cancer	胃癌	15 mg	.	SEVERE	YES	14	7	NO	DEATH
Rivaroxaban	370063018	YES	SOUTH AFRICA	BLACK	FEMALE	45	Pulmonary oedema	肺水腫	20 mg	.	MODERATE	YES	43		NO	IMPROVED
Rivaroxaban	370063018	YES	SOUTH AFRICA	BLACK	FEMALE	45	Cardiac failure	心不全	20 mg	.	MODERATE	YES	43		NO	IMPROVED
Rivaroxaban	370063018	YES	SOUTH AFRICA	BLACK	FEMALE	45	Lower respiratory tract infection	下気道感染	20 mg	.	MODERATE	YES	43	5	NO	IMPROVED
Rivaroxaban	370063018	YES	SOUTH AFRICA	BLACK	FEMALE	45	Congestive cardiomyopathy	うっ血性心筋症	20 mg	.	SEVERE	YES	118	2	YES	DEATH
Rivaroxaban	370063018	YES	SOUTH AFRICA	BLACK	FEMALE	45	Cardiac failure congestive	うっ血性心不全	20 mg	.	SEVERE	YES	118	2	YES	DEATH
Enoxaparin/VKA	370063019	YES	SOUTH AFRICA	BLACK	FEMALE	37	Haemoptysis	喀血			MILD	YES	19	12	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370073004	YES	SOUTH AFRICA	WHITE	FEMALE	78	Lung cancer metastatic	転移性肺癌			SEVERE	YES	165		NO	UNCHANGED
Enoxaparin/VKA	370073006	YES	SOUTH AFRICA	WHITE	MALE	77	Cholecystitis acute	急性胆嚢炎			SEVERE	YES	3	6	NO	RESOLVED
Rivaroxaban	370073015	YES	SOUTH AFRICA	WHITE	MALE	71	Sepsis	敗血症	20 mg	F	SEVERE	NO	112	6	NO	DEATH
Enoxaparin/VKA	370073022	YES	SOUTH AFRICA	WHITE	FEMALE	87	Hyperkalaemia	高カリウム血症			MILD	YES	141	28	NO	RESOLVED
Rivaroxaban	370073023	YES	SOUTH AFRICA	WHITE	FEMALE	65	Anxiety	不安	20 mg	.	MILD	YES	115	6	NO	IMPROVED
Rivaroxaban	370093004	YES	SOUTH AFRICA	WHITE	FEMALE	60	Pain in extremity	四肢痛	20 mg	.	SEVERE	YES	90	11	NO	RESOLVED
Rivaroxaban	370093008	YES	SOUTH AFRICA	ASIAN	FEMALE	53	Spinal disorder	脊椎障害	15 mg	.	MODERATE	YES	20	9	NO	RESOLVED
Rivaroxaban	370093008	YES	SOUTH AFRICA	ASIAN	FEMALE	53	Nervous system disorder	神経系障害	15 mg	.	MODERATE	YES	20	9	NO	RESOLVED
Rivaroxaban	370093009	YES	SOUTH AFRICA	WHITE	FEMALE	77	Diverticulitis	憩室炎	15 mg	.	MODERATE	YES	21	3	NO	RESOLVED
Rivaroxaban	370093015	YES	SOUTH AFRICA	BLACK	MALE	46	Subdiaphragmatic abscess	横隔膜下膿瘍	15 mg	.	MODERATE	YES	9	9	NO	RESOLVED
Rivaroxaban	370093017	YES	SOUTH AFRICA	WHITE	FEMALE	78	Anaemia	貧血	20 mg	.	SEVERE	YES	217	4	NO	RESOLVED
Rivaroxaban	370093017	YES	SOUTH AFRICA	WHITE	FEMALE	78	Colon cancer	結腸癌	20 mg	F	SEVERE	NO	373	1	NO	DEATH

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370113005	YES	SOUTH AFRICA	WHITE	FEMALE	68	Pneumonia	肺炎			SEVERE	YES	2	12	NO	RESOLVED
Enoxaparin/VKA	370113005	YES	SOUTH AFRICA	WHITE	FEMALE	68	Sepsis	敗血症			SEVERE	YES	2	12	NO	RESOLVED
Enoxaparin/VKA	370113005	YES	SOUTH AFRICA	WHITE	FEMALE	68	Pleural effusion	胸水			SEVERE	YES	2	12	NO	RESOLVED
Rivaroxaban	370113006	YES	SOUTH AFRICA	WHITE	MALE	76	Atrial fibrillation	心房細動	15 mg	.	MODERATE	YES	2	1	NO	RESOLVED
Rivaroxaban	370113006	YES	SOUTH AFRICA	WHITE	MALE	76	Gastrointestinal haemorrhage	胃腸出血	15 mg	.	MILD	YES	6	2	YES	RESOLVED
Rivaroxaban	370113014	YES	SOUTH AFRICA	WHITE	MALE	66	Haematuria	血尿	15 mg	.	SEVERE	YES	3	5	YES	RESOLVED
Rivaroxaban	370113026	YES	SOUTH AFRICA	WHITE	FEMALE	78	Epistaxis	鼻出血	15 mg	.	MODERATE	YES	4	1	YES	RESOLVED
Rivaroxaban	370113026	YES	SOUTH AFRICA	WHITE	FEMALE	78	Bronchopneumonia	気管支肺炎	15 mg	I	SEVERE	YES	23	8	NO	RESOLVED
Enoxaparin/VKA	370113027	YES	SOUTH AFRICA	WHITE	MALE	37	Soft tissue injury	軟部組織損傷			SEVERE	YES	282	11	NO	RESOLVED
Enoxaparin/VKA	370113027	YES	SOUTH AFRICA	WHITE	MALE	37	Idiopathic thrombocytopenic purpura	特発性血小板減少性紫斑病			MODERATE	YES	313	7	NO	RESOLVED
Rivaroxaban	370113028	YES	SOUTH AFRICA	WHITE	FEMALE	86	Pneumonia	肺炎	20 mg	.	SEVERE	YES	42	2	NO	DEATH
Enoxaparin/VKA	370113031	YES	SOUTH AFRICA	WHITE	FEMALE	63	Cystitis	膀胱炎			MODERATE	YES	91	4	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370113035	YES	SOUTH AFRICA	WHITE	FEMALE	42	Pneumonia	肺炎			MODERATE	YES	20	5	NO	RESOLVED
Enoxaparin/VKA	370113035	YES	SOUTH AFRICA	WHITE	FEMALE	42	Pneumonia primary atypical	原発性異型肺炎			SEVERE	YES	56	31	NO	RESOLVED
Rivaroxaban	370113040	YES	SOUTH AFRICA	WHITE	MALE	48	Pleural effusion	胸水	20 mg	.	MODERATE	YES	31	8	NO	IMPROVED
Rivaroxaban	370113040	YES	SOUTH AFRICA	WHITE	MALE	48	Pleural effusion	胸水	20 mg	I	SEVERE	YES	75	4	NO	RESOLVED
Enoxaparin/VKA	370113043	YES	SOUTH AFRICA	WHITE	MALE	70	Urinary tract infection	尿路感染			MODERATE	YES	132	6	NO	RESOLVED
Rivaroxaban	370113044	YES	SOUTH AFRICA	WHITE	FEMALE	79	Pyelonephritis	腎盂腎炎			MODERATE	YES	39	5	NO	RESOLVED
Rivaroxaban	370113045	YES	SOUTH AFRICA	WHITE	MALE	33	Dyspnoea	呼吸困難	15 mg	.	MODERATE	YES	5	3	NO	RESOLVED
Rivaroxaban	370153012	YES	SOUTH AFRICA	WHITE	FEMALE	26	Haemoptysis	喀血	20 mg	.	MILD	YES	91	1	NO	RESOLVED
Enoxaparin/VKA	370153016	YES	SOUTH AFRICA	ASIAN	FEMALE	68	Cholelithiasis	胆石症			MILD	YES	35		NO	UNCHANGED
Enoxaparin/VKA	370153016	YES	SOUTH AFRICA	ASIAN	FEMALE	68	Rectal haemorrhage	直腸出血			MILD	YES	41	1	NO	RESOLVED
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Epistaxis	鼻出血			SEVERE	YES	83	1	YES	RESOLVED
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Rectal haemorrhage	直腸出血			SEVERE	YES	83	2	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	370153017	YES	SOUTH AFRICA	BLACK	FEMALE	66	Lobar pneumonia	大葉性肺炎			SEVERE	NO	91	11	NO	DEATH
Rivaroxaban	370153018	YES	SOUTH AFRICA	BLACK	MALE	59	Sepsis	敗血症	20 mg	I	SEVERE	YES	85	99	NO	RESOLVED
Enoxaparin/VKA	370153019	YES	SOUTH AFRICA	BLACK	FEMALE	69	Gastrointestinal haemorrhage	胃腸出血			MODERATE	YES	30	11	YES	RESOLVED
Rivaroxaban	370153022	YES	SOUTH AFRICA	UNCODABLE	FEMALE	54	Acute myocardial infarction	急性心筋梗塞	20 mg	I	SEVERE	YES	32	12	NO	IMPROVED
Rivaroxaban	370153022	YES	SOUTH AFRICA	UNCODABLE	FEMALE	54	Cor pulmonale	肺性心	20 mg	.	SEVERE	YES	272	5	NO	IMPROVED
Enoxaparin/VKA	380043003	YES	CZECH REPUBLIC	WHITE	FEMALE	26	Abortion induced	人工流産			MILD	YES	246	1	NO	RESOLVED
Rivaroxaban	380043004	YES	CZECH REPUBLIC	WHITE	FEMALE	74	Urinary tract infection	尿路感染	15 mg	F	MODERATE	NO	35	17	NO	RESOLVED
Rivaroxaban	380043005	YES	CZECH REPUBLIC	WHITE	FEMALE	39	Abscess soft tissue	軟部組織膿瘍	20 mg	.	MODERATE	YES	29	5	NO	RESOLVED
Enoxaparin/VKA	380043009	YES	CZECH REPUBLIC	WHITE	FEMALE	74	Renal neoplasm	腎新生物			MODERATE	YES	3	42	NO	RESOLVED
Rivaroxaban	380043011	YES	CZECH REPUBLIC	WHITE	MALE	52	Angina unstable	不安定狭心症	20 mg	.	MODERATE	YES	83	5	NO	RESOLVED
Rivaroxaban	380043011	YES	CZECH REPUBLIC	WHITE	MALE	52	Shock hypoglycaemic	低血糖ショック	20 mg	.	MILD	YES	266	2	NO	RESOLVED
Rivaroxaban	380043011	YES	CZECH REPUBLIC	WHITE	MALE	52	Aortic aneurysm	大動脈瘤	20 mg	.	SEVERE	YES	293	17	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

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Enoxaparin/VKA	380043030	YES	CZECH REPUBLIC	WHITE	FEMALE	45	Uterine polyp	子宮ポリープ			MILD	YES	264	7	NO	RESOLVED
Enoxaparin/VKA	380043030	YES	CZECH REPUBLIC	WHITE	FEMALE	45	Uterine leiomyoma	子宮平滑筋腫			MODERATE	YES	347	30	NO	RESOLVED
Enoxaparin/VKA	380043061	YES	CZECH REPUBLIC	WHITE	FEMALE	78	Intestinal haemorrhage	腸出血			SEVERE	YES	52	2	YES	RESOLVED
Rivaroxaban	380043064	YES	CZECH REPUBLIC	WHITE	FEMALE	82	Biliary colic	胆道仙痛	20 mg	.	MODERATE	YES	149	7	NO	RESOLVED
Rivaroxaban	380043064	YES	CZECH REPUBLIC	WHITE	FEMALE	82	Cholangitis	胆管炎	20 mg	I	MODERATE	YES	150	15	NO	RESOLVED
Rivaroxaban	380043064	YES	CZECH REPUBLIC	WHITE	FEMALE	82	Dyspepsia	消化不良	20 mg	.	MODERATE	YES	268	9	NO	RESOLVED
Rivaroxaban	380043084	YES	CZECH REPUBLIC	WHITE	FEMALE	57	Liver function test abnormal	肝機能検査異常	20 mg	.	MODERATE	YES	35	29	YES	RESOLVED
Enoxaparin/VKA	380043099	YES	CZECH REPUBLIC	WHITE	MALE	53	Liver function test abnormal	肝機能検査異常			MODERATE	YES	305	11	YES	IMPROVED
Enoxaparin/VKA	380043103	YES	CZECH REPUBLIC	WHITE	MALE	69	Intestinal haemorrhage	腸出血			SEVERE	YES	7	1	YES	RESOLVED
Enoxaparin/VKA	380043103	YES	CZECH REPUBLIC	WHITE	MALE	69	Bronchopneumonia	気管支肺炎			MODERATE	YES	291	13	NO	RESOLVED
Enoxaparin/VKA	380043103	YES	CZECH REPUBLIC	WHITE	MALE	69	Gastrointestinal haemorrhage	胃腸出血			SEVERE	YES	305	14	YES	RESOLVED
Enoxaparin/VKA	380043103	YES	CZECH REPUBLIC	WHITE	MALE	69	Haemorrhagic anaemia	出血性貧血			SEVERE	YES	305	8	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	380043111	YES	CZECH REPUBLIC	WHITE	MALE	71	Atrial fibrillation	心房細動	20 mg	.	MODERATE	YES	237	31	NO	RESOLVED
Rivaroxaban	380043112	YES	CZECH REPUBLIC	WHITE	FEMALE	48	Metrorrhagia	不正子宮出血	20 mg	.	MODERATE	YES	38	10	YES	RESOLVED
Rivaroxaban	380043112	YES	CZECH REPUBLIC	WHITE	FEMALE	48	Metrorrhagia	不正子宮出血	20 mg	.	MODERATE	YES	76	11	YES	RESOLVED
Rivaroxaban	380043112	YES	CZECH REPUBLIC	WHITE	FEMALE	48	Uterine leiomyoma	子宮平滑筋腫	20 mg	.	MODERATE	YES	146	7	NO	RESOLVED
Rivaroxaban	380043116	YES	CZECH REPUBLIC	WHITE	MALE	52	Varicophlebitis	静脈瘤性静脈炎	20 mg	F	MODERATE	NO	386	51	NO	RESOLVED
Rivaroxaban	380043117	YES	CZECH REPUBLIC	WHITE	MALE	55	Optic ischaemic neuropathy	虚血性視神経症	20 mg	.	MODERATE	YES	113		NO	UNCHANGED
Enoxaparin/VKA	380043121	YES	CZECH REPUBLIC	WHITE	FEMALE	53	Alcoholism	アルコール症			MILD	YES	48	91	NO	RESOLVED
Rivaroxaban	380043129	YES	CZECH REPUBLIC	WHITE	MALE	71	Pleuritic pain	胸膜痛	15 mg	.	MODERATE	YES	13	2	NO	IMPROVED
Rivaroxaban	380043145	YES	CZECH REPUBLIC	WHITE	MALE	50	Angioedema	血管浮腫	20 mg	.	MODERATE	YES	47	11	NO	RESOLVED
Rivaroxaban	380043146	YES	CZECH REPUBLIC	WHITE	MALE	66	Peripheral ischaemia	末梢性虚血	20 mg	I	SEVERE	YES	59	3	NO	RESOLVED
Enoxaparin/VKA	380043147	YES	CZECH REPUBLIC	WHITE	FEMALE	48	Metrorrhagia	不正子宮出血			MODERATE	NO	200	10	YES	RESOLVED
Enoxaparin/VKA	380053012	YES	CZECH REPUBLIC	WHITE	FEMALE	68	Chest pain	胸痛			MILD	YES	70	15	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	380053012	YES	CZECH REPUBLIC	WHITE	FEMALE	68	Atrial fibrillation	心房細動			MODERATE	NO	382	5	NO	RESOLVED
Enoxaparin/VKA	380073022	YES	CZECH REPUBLIC	WHITE	FEMALE	80	Ischaemic stroke	虚血性脳卒中			MODERATE	YES	88	6	NO	RESOLVED
Rivaroxaban	380073049	YES	CZECH REPUBLIC	WHITE	FEMALE	66	Cardiac failure	心不全	20 mg	.	MODERATE	YES	151	4	NO	RESOLVED
Rivaroxaban	380083003	YES	CZECH REPUBLIC	WHITE	MALE	66	Pyelonephritis	腎盂腎炎	20 mg	.	MODERATE	YES	117	10	NO	RESOLVED
Rivaroxaban	380083036	YES	CZECH REPUBLIC	WHITE	FEMALE	63	Transaminases increased	トランスアミナーゼ上昇	20 mg	.	MODERATE	YES	208	22	YES	IMPROVED
Rivaroxaban	380083036	YES	CZECH REPUBLIC	WHITE	FEMALE	63	Transaminases increased	トランスアミナーゼ上昇	20 mg	.	MODERATE	YES	265	53	YES	IMPROVED
Rivaroxaban	380093009	YES	CZECH REPUBLIC	WHITE	MALE	70	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	15 mg	.	MILD	YES	6	3	NO	RESOLVED
Rivaroxaban	380093035	YES	CZECH REPUBLIC	WHITE	MALE	61	Lower gastrointestinal haemorrhage	下部消化管出血	15 mg	.	MODERATE	YES	1	6	NO	RESOLVED
Rivaroxaban	380093035	YES	CZECH REPUBLIC	WHITE	MALE	61	Gastric ulcer	胃潰瘍	15 mg	.	MODERATE	YES	2	12	NO	RESOLVED
Rivaroxaban	380093035	YES	CZECH REPUBLIC	WHITE	MALE	61	Duodenal ulcer	十二指腸潰瘍	15 mg	.	MODERATE	YES	2	12	NO	RESOLVED
Rivaroxaban	380093035	YES	CZECH REPUBLIC	WHITE	MALE	61	Rectal neoplasm	直腸新生物	15 mg	I	MODERATE	YES	20	101	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	380093046	YES	CZECH REPUBLIC	WHITE	MALE	80	Pulmonary embolism	肺塞栓症	15 mg	F	SEVERE	NO	29	1	NO	DEATH
Enoxaparin/VKA	380093079	YES	CZECH REPUBLIC	WHITE	FEMALE	59	Liver function test abnormal	肝機能検査異常			MODERATE	YES	52	41	NO	RESOLVED
Enoxaparin/VKA	380093079	YES	CZECH REPUBLIC	WHITE	FEMALE	59	Bile duct stone	胆管結石			MODERATE	YES	337	20	NO	RESOLVED
Rivaroxaban	380093091	YES	CZECH REPUBLIC	WHITE	MALE	63	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	20 mg	.	MODERATE	YES	70	36	NO	RESOLVED
Enoxaparin/VKA	380113001	YES	CZECH REPUBLIC	WHITE	MALE	72	Mantle cell lymphoma	マントル細胞リンパ腫			SEVERE	NO	30		NO	UNCHANGED
Enoxaparin/VKA	380113001	YES	CZECH REPUBLIC	WHITE	MALE	72	Febrile neutropenia	発熱性好中球減少症			SEVERE	NO	46	4	NO	RESOLVED
Rivaroxaban	390013031	YES	ISRAEL	WHITE	FEMALE	90	Cerebellar haemorrhage	小脳出血	20 mg	F	SEVERE	YES	284	1	YES	DEATH
Rivaroxaban	390013040	YES	ISRAEL	WHITE	MALE	74	Dizziness	浮動性めまい	20 mg	.	MILD	YES	265	4	NO	RESOLVED
Rivaroxaban	390013048	YES	ISRAEL	WHITE	MALE	97	Hip fracture	股関節部骨折	20 mg	I	MODERATE	YES	85	5	NO	RESOLVED
Rivaroxaban	390013048	YES	ISRAEL	WHITE	MALE	97	Dyspnoea	呼吸困難	20 mg	F	MODERATE	NO	194	6	NO	RESOLVED
Enoxaparin/VKA	390013052	YES	ISRAEL	WHITE	MALE	56	Dyspnoea	呼吸困難			MILD	YES	266	2	NO	RESOLVED
Rivaroxaban	390013055	YES	ISRAEL	WHITE	MALE	78	Liver function test abnormal	肝機能検査異常	15 mg	.	MILD	YES	3	14	NO	RESOLVED
Enoxaparin/V	390013060	YES	ISRAEL	WHITE	FEMALE	83	Back pain	背部痛			MILD	YES	14	3	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA																
Enoxaparin/VKA	390013060	YES	ISRAEL	WHITE	FEMALE	83	Pneumonia	肺炎			MILD	YES	31	4	NO	RESOLVED
Enoxaparin/VKA	390013060	YES	ISRAEL	WHITE	FEMALE	83	Hyponatraemia	低ナトリウム血症			MILD	YES	50	4	NO	RESOLVED
Enoxaparin/VKA	390013060	YES	ISRAEL	WHITE	FEMALE	83	Hyponatraemia	低ナトリウム血症			MILD	YES	78	9	NO	RESOLVED
Enoxaparin/VKA	390023006	YES	ISRAEL	WHITE	MALE	67	Drug eruption	薬疹			MILD	YES	116	3	NO	RESOLVED
Enoxaparin/VKA	390033001	YES	ISRAEL	WHITE	FEMALE	66	Deafness unilateral	片耳難聴			SEVERE	YES	146	22	NO	RESOLVED
Enoxaparin/VKA	390033002	YES	ISRAEL	WHITE	MALE	53	Lung adenocarcinoma	肺腺癌			MODERATE	YES	49	14	NO	RESOLVED
Enoxaparin/VKA	390033017	YES	ISRAEL	WHITE	FEMALE	50	Chest pain	胸痛			MODERATE	YES	31	4	NO	RESOLVED
Enoxaparin/VKA	390033018	YES	ISRAEL	WHITE	FEMALE	80	Traumatic haematoma	外傷性血腫			MILD	YES	21	6	NO	RESOLVED
Rivaroxaban	390033029	YES	ISRAEL	WHITE	FEMALE	26	Anxiety	不安	15 mg	.	MODERATE	YES	11	3	NO	RESOLVED
Rivaroxaban	390033044	YES	ISRAEL	WHITE	FEMALE	77	Dyspnoea	呼吸困難	20 mg	.	MODERATE	YES	52	4	NO	RESOLVED
Rivaroxaban	390033045	YES	ISRAEL	WHITE	FEMALE	74	Musculoskeletal chest pain	筋骨格系胸痛	20 mg	F	MODERATE	NO	191	4	NO	RESOLVED
Enoxaparin/VKA	390033047	YES	ISRAEL	WHITE	FEMALE	65	Procedural complication	処置合併症			MODERATE	NO	195	9	NO	RESOLVED
Rivaroxaban	390033048	YES	ISRAEL	WHITE	FEMALE	79	Dyspnoea	呼吸困難	20 mg	.	MODERATE	YES	128	9	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	390043009	YES	ISRAEL	WHITE	FEMALE	85	Ischaemic hepatitis	虚血性肝炎	15 mg	.	SEVERE	YES	4	5	NO	DEATH
Rivaroxaban	390043010	YES	ISRAEL	WHITE	FEMALE	62	Dyspnoea	呼吸困難	20 mg	.	MODERATE	YES	41	3	NO	RESOLVED
Rivaroxaban	390043010	YES	ISRAEL	WHITE	FEMALE	62	Radicular pain	神経根痛	20 mg	.	MODERATE	YES	129	5	NO	IMPROVED
Rivaroxaban	390053011	YES	ISRAEL	WHITE	FEMALE	29	Abortion induced	人工流産	20 mg	I	MODERATE	YES	66	1	NO	RESOLVED
Rivaroxaban	390053011	YES	ISRAEL	WHITE	FEMALE	29	Chest pain	胸痛	20 mg	.	MILD	YES	163	2	NO	RESOLVED
Rivaroxaban	390063004	YES	ISRAEL	WHITE	MALE	85	Urinary retention	尿閉	20 mg	.	MODERATE	YES	185	2	NO	RESOLVED
Rivaroxaban	390063004	YES	ISRAEL	WHITE	MALE	85	Urinary tract infection	尿路感染	20 mg	.	MODERATE	YES	185	9	NO	IMPROVED
Rivaroxaban	390063005	YES	ISRAEL	WHITE	MALE	85	Pulmonary congestion	肺うっ血	20 mg	I	MODERATE	YES	249	3	NO	RESOLVED
Enoxaparin/VKA	390063011	YES	ISRAEL	WHITE	FEMALE	62	Supraventricular tachycardia	上室性頻脈			MILD	YES	19	3	NO	RESOLVED
Enoxaparin/VKA	390063012	YES	ISRAEL	WHITE	MALE	71	Renal colic	腎仙痛			MODERATE	YES	26	5	NO	RESOLVED
Rivaroxaban	390063014	YES	ISRAEL	WHITE	FEMALE	69	Chest pain	胸痛	20 mg	.	MILD	YES	143	3	NO	RESOLVED
Rivaroxaban	390063015	YES	ISRAEL	WHITE	MALE	55	Back pain	背部痛	20 mg	.	MILD	YES	146	5	NO	RESOLVED
Rivaroxaban	390063015	YES	ISRAEL	WHITE	MALE	55	Acute myocardial infarction	急性心筋梗塞	20 mg	.	MILD	YES	221	7	NO	RESOLVED
Rivaroxaban	390083004	YES	ISRAEL	WHITE	MALE	51	Acute promyelocytic leukaemia	急性前骨髄球性白血病	20 mg	.	MILD	YES	61	26	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	390083005	YES	ISRAEL	WHITE	FEMALE	51	Menorrhagia	月経過多	15 mg	.	MODERATE	YES	2	3	YES	RESOLVED
Enoxaparin/VKA	390103001	YES	ISRAEL	WHITE	MALE	36	Headache	頭痛			MILD	YES	260	5	NO	RESOLVED
Enoxaparin/VKA	390103001	YES	ISRAEL	WHITE	MALE	36	Subdural haematoma	硬膜下血腫			MILD	YES	332	3	NO	RESOLVED
Rivaroxaban	390103014	YES	ISRAEL	WHITE	MALE	66	Lymphadenopathy	リンパ節症	20 mg	.	MODERATE	YES	311	363	NO	RESOLVED
Enoxaparin/VKA	390103027	YES	ISRAEL	WHITE	FEMALE	75	Haematuria	血尿			MILD	YES	27	6	NO	RESOLVED
Rivaroxaban	390103037	YES	ISRAEL	WHITE	MALE	65	Dyspnoea	呼吸困難	15 mg	.	MILD	YES	7	2	NO	RESOLVED
Rivaroxaban	390103039	YES	ISRAEL	WHITE	FEMALE	73	Haematemesis	吐血	15 mg	.	MODERATE	YES	15	7	YES	RESOLVED
Enoxaparin/VKA	390103040	YES	ISRAEL	WHITE	MALE	29	Pleural effusion	胸水			SEVERE	YES	4	20	NO	RESOLVED
Rivaroxaban	390103044	YES	ISRAEL	WHITE	MALE	41	Pyrexia	発熱	15 mg	.	MODERATE	YES	2	7	NO	RESOLVED
Enoxaparin/VKA	390103056	YES	ISRAEL	WHITE	FEMALE	73	Renal mass	腎腫瘤			SEVERE	NO	161	3	NO	RESOLVED
Enoxaparin/VKA	390103056	YES	ISRAEL	WHITE	FEMALE	73	Pneumonia	肺炎			SEVERE	NO	163	8	NO	RESOLVED
Enoxaparin/VKA	390103056	YES	ISRAEL	WHITE	FEMALE	73	Haematoma	血腫			MODERATE	NO	182	12	NO	RESOLVED
Enoxaparin/VKA	390103065	YES	ISRAEL	WHITE	MALE	84	Prostatic mass	前立腺腫瘤			MODERATE	YES	7	92	NO	RESOLVED
Enoxaparin/VKA	390103069	YES	ISRAEL	WHITE	MALE	38	Pleuritic pain	胸膜痛			MODERATE	YES	43	2	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	390103072	YES	ISRAEL	WHITE	MALE	91	Rectal haemorrhage	直腸出血	20 mg	I	MILD	YES	36	2	YES	RESOLVED
Rivaroxaban	390103076	YES	ISRAEL	WHITE	FEMALE	75	Gastrointestinal haemorrhage	胃腸出血	15 mg	.	SEVERE	YES	21	3	YES	RESOLVED
Rivaroxaban	390103076	YES	ISRAEL	WHITE	FEMALE	75	Atrial fibrillation	心房細動	15 mg	I	MODERATE	YES	25	9	NO	RESOLVED
Enoxaparin/VKA	390103077	YES	ISRAEL	WHITE	FEMALE	78	Vertigo	回転性めまい			MODERATE	YES	61	2	NO	RESOLVED
Rivaroxaban	390103080	YES	ISRAEL	WHITE	FEMALE	75	Fatigue	疲労	20 mg	F	MODERATE	NO	295	6	NO	RESOLVED
Enoxaparin/VKA	390103091	YES	ISRAEL	WHITE	FEMALE	58	Palpitations	動悸			MILD	YES	3	2	NO	RESOLVED
Enoxaparin/VKA	390113008	YES	ISRAEL	WHITE	MALE	71	Cholecystitis	胆嚢炎			SEVERE	YES	4	2	NO	RESOLVED
Rivaroxaban	400013002	YES	AUSTRALIA	WHITE	FEMALE	90	Chest pain	胸痛	20 mg	F	MILD	NO	198	7	NO	RESOLVED
Rivaroxaban	400013002	YES	AUSTRALIA	WHITE	FEMALE	90	Pneumonia	肺炎	20 mg	F	MILD	NO	198	7	NO	RESOLVED
Rivaroxaban	400013002	YES	AUSTRALIA	WHITE	FEMALE	90	Pleural effusion	胸水	20 mg	F	MILD	NO	198	7	NO	RESOLVED
Rivaroxaban	400013004	YES	AUSTRALIA	WHITE	FEMALE	77	Congestive cardiomyopathy	うっ血性心筋症	20 mg	.	SEVERE	YES	164		NO	UNCHANGED
Rivaroxaban	400013004	YES	AUSTRALIA	WHITE	FEMALE	77	Hepatic enzyme increased	肝酵素上昇	20 mg	F	SEVERE	YES	170		YES	IMPROVED
Rivaroxaban	400013004	YES	AUSTRALIA	WHITE	FEMALE	77	Hepatic encephalopathy	肝性脳症	20 mg	F	SEVERE	YES	170		YES	IMPROVED
Rivaroxaban	400013010	YES	AUSTRALIA	WHITE	MALE	66	Ischaemic stroke	虚血性脳卒中	20 mg	.	SEVERE	YES	40	21	NO	DEATH

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

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Rivaroxaban	400023009	YES	AUSTRALIA	WHITE	FEMALE	70	Oesophageal ulcer	食道潰瘍	20 mg	I	SEVERE	YES	91	3	YES	RESOLVED
Enoxaparin/VKA	400023022	YES	AUSTRALIA	WHITE	FEMALE	46	Headache	頭痛			SEVERE	YES	17	3	NO	RESOLVED
Enoxaparin/VKA	400023022	YES	AUSTRALIA	WHITE	FEMALE	46	Vision blurred	霧視			SEVERE	YES	17	3	NO	RESOLVED
Enoxaparin/VKA	400023022	YES	AUSTRALIA	WHITE	FEMALE	46	Muscular weakness	筋力低下			SEVERE	YES	17	3	NO	RESOLVED
Rivaroxaban	400023026	YES	AUSTRALIA	WHITE	MALE	33	Dyspnoea	呼吸困難	20 mg	I	SEVERE	YES	72	2	NO	IMPROVED
Rivaroxaban	400023026	YES	AUSTRALIA	WHITE	MALE	33	Palpitations	動悸	20 mg	I	SEVERE	YES	72	2	NO	IMPROVED
Enoxaparin/VKA	400023029	YES	AUSTRALIA	WHITE	MALE	38	Dyspnoea	呼吸困難			SEVERE	YES	20	2	NO	RESOLVED
Enoxaparin/VKA	400023035	YES	AUSTRALIA	WHITE	MALE	74	Glioblastoma multiforme	多形性神経膠芽細胞腫			SEVERE	NO	41	9	NO	RESOLVED
Enoxaparin/VKA	400023039	YES	AUSTRALIA	WHITE	MALE	64	Haemoptysis	喀血			MODERATE	YES	2	5	YES	RESOLVED
Rivaroxaban	400033012	YES	AUSTRALIA	WHITE	MALE	94	Acute myocardial infarction	急性心筋梗塞	20 mg	.	SEVERE	YES	98	2	NO	RESOLVED
Rivaroxaban	400033012	YES	AUSTRALIA	WHITE	MALE	94	Acute pulmonary oedema	急性肺水腫	20 mg	.	SEVERE	YES	98	6	NO	DEATH
Rivaroxaban	400033012	YES	AUSTRALIA	WHITE	MALE	94	Cardiac failure congestive	うっ血性心不全	20 mg	.	SEVERE	YES	98		NO	UNCHANGED
Enoxaparin/VKA	400033013	YES	AUSTRALIA	WHITE	FEMALE	69	Chest pain	胸痛			MILD	YES	172	5	NO	RESOLVED
Enoxaparin/VKA	400033013	YES	AUSTRALIA	WHITE	FEMALE	69	Sciatica	坐骨神経痛			SEVERE	YES	265		NO	UNCHANGED
Enoxaparin/V	400033017	YES	AUSTRALI	WHITE	MALE	53	Convulsion	痙攣			SEVERE	NO	206	1	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

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KA			A													
Enoxaparin/VKA	400033021	YES	AUSTRALIA	WHITE	FEMALE	56	Musculoskeletal pain	筋骨格痛			SEVERE	YES	74	27	NO	IMPROVED
Enoxaparin/VKA	400033021	YES	AUSTRALIA	WHITE	FEMALE	56	Pleural effusion	胸水			SEVERE	YES	158	8	NO	RESOLVED
Enoxaparin/VKA	400033021	YES	AUSTRALIA	WHITE	FEMALE	56	Pleural effusion	胸水			SEVERE	YES	181	4	NO	RESOLVED
Enoxaparin/VKA	400033021	YES	AUSTRALIA	WHITE	FEMALE	56	Malignant pleural effusion	悪性胸水			MODERATE	YES	195		NO	UNCHANGED
Enoxaparin/VKA	400033021	YES	AUSTRALIA	WHITE	FEMALE	56	Cellulitis	蜂巣炎			MODERATE	YES	269	13	NO	RESOLVED
Rivaroxaban	400033024	YES	AUSTRALIA	WHITE	FEMALE	76	Dysphagia	嚥下障害	20 mg	.	MODERATE	YES	92		NO	IMPROVED
Rivaroxaban	400033024	YES	AUSTRALIA	WHITE	FEMALE	76	Vomiting	嘔吐	20 mg	.	MODERATE	YES	92	6	NO	RESOLVED
Enoxaparin/VKA	400033035	YES	AUSTRALIA	WHITE	MALE	70	Pleural effusion	胸水			MODERATE	YES	62	3	NO	RESOLVED
Enoxaparin/VKA	400033035	YES	AUSTRALIA	WHITE	MALE	70	Mesothelioma malignant	悪性中皮腫			MODERATE	YES	87		NO	UNCHANGED
Enoxaparin/VKA	400033035	YES	AUSTRALIA	WHITE	MALE	70	Neutropenia	好中球減少症			MODERATE	NO	358	14	NO	RESOLVED
Rivaroxaban	400033042	YES	AUSTRALIA	WHITE	MALE	71	Musculoskeletal pain	筋骨格痛	20 mg	.	MODERATE	YES	56	3	NO	RESOLVED
Rivaroxaban	400033043	YES	AUSTRALIA	WHITE	MALE	73	Dyspnoea	呼吸困難	15 mg	.	SEVERE	YES	15	2	NO	DEATH

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	400033049	YES	AUSTRALIA	WHITE	FEMALE	73	Gastric ulcer haemorrhage	出血性胃潰瘍	15 mg	.	MODERATE	YES	9	13	YES	RESOLVED
Rivaroxaban	400033052	YES	AUSTRALIA	WHITE	MALE	58	Ischaemic stroke	虚血性脳卒中	20 mg	.	SEVERE	YES	39	4	NO	WORSENED
Rivaroxaban	400033052	YES	AUSTRALIA	WHITE	MALE	58	Haemorrhagic transformation stroke	卒中の出血性変化	20 mg	F	SEVERE	YES	42	21	NO	DEATH
Rivaroxaban	400033058	YES	AUSTRALIA	WHITE	MALE	62	Diverticulum	憩室	20 mg	F	SEVERE	NO	375	7	NO	RESOLVED
Enoxaparin/VKA	400033059	YES	AUSTRALIA	WHITE	MALE	85	Lower respiratory tract infection	下気道感染			MODERATE	YES	109	7	NO	RESOLVED
Enoxaparin/VKA	400033059	YES	AUSTRALIA	WHITE	MALE	85	Cardiac failure	心不全			MODERATE	YES	109	7	NO	RESOLVED
Rivaroxaban	400033068	YES	AUSTRALIA	WHITE	FEMALE	85	Aortic dissection	大動脈解離	20 mg	F	SEVERE	NO	122		NO	UNCHANGED
Rivaroxaban	400033072	YES	AUSTRALIA	WHITE	FEMALE	46	Chest pain	胸痛	20 mg	.	MODERATE	YES	121	1	NO	RESOLVED
Enoxaparin/VKA	400033077	YES	AUSTRALIA	WHITE	FEMALE	52	Lower respiratory tract infection	下気道感染			SEVERE	YES	19	21	NO	RESOLVED
Enoxaparin/VKA	400033077	YES	AUSTRALIA	WHITE	FEMALE	52	Abscess neck	頚部膿瘍			MODERATE	NO	52		NO	IMPROVED
Enoxaparin/VKA	400033085	YES	AUSTRALIA	WHITE	MALE	71	Syncope	失神			MODERATE	NO	202	9	NO	RESOLVED
Rivaroxaban	400053007	YES	AUSTRALIA	WHITE	MALE	49	Ankle fracture	足関節部骨折	20 mg	I	MODERATE	YES	44	2	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	400053007	YES	AUSTRALIA	WHITE	MALE	49	Joint injury	関節損傷	20 mg	.	MILD	YES	47	6	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Urosepsis	尿路性敗血症	20 mg	.	MODERATE	YES	95	10	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Urinary tract infection	尿路感染	20 mg	.	MODERATE	YES	133	9	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Urinary tract infection	尿路感染	20 mg	.	MILD	YES	151	12	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Dysuria	排尿困難	20 mg	.	MILD	YES	196	6	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Dermatitis exfoliative	剥脱性皮膚炎	20 mg	.	MODERATE	YES	214	14	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Urosepsis	尿路性敗血症	20 mg	I	MILD	YES	269	5	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Herpes simplex	単純ヘルペス	20 mg	F	MODERATE	NO	279	20	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Gastrointestinal haemorrhage	胃腸出血	20 mg	F	SEVERE	NO	298	10	NO	RESOLVED
Rivaroxaban	400053013	YES	AUSTRALIA	WHITE	FEMALE	78	Sepsis	敗血症	20 mg	F	SEVERE	NO	306	3	NO	DEATH
Enoxaparin/VKA	400063010	YES	AUSTRALIA	WHITE	FEMALE	62	Pleuritic pain	胸膜痛			MILD	YES	11	3	NO	RESOLVED
Enoxaparin/VKA	400063010	YES	AUSTRALIA	WHITE	FEMALE	62	Adrenal neoplasm	副腎新生物			MODERATE	YES	20	100	NO	RESOLVED
Enoxaparin/VKA	400063010	YES	AUSTRALIA	WHITE	FEMALE	62	Coagulation time shortened	凝固時間短縮			MILD	YES	107	1	NO	RESOLVED
Enoxaparin/VKA	400063013	YES	AUSTRALIA	WHITE	MALE	67	Urethral stenosis	尿道狭窄			MILD	YES	107	3	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400063025	YES	AUSTRALIA	WHITE	FEMALE	68	Liver function test abnormal	肝機能検査異常			MODERATE	YES	7	17	YES	RESOLVED
Enoxaparin/VKA	400063027	YES	AUSTRALIA	WHITE	MALE	53	Pyrexia	発熱			MODERATE	YES	16	8	NO	RESOLVED
Rivaroxaban	400073008	YES	AUSTRALIA	WHITE	MALE	76	Transient ischaemic attack	一過性脳虚血発作	20 mg	.	MILD	YES	62	1	NO	RESOLVED
Rivaroxaban	400073008	YES	AUSTRALIA	WHITE	MALE	76	Musculoskeletal pain	筋骨格痛	20 mg	.	MODERATE	YES	70	7	NO	RESOLVED
Rivaroxaban	400073008	YES	AUSTRALIA	WHITE	MALE	76	Diplopia	複視	20 mg	.	MODERATE	YES	76	1	NO	RESOLVED
Enoxaparin/VKA	400073032	YES	AUSTRALIA	WHITE	MALE	51	Cellulitis	蜂巣炎			MODERATE	YES	334	22	NO	RESOLVED
Rivaroxaban	400073037	YES	AUSTRALIA	WHITE	FEMALE	46	Pain in extremity	四肢痛	20 mg	.	MODERATE	YES	26		NO	UNCHANGED
Rivaroxaban	400073038	YES	AUSTRALIA	WHITE	FEMALE	57	Rotator cuff syndrome	肩回旋筋腱板症候群	20 mg	.	MODERATE	YES	77	134	NO	RESOLVED
Enoxaparin/VKA	400073046	YES	AUSTRALIA	WHITE	MALE	37	Liver function test abnormal	肝機能検査異常			MILD	YES	5	10	NO	RESOLVED
Rivaroxaban	400073049	YES	AUSTRALIA	WHITE	FEMALE	72	Neuropathy peripheral	末梢性ニューロパチー	20 mg	.	MODERATE	YES	84		NO	IMPROVED
Enoxaparin/VKA	400073050	YES	AUSTRALIA	WHITE	MALE	40	Haemoptysis	喀血			MILD	YES	127	3	YES	RESOLVED
Enoxaparin/VKA	400073052	YES	AUSTRALIA	WHITE	MALE	50	Lower gastrointestinal haemorrhage	下部消化管出血			MODERATE	YES	100	1	YES	RESOLVED
Rivaroxaban	400083010	YES	AUSTRALIA	WHITE	FEMALE	77	Anaemia	貧血	15 mg	.	MILD	YES	15	224	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400083013	YES	AUSTRALIA	WHITE	MALE	62	Herpes zoster	帯状疱疹			MODERATE	YES	45	64	NO	RESOLVED
Enoxaparin/VKA	400083013	YES	AUSTRALIA	WHITE	MALE	62	Ataxia	運動失調			MODERATE	YES	108		NO	IMPROVED
Enoxaparin/VKA	400083013	YES	AUSTRALIA	WHITE	MALE	62	Confusional state	錯乱状態			MODERATE	YES	108		NO	IMPROVED
Enoxaparin/VKA	400083022	YES	AUSTRALIA	WHITE	FEMALE	71	Pseudarthrosis	偽関節			SEVERE	YES	199	45	NO	RESOLVED
Rivaroxaban	400093004	YES	AUSTRALIA	WHITE	MALE	62	Convulsion	痙攣	15 mg	.	SEVERE	YES	7	2	YES	RESOLVED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Ischaemic stroke	虚血性脳卒中	20 mg	.	SEVERE	YES	25	6	NO	WORSENED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Ischaemic stroke	虚血性脳卒中	20 mg	.	SEVERE	YES	30		NO	UNCHANGED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Ischaemic stroke	虚血性脳卒中	20 mg	.	SEVERE	YES	52		NO	UNCHANGED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Disseminated intravascular coagulation	播種性血管内凝固	20 mg	F	SEVERE	NO	97		NO	UNCHANGED
Rivaroxaban	400093017	YES	AUSTRALIA	WHITE	MALE	84	Pancreatic carcinoma metastatic	転移性膵癌	20 mg	F	SEVERE	NO	103	9	NO	DEATH
Enoxaparin/VKA	400093019	YES	AUSTRALIA	WHITE	FEMALE	72	Chest pain	胸痛			MODERATE	YES	11	4	NO	RESOLVED
Enoxaparin/VKA	400093019	YES	AUSTRALIA	WHITE	FEMALE	72	Soft tissue injury	軟部組織損傷			MODERATE	YES	137	3	NO	RESOLVED
Enoxaparin/VKA	400093021	YES	AUSTRALIA	WHITE	FEMALE	30	Sinus tachycardia	洞性頻脈			MODERATE	YES	16	97	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	400093029	YES	AUSTRALIA	WHITE	FEMALE	32	Menorrhagia	月経過多	15 mg	.	SEVERE	NO	1	39	YES	RESOLVED
Rivaroxaban	400093029	YES	AUSTRALIA	WHITE	FEMALE	32	Anaemia	貧血	15 mg	.	SEVERE	YES	7	88	NO	RESOLVED
Rivaroxaban	400093034	YES	AUSTRALIA	WHITE	FEMALE	41	Liver function test abnormal	肝機能検査異常	20 mg	.	SEVERE	YES	146	62	YES	RESOLVED
Rivaroxaban	400093040	YES	AUSTRALIA	WHITE	FEMALE	46	Anal abscess	肛門膿瘍	20 mg	.	SEVERE	YES	243	12	NO	RESOLVED
Rivaroxaban	400093040	YES	AUSTRALIA	WHITE	FEMALE	46	Sepsis	敗血症	20 mg	.	SEVERE	YES	243	4	NO	RESOLVED
Enoxaparin/VKA	400093041	YES	AUSTRALIA	WHITE	MALE	67	Melaena	メレナ			MODERATE	YES	2	5	YES	RESOLVED
Enoxaparin/VKA	400093043	YES	AUSTRALIA	WHITE	FEMALE	36	Viral rash	ウイルス性発疹			MODERATE	YES	105	23	NO	RESOLVED
Enoxaparin/VKA	400093043	YES	AUSTRALIA	WHITE	FEMALE	36	Eosinophilia	好酸球増加症			MODERATE	YES	105	2	NO	RESOLVED
Enoxaparin/VKA	400093043	YES	AUSTRALIA	WHITE	FEMALE	36	Pleuritic pain	胸膜痛			MODERATE	YES	105	2	NO	RESOLVED
Rivaroxaban	400093044	YES	AUSTRALIA	WHITE	FEMALE	67	Lobar pneumonia	大葉性肺炎	20 mg	.	SEVERE	YES	99	27	NO	RESOLVED
Rivaroxaban	400093045	YES	AUSTRALIA	ASIAN	FEMALE	67	Neuropathy peripheral	末梢性ニューロパチー	20 mg	.	MODERATE	YES	78		NO	UNCHANGED
Rivaroxaban	400093045	YES	AUSTRALIA	ASIAN	FEMALE	67	Pulmonary hypertension	肺高血圧症	20 mg	.	SEVERE	YES	174		NO	UNCHANGED
Rivaroxaban	400093048	YES	AUSTRALIA	WHITE	MALE	81	Haematuria	血尿	20 mg	.	SEVERE	YES	272	2	YES	RESOLVED
Rivaroxaban	400093049	YES	AUSTRALIA	WHITE	MALE	60	Musculoskeletal pain	筋骨格痛	20 mg	.	MODERATE	YES	109	2	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400093051	YES	AUSTRALIA	WHITE	MALE	73	Eye haemorrhage	眼出血			MILD	YES	75	5	YES	RESOLVED
Enoxaparin/VKA	400093051	YES	AUSTRALIA	WHITE	MALE	73	Multiple myeloma	多発性骨髄腫			MILD	YES	215		NO	UNCHANGED
Enoxaparin/VKA	400093052	YES	AUSTRALIA	WHITE	MALE	66	Back pain	背部痛			MODERATE	YES	4	8	NO	RESOLVED
Enoxaparin/VKA	400093053	YES	AUSTRALIA	WHITE	FEMALE	29	Palpitations	動悸			MODERATE	YES	9	2	NO	RESOLVED
Rivaroxaban	400093056	YES	AUSTRALIA	WHITE	FEMALE	74	Left ventricular failure	左室不全	20 mg	.	MODERATE	YES	134		NO	IMPROVED
Rivaroxaban	400093056	YES	AUSTRALIA	WHITE	FEMALE	74	Hypertension	高血圧	20 mg	.	SEVERE	YES	160	45	NO	RESOLVED
Rivaroxaban	400093060	YES	AUSTRALIA	WHITE	FEMALE	37	Hypoglycaemia	低血糖症	20 mg	.	SEVERE	YES	303	1	NO	RESOLVED
Rivaroxaban	400093060	YES	AUSTRALIA	WHITE	FEMALE	37	Hypoglycaemia	低血糖症	20 mg	.	SEVERE	YES	317	1	NO	RESOLVED
Enoxaparin/VKA	400093062	YES	AUSTRALIA	WHITE	MALE	30	Distributive shock	血液分布異常性ショック			SEVERE	YES	323	7	NO	RESOLVED
Enoxaparin/VKA	400093062	YES	AUSTRALIA	WHITE	MALE	30	Metabolic disorder	代謝障害			SEVERE	YES	323	13	NO	RESOLVED
Enoxaparin/VKA	400093062	YES	AUSTRALIA	WHITE	MALE	30	Syncope	失神			MODERATE	NO	331	1	NO	RESOLVED
Enoxaparin/VKA	400093062	YES	AUSTRALIA	WHITE	MALE	30	Muscle twitching	筋攣縮			MODERATE	NO	331	1	NO	RESOLVED
Enoxaparin/VKA	400093067	YES	AUSTRALIA	WHITE	FEMALE	53	Foot fracture	足骨折			MODERATE	YES	149	29	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400093067	YES	AUSTRALIA	WHITE	FEMALE	53	Fibula fracture	腓骨骨折			MODERATE	YES	149	29	NO	RESOLVED
Rivaroxaban	400123004	YES	AUSTRALIA	WHITE	FEMALE	83	Pneumonia	肺炎	20 mg	.	SEVERE	YES	69	8	NO	RESOLVED
Enoxaparin/VKA	400123007	YES	AUSTRALIA	WHITE	FEMALE	82	Lower respiratory tract infection	下気道感染			MODERATE	YES	301	13	NO	RESOLVED
Rivaroxaban	400123012	YES	AUSTRALIA	WHITE	FEMALE	67	Small intestinal obstruction	小腸閉塞	20 mg	.	MODERATE	YES	36	4	NO	RESOLVED
Enoxaparin/VKA	400123023	YES	AUSTRALIA	WHITE	FEMALE	71	Decreased appetite	食欲減退			MODERATE	YES	15	11	NO	RESOLVED
Enoxaparin/VKA	400123029	YES	AUSTRALIA	WHITE	FEMALE	76	Lung neoplasm malignant	肺の悪性新生物			SEVERE	NO	24	96	NO	DEATH
Rivaroxaban	400123037	YES	AUSTRALIA	WHITE	FEMALE	78	Asthma	喘息	15 mg	.	MODERATE	YES	8	4	NO	RESOLVED
Rivaroxaban	400123037	YES	AUSTRALIA	WHITE	FEMALE	78	Haematuria	血尿	15 mg	.	MODERATE	YES	18	3	YES	RESOLVED
Rivaroxaban	400123037	YES	AUSTRALIA	WHITE	FEMALE	78	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	MODERATE	YES	84	8	NO	RESOLVED
Rivaroxaban	400123037	YES	AUSTRALIA	WHITE	FEMALE	78	Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪	20 mg	.	MODERATE	YES	120	25	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	400123037	YES	AUSTRALIA	WHITE	FEMALE	78	Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪	20 mg	.	MODERATE	YES	146	14	NO	RESOLVED
Rivaroxaban	400123037	YES	AUSTRALIA	WHITE	FEMALE	78	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	MODERATE	YES	174	10	NO	RESOLVED
Enoxaparin/VKA	400123044	YES	AUSTRALIA	WHITE	MALE	59	Localised infection	限局性感染			MODERATE	YES	33	10	NO	RESOLVED
Rivaroxaban	400123045	YES	AUSTRALIA	WHITE	MALE	61	Haematuria	血尿	20 mg	.	MILD	YES	98	3	YES	RESOLVED
Rivaroxaban	400123051	YES	AUSTRALIA	WHITE	FEMALE	80	Chest pain	胸痛	15 mg	.	MODERATE	YES	15	5	YES	RESOLVED
Rivaroxaban	400123056	YES	AUSTRALIA	WHITE	FEMALE	60	Rash morbilliform	麻疹様発疹	15 mg	.	MODERATE	YES	3	13	YES	RESOLVED
Enoxaparin/VKA	400123057	YES	AUSTRALIA	WHITE	FEMALE	76	Back pain	背部痛			MODERATE	YES	33	36	NO	RESOLVED
Enoxaparin/VKA	400123062	YES	AUSTRALIA	WHITE	MALE	61	Liver function test abnormal	肝機能検査異常			MODERATE	YES	5	51	NO	RESOLVED
Rivaroxaban	400153004	YES	AUSTRALIA	WHITE	FEMALE	38	Chest pain	胸痛	20 mg	.	MILD	YES	33		NO	UNCHANGED
Rivaroxaban	400153004	YES	AUSTRALIA	WHITE	FEMALE	38	Vaginal haemorrhage	膣出血	20 mg	.	MODERATE	YES	33	13	YES	RESOLVED
Rivaroxaban	400153019	YES	AUSTRALIA	WHITE	FEMALE	28	Tendon rupture	腱断裂	20 mg	.	SEVERE	YES	59	10	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	400153020	YES	AUSTRALIA	WHITE	MALE	57	Pneumonia	肺炎	15 mg	.	SEVERE	YES	21	3	NO	RESOLVED
Enoxaparin/VKA	400153021	YES	AUSTRALIA	WHITE	MALE	34	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MODERATE	YES	14	21	NO	RESOLVED
Enoxaparin/VKA	400163009	YES	AUSTRALIA	WHITE	FEMALE	29	Pleuritic pain	胸膜痛			MODERATE	YES	4	5	NO	RESOLVED
Enoxaparin/VKA	400163023	YES	AUSTRALIA	WHITE	MALE	49	Pleuritic pain	胸膜痛			MODERATE	YES	14	3	NO	RESOLVED
Enoxaparin/VKA	400163023	YES	AUSTRALIA	WHITE	MALE	49	Abdominal pain	腹痛			MODERATE	YES	40	6	NO	RESOLVED
Enoxaparin/VKA	400163023	YES	AUSTRALIA	WHITE	MALE	49	Chest pain	胸痛			MODERATE	YES	53	7	NO	RESOLVED
Enoxaparin/VKA	400163023	YES	AUSTRALIA	WHITE	MALE	49	Chest pain	胸痛			MODERATE	NO	69	4	NO	RESOLVED
Rivaroxaban	400163034	YES	AUSTRALIA	WHITE	MALE	64	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	MODERATE	YES	268	9	NO	RESOLVED
Rivaroxaban	400163035	YES	AUSTRALIA	WHITE	FEMALE	76	Facial bones fracture	顔面骨骨折	20 mg	I	MODERATE	YES	142	1	NO	RESOLVED
Rivaroxaban	400163035	YES	AUSTRALIA	WHITE	FEMALE	76	Fall	転倒	20 mg	I	MODERATE	YES	142	1	NO	RESOLVED
Enoxaparin/VKA	400163043	YES	AUSTRALIA	WHITE	FEMALE	66	Pericardial effusion	心嚢液貯留			MODERATE	NO	383	8	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400193004	YES	AUSTRALIA	WHITE	FEMALE	46	Chest pain	胸痛			SEVERE	YES	8	2	NO	RESOLVED
Rivaroxaban	400193011	YES	AUSTRALIA	WHITE	FEMALE	58	Pleuritic pain	胸膜痛	20 mg	.	SEVERE	YES	26	2	NO	RESOLVED
Rivaroxaban	400193011	YES	AUSTRALIA	WHITE	FEMALE	58	Atrial fibrillation	心房細動	20 mg	F	SEVERE	NO	185	1	NO	RESOLVED
Rivaroxaban	400193027	YES	AUSTRALIA	WHITE	MALE	61	Cardiac failure congestive	うっ血性心不全	15 mg	.	SEVERE	YES	2		NO	UNCHANGED
Rivaroxaban	400193027	YES	AUSTRALIA	WHITE	MALE	61	Hypotension	低血圧	15 mg	.	MODERATE	YES	17	1	NO	RESOLVED
Rivaroxaban	400203008	YES	AUSTRALIA	WHITE	FEMALE	55	Bronchitis	気管支炎	15 mg	.	SEVERE	YES	8	27	NO	RESOLVED
Rivaroxaban	400203019	YES	AUSTRALIA	WHITE	MALE	48	Headache	頭痛	15 mg	.	MODERATE	YES	18	8	YES	RESOLVED
Rivaroxaban	400213001	YES	AUSTRALIA	WHITE	MALE	61	Wound infection	創傷感染	15 mg	.	MILD	YES	3	37	NO	RESOLVED
Enoxaparin/VKA	400213003	YES	AUSTRALIA	WHITE	MALE	85	Metastases to central nervous system	中枢神経系転移			SEVERE	YES	83	58	NO	DEATH
Enoxaparin/VKA	400213003	YES	AUSTRALIA	WHITE	MALE	85	Melaena	メレナ			MODERATE	NO	118	6	NO	RESOLVED
Enoxaparin/VKA	400213020	YES	AUSTRALIA	AMERICAN INDIAN OR ALASKA NATIVE	MALE	75	Haematuria	血尿			MILD	YES	3	8	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400213020	YES	AUSTRALIA	AMERICAN INDIAN OR ALASKA NATIVE	MALE	75	Bladder neoplasm	膀胱新生物			MODERATE	YES	80	1	NO	RESOLVED
Enoxaparin/VKA	400213028	YES	AUSTRALIA	WHITE	FEMALE	66	Acute lymphocytic leukaemia	急性リンパ性白血病			SEVERE	YES	8		NO	UNCHANGED
Enoxaparin/VKA	400213028	YES	AUSTRALIA	WHITE	FEMALE	66	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MODERATE	YES	8		NO	UNCHANGED
Enoxaparin/VKA	400213028	YES	AUSTRALIA	WHITE	FEMALE	66	Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加			MODERATE	NO	18		NO	UNCHANGED
Enoxaparin/VKA	400213028	YES	AUSTRALIA	WHITE	FEMALE	66	Acute abdomen	急性腹症			SEVERE	NO	29	3	NO	DEATH
Enoxaparin/VKA	400213058	YES	AUSTRALIA	WHITE	MALE	52	Postoperative wound infection	術後創感染			MODERATE	YES	21	23	NO	RESOLVED
Rivaroxaban	400213069	YES	AUSTRALIA	WHITE	MALE	51	Anxiety	不安	20 mg	.	MODERATE	YES	77	18	NO	RESOLVED
Rivaroxaban	400213069	YES	AUSTRALIA	WHITE	MALE	51	Anxiety	不安	20 mg	.	MODERATE	YES	117	39	NO	RESOLVED
Enoxaparin/VKA	400213071	YES	AUSTRALIA	WHITE	MALE	76	Colitis	大腸炎			MODERATE	YES	48	8	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400213071	YES	AUSTRALIA	WHITE	MALE	76	Neutropenia	好中球減少症			SEVERE	YES	48	71	NO	RESOLVED
Enoxaparin/VKA	400213071	YES	AUSTRALIA	WHITE	MALE	76	Cardiomyopathy	心筋症			SEVERE	NO	70		NO	IMPROVED
Enoxaparin/VKA	400213080	YES	AUSTRALIA	WHITE	MALE	61	Prostate cancer	前立腺癌			MILD	YES	134	3	NO	RESOLVED
Enoxaparin/VKA	400213082	YES	AUSTRALIA	WHITE	MALE	79	Urinary tract infection	尿路感染			MILD	YES	81	31	NO	RESOLVED
Enoxaparin/VKA	400213082	YES	AUSTRALIA	WHITE	MALE	79	Acute myocardial infarction	急性心筋梗塞			MILD	YES	82	2	NO	RESOLVED
Enoxaparin/VKA	400213092	YES	AUSTRALIA	WHITE	FEMALE	50	Osteoarthritis	変形性関節症			MODERATE	YES	149	9	NO	RESOLVED
Enoxaparin/VKA	400213092	YES	AUSTRALIA	WHITE	FEMALE	50	Post procedural haemorrhage	処置後出血			SEVERE	YES	151	2	NO	RESOLVED
Rivaroxaban	400233003	YES	AUSTRALIA	WHITE	FEMALE	70	Chest discomfort	胸部不快感	20 mg	.	MODERATE	YES	241	2	NO	RESOLVED
Rivaroxaban	400233005	YES	AUSTRALIA	WHITE	FEMALE	40	Haemorrhagic anaemia	出血性貧血	15 mg	.	MODERATE	YES	8	18	YES	RESOLVED
Rivaroxaban	400233005	YES	AUSTRALIA	WHITE	FEMALE	40	Menorrhagia	月経過多	15 mg	.	MODERATE	YES	8	18	YES	RESOLVED
Rivaroxaban	400233005	YES	AUSTRALIA	WHITE	FEMALE	40	Sinusitis	副鼻腔炎	15 mg	.	SEVERE	YES	13	3	NO	RESOLVED
Rivaroxaban	400233005	YES	AUSTRALIA	WHITE	FEMALE	40	Musculoskeletal chest pain	筋骨格系胸痛	20 mg	.	MILD	YES	40	51	NO	RESOLVED
Rivaroxaban	400233005	YES	AUSTRALIA	WHITE	FEMALE	40	Dyspnoea	呼吸困難	20 mg	.	MODERATE	YES	40	51	NO	RESOLVED
Rivaroxaban	400233006	YES	AUSTRALIA	WHITE	FEMALE	66	Palpitations	動悸	20 mg	.	MODERATE	YES	165	6	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400233012	YES	AUSTRALIA	WHITE	MALE	66	Pneumonia	肺炎			MODERATE	YES	6	9	NO	RESOLVED
Enoxaparin/VKA	400243003	YES	AUSTRALIA	WHITE	MALE	62	Bronchiectasis	気管支拡張症			MILD	YES	43	7	NO	RESOLVED
Enoxaparin/VKA	400243003	YES	AUSTRALIA	WHITE	MALE	62	Bronchiectasis	気管支拡張症			MILD	YES	61	8	NO	RESOLVED
Rivaroxaban	400243005	YES	AUSTRALIA	WHITE	MALE	53	Haematoma	血腫	15 mg	F	SEVERE	YES	5		YES	RESOLVED
Enoxaparin/VKA	400243021	YES	AUSTRALIA	WHITE	FEMALE	70	Thyroid cancer	甲状腺癌			MILD	YES	82	10	NO	RESOLVED
Rivaroxaban	400243023	YES	AUSTRALIA	WHITE	FEMALE	50	Lower gastrointestinal haemorrhage	下部消化管出血	15 mg	.	MILD	YES	3	1	NO	RESOLVED
Enoxaparin/VKA	400253007	YES	AUSTRALIA	WHITE	FEMALE	80	Metastases to liver	肝転移			SEVERE	YES	56		NO	UNCHANGED
Enoxaparin/VKA	400253007	YES	AUSTRALIA	WHITE	FEMALE	80	Sepsis	敗血症			MODERATE	NO	119	9	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Haematochezia	血便排泄			MILD	YES	1	24	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Bile duct cancer non-resectable	切除不能な胆管癌			SEVERE	YES	7	28	NO	DEATH
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Biliary sepsis	胆道性敗血症			MODERATE	YES	8	26	NO	RESOLVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Lower gastrointestinal haemorrhage	下部消化管出血			MILD	YES	8		YES	UNCHANGED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Hepatic failure	肝不全			SEVERE	YES	8		NO	UNCHANGED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Dehydration	脱水			SEVERE	YES	9	4	NO	IMPROVED
Enoxaparin/VKA	400253008	YES	AUSTRALIA	WHITE	FEMALE	68	Haemoptysis	喀血			MILD	NO	15	1	YES	RESOLVED
Rivaroxaban	400253012	YES	AUSTRALIA	WHITE	MALE	43	Lobar pneumonia	大葉性肺炎	15 mg	.	MODERATE	YES	1	7	NO	RESOLVED
Rivaroxaban	400253012	YES	AUSTRALIA	WHITE	MALE	43	Lower respiratory tract infection	下気道感染	15 mg	.	MODERATE	YES	13	8	NO	RESOLVED
Enoxaparin/VKA	400263001	YES	AUSTRALIA	WHITE	FEMALE	26	Polycythaemia vera	真性多血症			MODERATE	YES	34	4	NO	IMPROVED
Rivaroxaban	440013004	YES	AUSTRIA	WHITE	MALE	63	Colonic polyp	結腸ポリープ	20 mg	I	SEVERE	YES	103	39	NO	RESOLVED
Rivaroxaban	440013005	YES	AUSTRIA	WHITE	MALE	50	Lung neoplasm malignant	肺の悪性新生物	20 mg	F	SEVERE	YES	24		NO	UNCHANGED
Rivaroxaban	440013005	YES	AUSTRIA	WHITE	MALE	50	Pulmonary embolism	肺塞栓症	20 mg	F	SEVERE	NO	41	3	NO	DEATH
Rivaroxaban	440013005	YES	AUSTRIA	WHITE	MALE	50	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	20 mg	F	SEVERE	NO	43		NO	UNCHANGED
Rivaroxaban	440013005	YES	AUSTRIA	WHITE	MALE	50	Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	20 mg	F	SEVERE	NO	43		NO	UNCHANGED
Enoxaparin/VKA	440013013	YES	AUSTRIA	WHITE	FEMALE	21	Dyspnoea	呼吸困難			MODERATE	YES	18	1	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	440013021	YES	AUSTRIA	WHITE	MALE	46	Facial bones fracture	顔面骨骨折	20 mg	.	MODERATE	YES	44	3	NO	RESOLVED
Rivaroxaban	440013021	YES	AUSTRIA	WHITE	MALE	46	Contusion	挫傷	20 mg	.	MODERATE	YES	44	3	NO	RESOLVED
Rivaroxaban	440013028	YES	AUSTRIA	WHITE	MALE	74	Osteoarthritis	変形性関節症	20 mg	I	MODERATE	YES	318	10	NO	IMPROVED
Rivaroxaban	440013029	YES	AUSTRIA	WHITE	MALE	45	Pulmonary haemorrhage	肺出血	15 mg	.	SEVERE	YES	2	1	YES	RESOLVED
Rivaroxaban	440013039	YES	AUSTRIA	WHITE	FEMALE	60	Leukoencephalopathy	白質脳症	20 mg	.	MODERATE	YES	44		NO	UNCHANGED
Rivaroxaban	440013039	YES	AUSTRIA	WHITE	FEMALE	60	Fall	転倒	20 mg	.	MODERATE	YES	93	1	NO	RESOLVED
Enoxaparin/VKA	440013045	YES	AUSTRIA	WHITE	MALE	45	Nephrolithiasis	腎結石症			MODERATE	YES	7	7	NO	IMPROVED
Enoxaparin/VKA	440013045	YES	AUSTRIA	WHITE	MALE	45	Nephrolithiasis	腎結石症			SEVERE	YES	32	13	NO	RESOLVED
Enoxaparin/VKA	440013053	YES	AUSTRIA	WHITE	FEMALE	48	Menorrhagia	月経過多			SEVERE	YES	5	13	YES	RESOLVED
Enoxaparin/VKA	440013053	YES	AUSTRIA	WHITE	FEMALE	48	Liver function test abnormal	肝機能検査異常			SEVERE	YES	7	9	NO	RESOLVED
Enoxaparin/VKA	440013073	YES	AUSTRIA	WHITE	MALE	47	Bronchial carcinoma	気管支癌			SEVERE	YES	166		NO	UNCHANGED
Enoxaparin/VKA	440013074	YES	AUSTRIA	WHITE	MALE	29	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MILD	YES	16	29	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	440013080	YES	AUSTRIA	WHITE	FEMALE	26	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MILD	YES	11	17	YES	RESOLVED
Rivaroxaban	440013085	YES	AUSTRIA	WHITE	MALE	77	Pulmonary hypertension	肺高血圧症	20 mg	.	SEVERE	YES	53	37	NO	IMPROVED
Rivaroxaban	440013085	YES	AUSTRIA	WHITE	MALE	77	Anaemia	貧血	20 mg	F	SEVERE	NO	88	2	YES	IMPROVED
Enoxaparin/VKA	440013100	YES	AUSTRIA	WHITE	MALE	51	Coronary artery disease	冠動脈疾患			SEVERE	YES	270	3	NO	RESOLVED
Enoxaparin/VKA	440013124	YES	AUSTRIA	WHITE	FEMALE	68	Rectal haemorrhage	直腸出血			MILD	YES	67	5	YES	RESOLVED
Rivaroxaban	440013127	YES	AUSTRIA	WHITE	MALE	70	Gastrointestinal haemorrhage	胃腸出血	20 mg	.	MODERATE	YES	140		YES	UNCHANGED
Rivaroxaban	440033013	YES	AUSTRIA	WHITE	FEMALE	38	Abortion induced	人工流産	20 mg	I	MODERATE	YES	295	1	NO	RESOLVED
Enoxaparin/VKA	440033026	YES	AUSTRIA	WHITE	MALE	65	Phimosis	包茎			MODERATE	YES	272	3	NO	RESOLVED
Enoxaparin/VKA	440033036	YES	AUSTRIA	WHITE	FEMALE	74	Vomiting	嘔吐			MILD	YES	310	1	NO	RESOLVED
Enoxaparin/VKA	440033040	YES	AUSTRIA	WHITE	MALE	73	Prostatitis	前立腺炎			MODERATE	YES	15		NO	UNCHANGED
Rivaroxaban	440043003	YES	AUSTRIA	WHITE	MALE	44	Limb injury	四肢損傷	20 mg	.	SEVERE	YES	342	5	NO	RESOLVED
Enoxaparin/VKA	440043027	YES	AUSTRIA	WHITE	FEMALE	70	Goitre	甲状腺腫			MILD	NO	195	7	NO	RESOLVED
Enoxaparin/VKA	440043027	YES	AUSTRIA	WHITE	FEMALE	70	Hypocalcaemia	低カルシウム血症			MILD	NO	203	9	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	440043030	YES	AUSTRIA	WHITE	FEMALE	68	Tibia fracture	脛骨骨折	20 mg	.	MODERATE	YES	38	16	NO	RESOLVED
Rivaroxaban	440043030	YES	AUSTRIA	WHITE	FEMALE	68	Fibula fracture	腓骨骨折	20 mg	.	MODERATE	YES	38	16	NO	RESOLVED
Rivaroxaban	440043030	YES	AUSTRIA	WHITE	FEMALE	68	Vertigo	回転性めまい	20 mg	.	MILD	YES	266	10	NO	RESOLVED
Rivaroxaban	440043030	YES	AUSTRIA	WHITE	FEMALE	68	Urinary tract infection	尿路感染	20 mg	.	MILD	YES	338	9	NO	RESOLVED
Rivaroxaban	440043030	YES	AUSTRIA	WHITE	FEMALE	68	Pain in extremity	四肢痛	20 mg	F	MILD	NO	408	6	NO	RESOLVED
Rivaroxaban	440043032	YES	AUSTRIA	WHITE	FEMALE	76	Breast cancer	乳癌	20 mg	I	MILD	YES	33		NO	UNCHANGED
Enoxaparin/VKA	440043045	YES	AUSTRIA	WHITE	FEMALE	58	Goitre	甲状腺腫			MILD	YES	94	6	NO	RESOLVED
Enoxaparin/VKA	440053008	YES	AUSTRIA	WHITE	MALE	58	Prostatic specific antigen increased	前立腺特異性抗原増加			MILD	YES	250	2	NO	RESOLVED
Enoxaparin/VKA	440053041	YES	AUSTRIA	WHITE	MALE	83	Dyspnoea	呼吸困難			MODERATE	YES	76	16	NO	RESOLVED
Enoxaparin/VKA	440053041	YES	AUSTRIA	WHITE	MALE	83	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患			SEVERE	YES	104	21	NO	RESOLVED
Rivaroxaban	440053043	YES	AUSTRIA	WHITE	FEMALE	73	Chest pain	胸痛	20 mg	.	MILD	YES	89	5	NO	RESOLVED
Rivaroxaban	440053043	YES	AUSTRIA	WHITE	FEMALE	73	Lichen planus	扁平苔癬	20 mg	.	MILD	YES	268	42	NO	RESOLVED
Enoxaparin/VKA	440063023	YES	AUSTRIA	WHITE	MALE	83	Muscular weakness	筋力低下			MODERATE	YES	173	4	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	440063027	YES	AUSTRIA	WHITE	MALE	71	Colonic polyp	結腸ポリープ	20 mg	I	MODERATE	YES	271	2	NO	RESOLVED
Rivaroxaban	440063038	YES	AUSTRIA	WHITE	MALE	71	Colon cancer	結腸癌	15 mg	.	MODERATE	YES	4	17	NO	RESOLVED
Enoxaparin/VKA	440103001	YES	AUSTRIA	WHITE	FEMALE	78	Splenic infarction	脾臓梗塞			SEVERE	YES	11	19	NO	RESOLVED
Enoxaparin/VKA	440103001	YES	AUSTRIA	WHITE	FEMALE	78	Splenic haemorrhage	脾臓出血			SEVERE	YES	11	19	YES	RESOLVED
Enoxaparin/VKA	440103001	YES	AUSTRIA	WHITE	FEMALE	78	Histiocytosis haematophagic	貪食細胞性組織球症			SEVERE	NO	27	146	NO	RESOLVED
Enoxaparin/VKA	440103001	YES	AUSTRIA	WHITE	FEMALE	78	B-cell lymphoma	Ｂ細胞性リンパ腫			SEVERE	NO	39	134	NO	RESOLVED
Enoxaparin/VKA	460033012	YES	HUNGARY	WHITE	MALE	46	Pulmonary embolism	肺塞栓症			SEVERE	YES	2	1	NO	DEATH
Enoxaparin/VKA	460033031	YES	HUNGARY	WHITE	MALE	79	Adrenal haemorrhage	副腎出血			SEVERE	YES	13	15	YES	RESOLVED
Rivaroxaban	460053043	YES	HUNGARY	WHITE	MALE	70	Vertigo positional	頭位性回転性めまい	20 mg	.	SEVERE	YES	210	10	NO	RESOLVED
Rivaroxaban	460053045	YES	HUNGARY	WHITE	MALE	83	Ventricular tachycardia	心室性頻脈	15 mg	.	MODERATE	YES	5	1	NO	RESOLVED
Enoxaparin/VKA	460063020	YES	HUNGARY	WHITE	MALE	43	Road traffic accident	交通事故			SEVERE	YES	96	64	NO	RESOLVED
Rivaroxaban	460063029	YES	HUNGARY	WHITE	MALE	41	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	20 mg	.	MILD	YES	126	111	YES	IMPROVED
Enoxaparin/VKA	460063050	YES	HUNGARY	WHITE	MALE	39	Subarachnoid haemorrhage	くも膜下出血			MODERATE	YES	201	6	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	460063050	YES	HUNGARY	WHITE	MALE	39	Cervical vertebral fracture	頚椎骨折			SEVERE	YES	201	67	NO	RESOLVED
Enoxaparin/VKA	460063050	YES	HUNGARY	WHITE	MALE	39	Brain contusion	脳挫傷			SEVERE	YES	201	6	NO	RESOLVED
Enoxaparin/VKA	460063050	YES	HUNGARY	WHITE	MALE	39	Mental disorder due to a general medical condition	身体疾患による精神障害			SEVERE	YES	206	29	NO	RESOLVED
Rivaroxaban	460063056	YES	HUNGARY	WHITE	FEMALE	77	Duodenal ulcer	十二指腸潰瘍			SEVERE	YES	232	3	NO	DEATH
Rivaroxaban	460063059	YES	HUNGARY	WHITE	MALE	63	Colon neoplasm	結腸新生物	20 mg	.	SEVERE	YES	104	23	NO	RESOLVED
Rivaroxaban	460093009	YES	HUNGARY	WHITE	FEMALE	73	Gastritis haemorrhagic	出血性胃炎	20 mg	.	MILD	YES	165	211	YES	RESOLVED
Rivaroxaban	460093032	YES	HUNGARY	WHITE	FEMALE	50	Genital haemorrhage	性器出血	20 mg	.	MILD	YES	85	19	NO	RESOLVED
Rivaroxaban	460093032	YES	HUNGARY	WHITE	FEMALE	50	Uterine leiomyoma	子宮平滑筋腫	20 mg	.	MILD	YES	103		NO	UNCHANGED
Rivaroxaban	460093038	YES	HUNGARY	WHITE	FEMALE	68	Pernicious anaemia	悪性貧血	20 mg	.	MODERATE	YES	194	50	NO	RESOLVED
Enoxaparin/VKA	460093039	YES	HUNGARY	WHITE	MALE	76	Intestinal polyp	腸管ポリープ			MILD	YES	152	4	NO	RESOLVED
Rivaroxaban	460093043	YES	HUNGARY	WHITE	MALE	45	Lung squamous cell carcinoma stage unspecified	肺扁平上皮癌、病期不明	20 mg	.	MODERATE	YES	57		NO	UNCHANGED
Enoxaparin/VKA	460093049	YES	HUNGARY	WHITE	FEMALE	42	Cervical dysplasia	子宮頚部上皮異形成			MODERATE	YES	98	5	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	460093053	YES	HUNGARY	WHITE	FEMALE	48	Menorrhagia	月経過多	15 mg	.	MODERATE	YES	10	13	YES	RESOLVED
Rivaroxaban	460093054	YES	HUNGARY	WHITE	MALE	65	Ventricular tachycardia	心室性頻脈	15 mg	.	MILD	YES	1	1	NO	RESOLVED
Rivaroxaban	460093057	YES	HUNGARY	WHITE	FEMALE	69	Angina pectoris	狭心症	20 mg	F	MILD	NO	376	2	NO	RESOLVED
Rivaroxaban	460093059	YES	HUNGARY	WHITE	MALE	57	Lung neoplasm malignant	肺の悪性新生物	20 mg	.	SEVERE	YES	50	23	NO	DEATH
Enoxaparin/VKA	460093063	YES	HUNGARY	WHITE	MALE	62	Acute myocardial infarction	急性心筋梗塞			MODERATE	YES	210	7	NO	RESOLVED
Enoxaparin/VKA	460093063	YES	HUNGARY	WHITE	MALE	62	Acute myocardial infarction	急性心筋梗塞			SEVERE	NO	325	8	NO	RESOLVED
Enoxaparin/VKA	460103017	YES	HUNGARY	WHITE	FEMALE	80	Cardiac failure acute	急性心不全			MODERATE	YES	347	13	NO	RESOLVED
Enoxaparin/VKA	460103017	YES	HUNGARY	WHITE	FEMALE	80	Cardiac failure acute	急性心不全			MODERATE	NO	364	13	NO	RESOLVED
Rivaroxaban	460103026	YES	HUNGARY	WHITE	MALE	42	Myalgia	筋肉痛	20 mg	.	MILD	YES	234	4	NO	RESOLVED
Enoxaparin/VKA	460113001	YES	HUNGARY	WHITE	MALE	80	Myocardial infarction	心筋梗塞			SEVERE	YES	49	10	NO	IMPROVED
Enoxaparin/VKA	460113001	YES	HUNGARY	WHITE	MALE	80	Nephropathy toxic	中毒性ネフロパシー			MODERATE	YES	59	97	NO	RESOLVED
Rivaroxaban	460113002	YES	HUNGARY	WHITE	FEMALE	77	Renal failure acute	急性腎不全	15 mg	.	MILD	YES	7	3	NO	RESOLVED
Rivaroxaban	460123002	YES	HUNGARY	WHITE	FEMALE	70	Atrial fibrillation	心房細動	20 mg	.	MILD	YES	23		NO	UNCHANGED
Enoxaparin/VKA	500033011	YES	BRAZIL	WHITE	FEMALE	81	Convulsion	痙攣			SEVERE	YES	31	1	NO	RESOLVED
Enoxaparin/V	500033011	YES	BRAZIL	WHITE	FEMALE	81	Acute	急性呼吸不			SEVERE	NO	56	20	NO	DEATH

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA							respiratory failure	全								
Enoxaparin/VKA	500033024	YES	BRAZIL	WHITE	FEMALE	24	Skin bacterial infection	皮膚細菌感染			MILD	YES	54	86	NO	RESOLVED
Rivaroxaban	500063002	YES	BRAZIL	BLACK	FEMALE	42	Thrombophlebitis superficial	表在性血栓性静脈炎	20 mg	.	SEVERE	YES	110		NO	IMPROVED
Enoxaparin/VKA	540053009	YES	CHINA	ASIAN	MALE	58	Supraventricular tachycardia	上室性頻脈			SEVERE	YES	1	1	NO	RESOLVED
Enoxaparin/VKA	540053009	YES	CHINA	ASIAN	MALE	58	Atrial fibrillation	心房細動			SEVERE	YES	1	1	NO	RESOLVED
Enoxaparin/VKA	540053009	YES	CHINA	ASIAN	MALE	58	Atrial fibrillation	心房細動			MODERATE	YES	57	1	NO	RESOLVED
Enoxaparin/VKA	540053009	YES	CHINA	ASIAN	MALE	58	Overdose	過量投与			MODERATE	YES	57	2	YES	RESOLVED
Enoxaparin/VKA	540053009	YES	CHINA	ASIAN	MALE	58	Supraventricular tachycardia	上室性頻脈			MODERATE	YES	57	1	NO	RESOLVED
Rivaroxaban	540053010	YES	CHINA	ASIAN	MALE	57	Transient ischaemic attack	一過性脳虚血発作	20 mg	.	MODERATE	YES	22	9	NO	RESOLVED
Rivaroxaban	540053010	YES	CHINA	ASIAN	MALE	57	Ischaemic stroke	虚血性脳卒中	20 mg	I	MODERATE	YES	29		NO	UNCHANGED
Enoxaparin/VKA	540053012	YES	CHINA	ASIAN	FEMALE	73	Dyspnoea	呼吸困難			SEVERE	YES	151	11	NO	RESOLVED
Enoxaparin/VKA	540053014	YES	CHINA	ASIAN	FEMALE	80	Transaminases increased	トランスアミナーゼ上昇			MILD	NO	1	14	NO	RESOLVED
Enoxaparin/VKA	540053028	YES	CHINA	ASIAN	FEMALE	70	Appendicitis	虫垂炎			MODERATE	YES	215	8	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	540053029	YES	CHINA	ASIAN	FEMALE	85	Bronchitis	気管支炎			SEVERE	YES	11	10	NO	RESOLVED
Rivaroxaban	540053036	YES	CHINA	ASIAN	FEMALE	57	Haemoglobin decreased	ヘモグロビン減少	15 mg	.	SEVERE	YES	8		NO	UNCHANGED
Rivaroxaban	540053036	YES	CHINA	ASIAN	FEMALE	57	Gastric cancer	胃癌	15 mg	.	SEVERE	YES	13	58	NO	DEATH
Rivaroxaban	540053036	YES	CHINA	ASIAN	FEMALE	57	Metastases to liver	肝転移	15 mg	.	SEVERE	YES	13	58	NO	DEATH
Rivaroxaban	540053038	YES	CHINA	ASIAN	MALE	77	Ischaemic stroke	虚血性脳卒中	20 mg	F	SEVERE	NO	191	34	NO	RESOLVED
Enoxaparin/VKA	540063042	YES	CHINA	ASIAN	MALE	55	Acute myocardial infarction	急性心筋梗塞			SEVERE	YES	132	3	NO	RESOLVED
Enoxaparin/VKA	540083003	YES	CHINA	ASIAN	FEMALE	59	Upper gastrointestinal haemorrhage	上部消化管出血			SEVERE	YES	277	8	YES	RESOLVED
Enoxaparin/VKA	540083007	YES	CHINA	ASIAN	FEMALE	71	Sudden hearing loss	突発難聴			SEVERE	YES	33	39	NO	IMPROVED
Rivaroxaban	540103009	YES	CHINA	ASIAN	FEMALE	25	Activated partial thromboplastin time prolonged	活性化部分トロンボプラスチン時間延長	15 mg	.	SEVERE	YES	2	13	YES	RESOLVED
Rivaroxaban	540153004	YES	CHINA	ASIAN	MALE	51	Right ventricular failure	右室不全	20 mg	.	SEVERE	YES	35	32	NO	DEATH
Rivaroxaban	540153004	YES	CHINA	ASIAN	MALE	51	Dermatomyositis	皮膚筋炎	20 mg	.	SEVERE	YES	40	27	NO	DEATH
Rivaroxaban	540153004	YES	CHINA	ASIAN	MALE	51	Rheumatoid arthritis	関節リウマチ	20 mg	.	SEVERE	YES	40	27	NO	DEATH
Rivaroxaban	540153005	YES	CHINA	ASIAN	MALE	58	Lung neoplasm malignant	肺の悪性新生物	20 mg	.	SEVERE	YES	28	1	NO	DEATH
Enoxaparin/V	540153007	YES	CHINA	ASIAN	MALE	43	Liver function	肝機能検査			MILD	YES	1	30	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
KA							test abnormal	異常								
Enoxaparin/VKA	540153011	YES	CHINA	ASIAN	MALE	59	Hepatic function abnormal	肝機能異常			SEVERE	YES	5	11	YES	RESOLVED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Metastases to lung	肺転移			SEVERE	YES	16		NO	UNCHANGED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Metastases to liver	肝転移			MODERATE	YES	16		NO	UNCHANGED
Enoxaparin/VKA	540163001	YES	CHINA	ASIAN	FEMALE	74	Hypovolaemic shock	血液量減少性ショック			SEVERE	NO	68	1	NO	DEATH
Rivaroxaban	540163004	YES	CHINA	ASIAN	MALE	83	Asthma	喘息	20 mg	.	MILD	YES	111	16	NO	RESOLVED
Rivaroxaban	540163004	YES	CHINA	ASIAN	MALE	83	Cor pulmonale chronic	慢性肺性心	20 mg	.	MODERATE	YES	111	16	NO	RESOLVED
Rivaroxaban	540163004	YES	CHINA	ASIAN	MALE	83	Jaundice	黄疸	20 mg	.	MODERATE	YES	130	23	NO	RESOLVED
Rivaroxaban	540163007	YES	CHINA	ASIAN	MALE	76	Asthma	喘息	15 mg	.	MODERATE	YES	20	7	NO	RESOLVED
Enoxaparin/VKA	540163009	YES	CHINA	ASIAN	FEMALE	78	Cor pulmonale chronic	慢性肺性心			SEVERE	YES	181	38	NO	RESOLVED
Enoxaparin/VKA	540183002	YES	CHINA	ASIAN	MALE	63	Coronary artery disease	冠動脈疾患			MODERATE	YES	28	15	NO	RESOLVED
Enoxaparin/VKA	540183006	YES	CHINA	ASIAN	MALE	55	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MODERATE	YES	6	31	YES	RESOLVED
Enoxaparin/VKA	540183006	YES	CHINA	ASIAN	MALE	55	Aspartate aminotransferase increased	アスパラギン酸アミノトランスフ			MODERATE	YES	6	11	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

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								ェラーゼ増加								
Rivaroxaban	540183011	YES	CHINA	ASIAN	FEMALE	74	Cor pulmonale	肺性心	20 mg	.	SEVERE	YES	81		NO	UNCHANGED
Rivaroxaban	540183011	YES	CHINA	ASIAN	FEMALE	74	Pulmonary embolism	肺塞栓症	20 mg	.	SEVERE	YES	87	1	NO	DEATH
Rivaroxaban	540183012	YES	CHINA	ASIAN	MALE	67	Upper gastrointestinal haemorrhage	上部消化管出血	15 mg	.	SEVERE	YES	1	2	YES	RESOLVED
Rivaroxaban	540193013	YES	CHINA	ASIAN	MALE	80	Bronchitis	気管支炎	15 mg	.	SEVERE	YES	12	14	NO	RESOLVED
Rivaroxaban	540193013	YES	CHINA	ASIAN	MALE	80	Bronchitis	気管支炎	20 mg	.	MODERATE	YES	126	20	NO	RESOLVED
Rivaroxaban	540193013	YES	CHINA	ASIAN	MALE	80	Colon cancer	結腸癌	20 mg	F	SEVERE	NO	144	1	NO	RESOLVED
Rivaroxaban	540193013	YES	CHINA	ASIAN	MALE	80	Intestinal fistula	腸管瘻	20 mg	F	SEVERE	NO	150	4	NO	DEATH
Rivaroxaban	540193013	YES	CHINA	ASIAN	MALE	80	Sepsis	敗血症	20 mg	F	SEVERE	NO	151	3	NO	DEATH
Rivaroxaban	540193024	YES	CHINA	ASIAN	MALE	66	Cor pulmonale acute	急性肺性心	20 mg	.	SEVERE	YES	32	33	NO	RESOLVED
Rivaroxaban	540193026	YES	CHINA	ASIAN	MALE	78	Ischaemic stroke	虚血性脳卒中	20 mg	F	MODERATE	YES	26		NO	IMPROVED
Enoxaparin/VKA	540193029	YES	CHINA	ASIAN	FEMALE	80	Cerebral haemorrhage	脳出血			SEVERE	YES	39	6	YES	DEATH
Enoxaparin/VKA	540203003	YES	CHINA	ASIAN	MALE	65	Pneumonia	肺炎			SEVERE	NO	35	1	NO	DEATH
Rivaroxaban	540223015	YES	CHINA	ASIAN	MALE	71	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	F	MODERATE	NO	181	13	NO	IMPROVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	540243004	YES	CHINA	ASIAN	MALE	30	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	15 mg	.	MILD	YES	5	17	NO	RESOLVED
Enoxaparin/VKA	540243005	YES	CHINA	ASIAN	MALE	39	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加			MILD	YES	13	42	NO	RESOLVED
Enoxaparin/VKA	540253002	YES	CHINA	ASIAN	FEMALE	50	Acute myocardial infarction	急性心筋梗塞			SEVERE	YES	74		NO	IMPROVED
Enoxaparin/VKA	540253005	YES	CHINA	ASIAN	MALE	64	Lung abscess	肺膿瘍			SEVERE	NO	10		NO	INSUFFICIENT FOLLOW-UP
Rivaroxaban	550043035	YES	INDONESIA	ASIAN	FEMALE	28	Haemolytic anaemia	溶血性貧血	15 mg	.	SEVERE	YES	3	120	NO	RESOLVED
Enoxaparin/VKA	560043001	YES	KOREA (SOUTH)	ASIAN	MALE	73	Chest pain	胸痛			MODERATE	YES	93	13	NO	RESOLVED
No study medication	560043003	NO	KOREA (SOUTH)	ASIAN	MALE	28	Acute myeloid leukaemia	急性骨髄性白血病			SEVERE	YES			NO	UNCHANGED
Enoxaparin/VKA	570023002	YES	LITHUANIA	WHITE	FEMALE	57	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患			MILD	YES	213	5	NO	RESOLVED
Enoxaparin/VKA	570023002	YES	LITHUANIA	WHITE	FEMALE	57	Myocardial ischaemia	心筋虚血			MILD	YES	214		NO	UNCHANGED
Enoxaparin/VKA	570023002	YES	LITHUANIA	WHITE	FEMALE	57	Angina pectoris	狭心症			MILD	YES	214		NO	UNCHANGED
Enoxaparin/VKA	570023002	YES	LITHUANIA	WHITE	FEMALE	57	Chronic obstructive	慢性閉塞性肺疾患			MODERATE	YES	244	13	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							pulmonary disease									
Enoxaparin/VKA	570023002	YES	LITHUANIA	WHITE	FEMALE	57	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患			MODERATE	YES	287	9	NO	RESOLVED
Rivaroxaban	570023005	YES	LITHUANIA	WHITE	MALE	50	Pneumonia	肺炎	15 mg	.	MODERATE	YES	14	21	NO	RESOLVED
Rivaroxaban	570023005	YES	LITHUANIA	WHITE	MALE	50	Pneumonia	肺炎	20 mg	.	MODERATE	YES	56	14	NO	RESOLVED
Rivaroxaban	570023005	YES	LITHUANIA	WHITE	MALE	50	Lung neoplasm malignant	肺の悪性新生物	20 mg	.	SEVERE	YES	65		NO	UNCHANGED
Rivaroxaban	570023005	YES	LITHUANIA	WHITE	MALE	50	Pneumonia	肺炎	20 mg	.	SEVERE	YES	96	19	NO	DEATH
Rivaroxaban	580023021	YES	SWITZERLAND	WHITE	MALE	78	Osteoarthritis	変形性関節症	20 mg	.	MODERATE	YES	143	18	NO	RESOLVED
Enoxaparin/VKA	580023022	YES	SWITZERLAND	WHITE	MALE	79	Gastrointestinal haemorrhage	胃腸出血			SEVERE	YES	8	20	YES	RESOLVED
Rivaroxaban	580023023	YES	SWITZERLAND	WHITE	FEMALE	79	Pulmonary venous thrombosis	肺静脈血栓症	20 mg	.	SEVERE	YES	136	3	YES	RESOLVED
Rivaroxaban	580023023	YES	SWITZERLAND	WHITE	FEMALE	79	Aortic dissection	大動脈解離	20 mg	F	SEVERE	YES	138	12	NO	RESOLVED
Enoxaparin/VKA	580043002	YES	SWITZERLAND	WHITE	FEMALE	61	Pneumothorax	気胸			MODERATE	YES	134		NO	UNCHANGED
Enoxaparin/VKA	580043002	YES	SWITZERLAND	WHITE	FEMALE	61	Metastatic neoplasm	転移性新生物			SEVERE	YES	218	5	NO	DEATH

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	580043003	YES	SWITZERLAND	WHITE	MALE	72	Cardiac failure	心不全			MODERATE	NO	20		NO	IMPROVED
Enoxaparin/VKA	580043003	YES	SWITZERLAND	WHITE	MALE	72	Atrial fibrillation	心房細動			MODERATE	NO	20		NO	IMPROVED
Enoxaparin/VKA	580043003	YES	SWITZERLAND	WHITE	MALE	72	General physical health deterioration	全身健康状態低下			MODERATE	NO	260	20	NO	IMPROVED
Rivaroxaban	580043010	YES	SWITZERLAND	WHITE	MALE	68	Cholecystitis	胆嚢炎	20 mg	.	MODERATE	YES	60	8	YES	RESOLVED
Rivaroxaban	580043015	YES	SWITZERLAND	WHITE	MALE	65	Atrial fibrillation	心房細動	20 mg	.	MODERATE	YES	127	100	NO	RESOLVED
Enoxaparin/VKA	580043022	YES	SWITZERLAND	WHITE	MALE	69	Cardiac failure	心不全			MODERATE	YES	174	11	NO	RESOLVED
Rivaroxaban	580043027	YES	SWITZERLAND	WHITE	FEMALE	69	Gastrointestinal haemorrhage	胃腸出血	20 mg	.	MODERATE	YES	22	111	YES	RESOLVED
Rivaroxaban	580043028	YES	SWITZERLAND	WHITE	MALE	74	Dyspnoea	呼吸困難	20 mg	.	MILD	YES	34	2	NO	RESOLVED
Enoxaparin/VKA	580123007	YES	SWITZERLAND	WHITE	FEMALE	79	Atrial flutter	心房粗動			MODERATE	YES	5	9	NO	RESOLVED
Enoxaparin/VKA	580123007	YES	SWITZERLAND	WHITE	FEMALE	79	Urosepsis	尿路性敗血症			SEVERE	YES	31	6	NO	RESOLVED
Enoxaparin/VKA	580183001	YES	SWITZERLAND	WHITE	FEMALE	42	Drug intolerance	薬物不耐性			MODERATE	YES	4	95	YES	RESOLVED
Rivaroxaban	590023004	YES	FINLAND	WHITE	FEMALE	69	Anaemia	貧血	20 mg	.	MILD	YES	127	17	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Rivaroxaban	590023004	YES	FINLAND	WHITE	FEMALE	69	Anaemia	貧血	20 mg	.	MODERATE	YES	176	34	YES	RESOLVED
Enoxaparin/VKA	590023005	YES	FINLAND	WHITE	FEMALE	65	Chest pain	胸痛			MILD	YES	7	2	NO	RESOLVED
Rivaroxaban	610013001	YES	TAIWAN	ASIAN	MALE	80	Small cell lung cancer stage unspecified	小細胞肺癌、病期不明	15 mg	F	SEVERE	NO	27		NO	UNCHANGED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Lung neoplasm malignant	肺の悪性新生物	20 mg	.	SEVERE	YES	26	14	NO	IMPROVED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Lobar pneumonia	大葉性肺炎	20 mg	.	MODERATE	YES	74	14	NO	RESOLVED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Dyspnoea	呼吸困難	20 mg	.	MODERATE	YES	187	4	NO	RESOLVED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Pneumonia	肺炎	20 mg	.	MODERATE	YES	187	4	NO	RESOLVED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Oedema peripheral	末梢性浮腫	20 mg	.	MODERATE	YES	227	16	NO	RESOLVED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Muscular weakness	筋力低下	20 mg	.	MODERATE	YES	227	16	NO	RESOLVED
Rivaroxaban	610013004	YES	TAIWAN	ASIAN	MALE	41	Lung neoplasm malignant	肺の悪性新生物	20 mg	F	SEVERE	YES	261	1	NO	DEATH
No study medication	610013005	NO	TAIWAN	ASIAN	FEMALE	84	Non-small cell lung cancer	非小細胞肺癌			SEVERE	NO		22	NO	DEATH
No study medication	610013005	NO	TAIWAN	ASIAN	FEMALE	84	Malignant pleural effusion	悪性胸水			MODERATE	NO		22	NO	DEATH

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
No study medication	610013005	NO	TAIWAN	ASIAN	FEMALE	84	Lymphangiosis carcinomatosa	癌性リンパ管症			MODERATE	NO		22	NO	DEATH
Rivaroxaban	650023003	YES	HONGKONG	ASIAN	FEMALE	33	Cellulitis	蜂巣炎	20 mg	F	MILD	NO	202	21	NO	RESOLVED
Rivaroxaban	660013012	YES	MALAYSIA	ASIAN	FEMALE	44	Menorrhagia	月経過多	20 mg	.	MODERATE	YES	159	10	YES	RESOLVED
Rivaroxaban	660013012	YES	MALAYSIA	ASIAN	FEMALE	44	Menorrhagia	月経過多	20 mg	.	MODERATE	YES	236	5	YES	RESOLVED
Rivaroxaban	660013012	YES	MALAYSIA	ASIAN	FEMALE	44	Menorrhagia	月経過多	20 mg	.	MODERATE	YES	307	21	YES	RESOLVED
Rivaroxaban	670013005	YES	PHILIPPINES	ASIAN	FEMALE	72	Haemoptysis	喀血	20 mg	.	MILD	YES	355	1	YES	RESOLVED
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Ascites	腹水			MODERATE	YES	55		NO	IMPROVED
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Metastases to liver	肝転移			SEVERE	YES	121		NO	UNCHANGED
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Pleural effusion	胸水			MODERATE	YES	222	10	NO	IMPROVED
Enoxaparin/VKA	670013015	YES	PHILIPPINES	ASIAN	MALE	47	Acute respiratory failure	急性呼吸不全			SEVERE	NO	229	3	NO	DEATH
Rivaroxaban	670013021	YES	PHILIPPINES	ASIAN	MALE	83	Cerebrovascular accident	脳血管発作	15 mg	.	SEVERE	YES	6		YES	UNCHANGED
Rivaroxaban	670013021	YES	PHILIPPINES	ASIAN	MALE	83	Cardio-respiratory arrest	心肺停止	15 mg	F	SEVERE	YES	7	1	NO	DEATH

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	670013022	YES	PHILIPPINES	ASIAN	MALE	58	Hepatic steatosis	脂肪肝			MILD	NO	218		NO	UNCHANGED
Rivaroxaban	670013023	YES	PHILIPPINES	ASIAN	FEMALE	37	Pneumonia	肺炎	20 mg	.	MODERATE	YES	25		NO	IMPROVED
Enoxaparin/VKA	680023011	YES	SINGAPORE	ASIAN	MALE	67	Scoliosis	側弯症			SEVERE	YES	154	2	NO	RESOLVED
Enoxaparin/VKA	680023011	YES	SINGAPORE	ASIAN	MALE	67	Spinal column stenosis	脊柱管狭窄症			SEVERE	YES	154	2	NO	RESOLVED
Enoxaparin/VKA	700023007	YES	NEW ZEALAND	WHITE	FEMALE	80	Cellulitis	蜂巣炎			MODERATE	YES	8	8	NO	IMPROVED
Rivaroxaban	700023015	YES	NEW ZEALAND	WHITE	MALE	60	Groin pain	鼠径部痛	20 mg	.	MODERATE	YES	229		NO	IMPROVED
Enoxaparin/VKA	700023030	YES	NEW ZEALAND	WHITE	FEMALE	78	Pleuritic pain	胸膜痛			MODERATE	YES	4	3	NO	RESOLVED
Rivaroxaban	700023031	YES	NEW ZEALAND	WHITE	MALE	34	Wound infection	創傷感染	20 mg	.	MODERATE	YES	209	11	NO	RESOLVED
Rivaroxaban	700023031	YES	NEW ZEALAND	WHITE	MALE	34	Wound infection	創傷感染	20 mg	.	MODERATE	YES	225	20	NO	RESOLVED
Enoxaparin/VKA	700023033	YES	NEW ZEALAND	WHITE	FEMALE	68	Abdominal pain upper	上腹部痛			MODERATE	YES	174		NO	UNCHANGED
Enoxaparin/VKA	700023033	YES	NEW ZEALAND	WHITE	FEMALE	68	Muscular weakness	筋力低下			MODERATE	YES	201	14	NO	RESOLVED
Enoxaparin/VKA	700023036	YES	NEW ZEALAND	WHITE	FEMALE	66	Dehydration	脱水			SEVERE	YES	69	4	NO	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	700033004	YES	NEW ZEALAND	WHITE	MALE	67	Angina pectoris	狭心症			MODERATE	YES	42	249	NO	RESOLVED
Enoxaparin/VKA	700033006	YES	NEW ZEALAND	WHITE	FEMALE	69	Vomiting	嘔吐			MODERATE	YES	206	2	NO	RESOLVED
Enoxaparin/VKA	700033025	YES	NEW ZEALAND	WHITE	FEMALE	68	Subdural haematoma	硬膜下血腫			SEVERE	YES	130		YES	IMPROVED
Enoxaparin/VKA	700033035	YES	NEW ZEALAND	WHITE	MALE	53	Pleurisy	胸膜炎			MODERATE	YES	6	18	NO	RESOLVED
Enoxaparin/VKA	700033038	YES	NEW ZEALAND	WHITE	MALE	74	Prostate cancer	前立腺癌			MILD	YES	115		NO	UNCHANGED
Rivaroxaban	700033040	YES	NEW ZEALAND	ASIAN	MALE	60	Lower respiratory tract infection	下気道感染	20 mg	F	SEVERE	NO	383	8	NO	RESOLVED
Rivaroxaban	700033042	YES	NEW ZEALAND	WHITE	FEMALE	73	Colon cancer	結腸癌	20 mg	.	MODERATE	YES	80	56	NO	RESOLVED
Rivaroxaban	700033047	YES	NEW ZEALAND	WHITE	MALE	26	Pleural effusion	胸水	15 mg	.	SEVERE	YES	18	39	NO	RESOLVED
Enoxaparin/VKA	700033049	YES	NEW ZEALAND	WHITE	MALE	36	Chest pain	胸痛			MODERATE	YES	27	12	NO	RESOLVED
Rivaroxaban	700043002	YES	NEW ZEALAND	WHITE	FEMALE	69	Urticaria	蕁麻疹	15 mg	.	MODERATE	YES	4	13	YES	RESOLVED
Rivaroxaban	700043004	YES	NEW ZEALAND	ASIAN	MALE	57	Angina pectoris	狭心症	20 mg	.	MODERATE	YES	181	4	NO	RESOLVED
Enoxaparin/VKA	700043007	YES	NEW ZEALAND	WHITE	MALE	48	Haemorrhage intracranial	頭蓋内出血			MILD	YES	232	4	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	700043007	YES	NEW ZEALAND	WHITE	MALE	48	Loss of consciousness	意識消失			MILD	YES	232	2	NO	RESOLVED
Enoxaparin/VKA	700043007	YES	NEW ZEALAND	WHITE	MALE	48	Tension headache	緊張性頭痛			MODERATE	YES	232	4	YES	RESOLVED
Enoxaparin/VKA	700043007	YES	NEW ZEALAND	WHITE	MALE	48	Loss of consciousness	意識消失			MODERATE	YES	344	2	NO	RESOLVED
Enoxaparin/VKA	700043007	YES	NEW ZEALAND	WHITE	MALE	48	Convulsion	痙攣			MODERATE	YES	344	2	NO	RESOLVED
Enoxaparin/VKA	700043009	YES	NEW ZEALAND	ASIAN	FEMALE	59	Acute myocardial infarction	急性心筋梗塞			MODERATE	YES	83	8	NO	RESOLVED
Enoxaparin/VKA	700043009	YES	NEW ZEALAND	ASIAN	FEMALE	59	Chest pain	胸痛			MODERATE	YES	83	8	NO	RESOLVED
Enoxaparin/VKA	700043009	YES	NEW ZEALAND	ASIAN	FEMALE	59	Coronary artery dissection	冠動脈解離			MODERATE	YES	83	8	NO	RESOLVED
Rivaroxaban	700043012	YES	NEW ZEALAND	WHITE	MALE	36	Skin ulcer	皮膚潰瘍	20 mg	.	MODERATE	YES	351		NO	IMPROVED
Enoxaparin/VKA	700043017	YES	NEW ZEALAND	WHITE	MALE	48	Gout	痛風			MODERATE	YES	128		YES	IMPROVED
Rivaroxaban	700043030	YES	NEW ZEALAND	WHITE	FEMALE	54	Convulsion	痙攣	15 mg	F	MODERATE	NO	35	3	NO	RESOLVED
Enoxaparin/VKA	700043038	YES	NEW ZEALAND	WHITE	MALE	44	Gastritis	胃炎			MODERATE	YES	55	9	YES	RESOLVED
Rivaroxaban	700043039	YES	NEW ZEALAND	WHITE	FEMALE	66	Pulmonary infarction	肺梗塞	15 mg	.	SEVERE	YES	1	2	YES	RESOLVED

表 2.7.4.7-20 すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Enoxaparin/VKA	700053037	YES	NEW ZEALAND	WHITE	MALE	55	Bladder cancer	膀胱癌			SEVERE	YES	133	34	NO	RESOLVED
Enoxaparin/VKA	700053038	YES	NEW ZEALAND	WHITE	FEMALE	67	Large intestine perforation	大腸穿孔			SEVERE	YES	85	10	NO	RESOLVED
Rivaroxaban	700053039	YES	NEW ZEALAND	WHITE	FEMALE	71	Cellulitis	蜂巣炎	20 mg	.	SEVERE	YES	124	60	NO	RESOLVED
Rivaroxaban	700053039	YES	NEW ZEALAND	WHITE	FEMALE	71	Chest pain	胸痛	20 mg	.	SEVERE	YES	128	4	NO	RESOLVED
Rivaroxaban	700053039	YES	NEW ZEALAND	WHITE	FEMALE	71	Muscular weakness	筋力低下	20 mg	.	SEVERE	YES	308		NO	UNCHANGED
Rivaroxaban	710023020	YES	THAILAND	ASIAN	FEMALE	79	Muscular weakness	筋力低下	20 mg	.	MODERATE	YES	72	38	NO	RESOLVED
Rivaroxaban	710023020	YES	THAILAND	ASIAN	FEMALE	79	Altered state of consciousness	意識変容状態	20 mg	.	SEVERE	YES	127	4	NO	RESOLVED
Rivaroxaban	710023020	YES	THAILAND	ASIAN	FEMALE	79	Sepsis	敗血症	20 mg	.	SEVERE	YES	137	41	NO	DEATH
Enoxaparin/VKA	710023023	YES	THAILAND	ASIAN	FEMALE	83	Colon cancer metastatic	転移性結腸癌			SEVERE	YES	106	61	NO	DEATH
Enoxaparin/VKA	710053002	YES	THAILAND	WHITE	MALE	70	Pulmonary infarction	肺梗塞			MODERATE	YES	3		NO	IMPROVED
Rivaroxaban	710053003	YES	THAILAND	ASIAN	MALE	78	Post procedural haemorrhage	処置後出血	15 mg	.	SEVERE	YES	3	3	NO	RESOLVED
Rivaroxaban	710053003	YES	THAILAND	ASIAN	MALE	78	Respiratory failure	呼吸不全	15 mg	.	SEVERE	YES	3	16	YES	RESOLVED
No study medication	760023001	NO	LATVIA	WHITE	MALE	73	Ischaemic stroke	虚血性脳卒中			MODERATE	NO		31	NO	RESOLVED

Only All serious AEs (TEAE and non-TEAE) are presented.

表 2.7.4.7-20　すべての重篤な有害事象の一覧（試験 11702-PE、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {14.1})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
TE: Treatment emergent (time window: 2 days) Relative day is calculated from the first day of study drug administration: The formula for this calculation is (onset day of AE minus medication day) plus 1 day. Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed. Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase, F will be listed.																

表 2.7.4.7-21 すべての重篤な有害事象の一覧（試験 11899、割り付けられた被験者）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {12.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Placebo	100094003	YES	GERMANY	WHITE	MALE	64	Traumatic fracture	外傷性骨折			SEVERE	YES	64	17	NO	RESOLVED
Placebo	120025001	YES	UNITED KINGDOM	WHITE	MALE	46	Diabetic ketoacidosis	糖尿病性ケトアシドーシス			SEVERE	YES	166	10	NO	RESOLVED
BAY 59-7939	120115003	YES	UNITED KINGDOM	WHITE	MALE	80	Acute myocardial infarction	急性心筋梗塞	20 mg	F	SEVERE	NO	180	6	NO	RESOLVED
BAY 59-7939	140175001	YES	UNITED STATES	WHITE	MALE	78	Gastrointestinal haemorrhage	胃腸出血	20 mg	.	SEVERE	YES	100	4	YES	RESOLVED
BAY 59-7939	160023003	YES	FRANCE	N.A.	MALE	76	Bradycardia	徐脈	20 mg	.	SEVERE	YES	154	5	NO	RESOLVED
BAY 59-7939	160125004	YES	FRANCE	N.A.	FEMALE	73	Osteoarthritis	骨関節炎	20 mg	.	MODERATE	YES	49	9	NO	RESOLVED
BAY 59-7939	160125004	YES	FRANCE	N.A.	FEMALE	73	Depression	うつ病	20 mg	.	SEVERE	YES	90	4	NO	RESOLVED
BAY 59-7939	160125004	YES	FRANCE	N.A.	FEMALE	73	Depression	うつ病	20 mg	F	SEVERE	YES	128	15	NO	RESOLVED
BAY 59-7939	160174003	YES	FRANCE	N.A.	FEMALE	35	Menometrorrhagia	機能性子宮出血	20 mg	F	SEVERE	YES	90	3	YES	RESOLVED
BAY 59-7939	160174004	YES	FRANCE	N.A.	MALE	57	Hepatic neoplasm	肝新生物	20 mg	F	MODERATE	NO	30	3	NO	RESOLVED
BAY 59-7939	160174004	YES	FRANCE	N.A.	MALE	57	Sarcoma	肉腫	20 mg	F	SEVERE	NO	31		NO	UNCHANGED
BAY 59-7939	160214007	YES	FRANCE	N.A.	FEMALE	69	Joint dislocation	関節脱臼	20 mg	.	MILD	YES	170	17	NO	RESOLVED
BAY 59-7939	160234011	YES	FRANCE	N.A.	MALE	70	Localised infection	限局性感染	20 mg	.	SEVERE	YES	7	5	NO	RESOLVED
BAY 59-7939	160234040	YES	FRANCE	N.A.	MALE	56	Epilepsy	てんかん	20 mg	F	MILD	NO	209	2	NO	RESOLVED
Placebo	160264001	NO	FRANCE	N.A.	MALE	68	Renal failure	腎不全			SEVERE	YES	149		NO	UNCHANGED
Placebo	160264001	NO	FRANCE	N.A.	MALE	68	Pyelonephritis	腎盂腎炎			SEVERE	YES	149	2	NO	RESOLVED

表 2.7.4.7-21 すべての重篤な有害事象の一覧（試験 11899、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {12.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Placebo	160264001	NO	FRANCE	N.A.	MALE	68	Septic shock	敗血症性ショック			SEVERE	YES	150	4	NO	RESOLVED
Placebo	160264001	NO	FRANCE	N.A.	MALE	68	Multi-organ failure	多臓器不全			SEVERE	YES	150	9	NO	RESOLVED
Placebo	160264001	NO	FRANCE	N.A.	MALE	68	General physical health deterioration	全身健康状態低下			SEVERE	NO	176	2	NO	DEATH
Placebo	160293004	YES	FRANCE	N.A.	MALE	82	Acute myocardial infarction	急性心筋梗塞			SEVERE	YES	18	11	NO	RESOLVED
Placebo	160293004	YES	FRANCE	N.A.	MALE	82	Pharyngitis	咽頭炎			MODERATE	NO	36	6	NO	RESOLVED
Placebo	160293010	YES	FRANCE	N.A.	FEMALE	82	Atrial fibrillation	心房細動			MODERATE	YES	118	21	NO	RESOLVED
Placebo	160293010	YES	FRANCE	N.A.	FEMALE	82	Haematoma	血腫			MODERATE	YES	124	5	YES	RESOLVED
BAY 59-7939	160294006	YES	FRANCE	N.A.	MALE	73	Epilepsy	てんかん	20 mg	I	MODERATE	YES	38	13	NO	RESOLVED
BAY 59-7939	160294006	YES	FRANCE	N.A.	MALE	73	Transient ischaemic attack	一過性脳虚血発作	20 mg	.	MODERATE	YES	151	10	NO	RESOLVED
BAY 59-7939	160294006	YES	FRANCE	N.A.	MALE	73	Epilepsy	てんかん	20 mg	F	MODERATE	NO	211	13	NO	RESOLVED
BAY 59-7939	180055001	YES	POLAND	WHITE	MALE	55	Angina unstable	不安定狭心症	20 mg	.	SEVERE	YES	286	12	NO	RESOLVED
BAY 59-7939	180055001	YES	POLAND	WHITE	MALE	55	Post procedural haemorrhage	処置後出血	20 mg	F	SEVERE	NO	291	2	NO	RESOLVED

表 2.7.4.7-21 すべての重篤な有害事象の一覧（試験 11899、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {12.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
BAY 59-7939	180105020	YES	POLAND	WHITE	MALE	55	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	SEVERE	YES	138	28	NO	RESOLVED
BAY 59-7939	220014004	YES	ITALY	WHITE	FEMALE	74	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	MODERATE	YES	106	16	NO	RESOLVED
BAY 59-7939	220014004	YES	ITALY	WHITE	FEMALE	74	Cardiac arrest	心停止	20 mg	.	SEVERE	YES	272	1	NO	DEATH
Placebo	220014018	YES	ITALY	WHITE	MALE	74	Asthenia	無力症			MODERATE	YES	70	13	NO	RESOLVED
BAY 59-7939	220044002	YES	ITALY	WHITE	MALE	80	Intestinal obstruction	腸閉塞	20 mg	.	SEVERE	YES	24	5	NO	RESOLVED
BAY 59-7939	220065006	YES	ITALY	WHITE	FEMALE	79	Rheumatoid arthritis	関節リウマチ	20 mg	.	MODERATE	YES	2	21	NO	RESOLVED
Placebo	220065008	YES	ITALY	WHITE	MALE	84	Abdominal pain	腹痛			SEVERE	YES	98	9	NO	RESOLVED
BAY 59-7939	220133007	YES	ITALY	WHITE	MALE	68	Gastroenteritis	胃腸炎	20 mg	I	MODERATE	YES	113	9	NO	RESOLVED
BAY 59-7939	220133007	YES	ITALY	WHITE	MALE	68	Gastroenteritis	胃腸炎	20 mg	I	MODERATE	YES	123	14	NO	RESOLVED
BAY 59-7939	220135005	YES	ITALY	WHITE	FEMALE	47	Pneumonia	肺炎	20 mg	F	MODERATE	NO	210	18	NO	RESOLVED
Placebo	240075005	YES	SPAIN	WHITE	MALE	40	Epilepsy	てんかん			MILD	YES	57	2	NO	RESOLVED
Placebo	240075006	YES	SPAIN	WHITE	FEMALE	67	Costochondritis	肋軟骨炎			SEVERE	NO	186	11	NO	IMPROVED
BAY 59-7939	280083007	YES	BELGIUM	WHITE	MALE	89	Pneumonia	肺炎	20 mg	.	SEVERE	YES	175	46	NO	RESOLVED

表 2.7.4.7-21 すべての重篤な有害事象の一覧（試験 11899、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {12.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Placebo	300073177	YES	NETHERLANDS	WHITE	MALE	51	Ischaemic stroke	虚血性脳卒中			SEVERE	YES	87	11	NO	RESOLVED
BAY 59-7939	300074009	YES	NETHERLANDS	WHITE	MALE	48	Appendicitis	虫垂炎	20 mg	.	SEVERE	YES	161	4	NO	RESOLVED
BAY 59-7939	300074009	YES	NETHERLANDS	WHITE	MALE	48	Appendicectomy	虫垂切除	20 mg	I	MODERATE	YES	162	1	NO	RESOLVED
BAY 59-7939	300074009	YES	NETHERLANDS	WHITE	MALE	48	Postoperative abscess	術後膿瘍	20 mg	I	MODERATE	YES	165	3	NO	RESOLVED
BAY 59-7939	300074009	YES	NETHERLANDS	WHITE	MALE	48	Abdominal abscess	腹部膿瘍	20 mg	I	MODERATE	YES	174	5	NO	RESOLVED
Placebo	300075001	YES	NETHERLANDS	WHITE	FEMALE	29	Drug exposure during pregnancy	妊娠時の薬物曝露			SEVERE	YES			NO	RESOLVED
Placebo	340014011	YES	SWEDEN	WHITE	FEMALE	74	Humerus fracture	上腕骨骨折			SEVERE	NO	167	8	NO	IMPROVED
Placebo	340015017	YES	SWEDEN	WHITE	FEMALE	74	Urinary tract infection	尿路感染			MODERATE	YES	265	4	NO	RESOLVED
BAY 59-7939	340015021	YES	SWEDEN	WHITE	MALE	70	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	MODERATE	YES	192	5	NO	RESOLVED
BAY 59-7939	340015021	YES	SWEDEN	WHITE	MALE	70	Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 mg	.	MODERATE	YES	208	2	NO	RESOLVED
Placebo	340045004	YES	SWEDEN	WHITE	MALE	70	Bradycardia	徐脈			SEVERE	YES	53	2	NO	RESOLVED
BAY 59-7939	340055002	YES	SWEDEN	WHITE	MALE	56	Chest pain	胸痛			MODERATE	NO	-2	1	NO	RESOLVED

表 2.7.4.7-21 すべての重篤な有害事象の一覧（試験 11899、割り付けられた被験者）（続き）

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BAY 59-7939	340055002	YES	SWEDEN	WHITE	MALE	56	Chest pain	胸痛	20 mg	.	MODERATE	YES	40	2	NO	RESOLVED
BAY 59-7939	340055002	YES	SWEDEN	WHITE	MALE	56	Abdominal pain upper	上腹部痛	20 mg	.	MODERATE	YES	147	8	YES	RESOLVED
Placebo	340055009	YES	SWEDEN	WHITE	MALE	76	Chest pain	胸痛			MODERATE	NO	53	2	NO	IMPROVED
BAY 59-7939	340055014	YES	SWEDEN	WHITE	MALE	88	Skull fracture	頭蓋骨骨折	20 mg	.	MODERATE	YES	123	16	NO	RESOLVED
Placebo	340055018	YES	SWEDEN	WHITE	FEMALE	80	Cholecystitis	胆嚢炎			SEVERE	YES	278	6	NO	RESOLVED
Placebo	340055027	YES	SWEDEN	WHITE	FEMALE	70	Intestinal gangrene	腸壊疽			SEVERE	YES	54	17	NO	RESOLVED
BAY 59-7939	340055035	YES	SWEDEN	WHITE	FEMALE	84	Oesophageal neoplasm	食道新生物	20 mg	I	MODERATE	YES	155		NO	UNCHANGED
BAY 59-7939	340055035	YES	SWEDEN	WHITE	FEMALE	84	Abdominal pain	腹痛	20 mg	I	MODERATE	YES	157	6	NO	RESOLVED
Placebo	360045005	YES	NORWAY	WHITE	MALE	49	Anxiety	不安			MODERATE	YES	6	1	NO	RESOLVED
BAY 59-7939	360045007	YES	NORWAY	WHITE	MALE	50	Bladder calculus removal	膀胱結石除去	20 mg	I	MODERATE	YES	33	3	NO	RESOLVED
BAY 59-7939	370024006	YES	SOUTH AFRICA	WHITE	MALE	64	Melaena	メレナ	20 mg	F	MILD	YES	15	4	YES	RESOLVED
BAY 59-7939	370024006	YES	SOUTH AFRICA	WHITE	MALE	64	Adenocarcinoma	腺癌	20 mg	F	MODERATE	NO	36	24	NO	RESOLVED
BAY 59-7939	370054025	YES	SOUTH AFRICA	WHITE	FEMALE	86	Pain in extremity	四肢痛	20 mg	.	MODERATE	YES	106		NO	INSUFFICIENT FOLLOW-

表 2.7.4.7-21 すべての重篤な有害事象の一覧（試験 11899、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {12.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
																UP
Placebo	370065008	YES	SOUTH AFRICA	BLACK	FEMALE	52	Stevens-Johnson syndrome	スティーブンス・ジョンソン症候群			SEVERE	YES	79	14	NO	RESOLVED
BAY 59-7939	370073006	YES	SOUTH AFRICA	WHITE	MALE	77	Gastrointestinal haemorrhage	胃腸出血	20 mg	.	MODERATE	YES	2	11	NO	RESOLVED
BAY 59-7939	370073006	YES	SOUTH AFRICA	WHITE	MALE	77	Gastrointestinal haemorrhage	胃腸出血	20 mg	.	MODERATE	YES	51	3	YES	RESOLVED
Placebo	370113002	YES	SOUTH AFRICA	WHITE	FEMALE	78	Colitis	大腸炎			SEVERE	NO	201	16	NO	RESOLVED
Placebo	370113002	YES	SOUTH AFRICA	WHITE	FEMALE	78	Rectal haemorrhage	直腸出血			SEVERE	NO	204	2	NO	RESOLVED
Placebo	370113002	YES	SOUTH AFRICA	WHITE	FEMALE	78	Rectal haemorrhage	直腸出血			SEVERE	NO	206	2	NO	RESOLVED
Placebo	370113002	YES	SOUTH AFRICA	WHITE	FEMALE	78	Large intestinal ulcer	大腸潰瘍			SEVERE	NO	214	7	NO	RESOLVED
BAY 59-7939	370135001	YES	SOUTH AFRICA	WHITE	FEMALE	55	Hepatic enzyme increased	肝酵素上昇	20 mg	.	SEVERE	YES	145	16	NO	IMPROVED
Placebo	380043014	YES	CZECH REPUBLIC	WHITE	FEMALE	73	Hydronephrosis	水腎症			SEVERE	YES	147	15	NO	RESOLVED
Placebo	380043014	YES	CZECH REPUBLIC	WHITE	FEMALE	73	Colon cancer	結腸癌			SEVERE	YES	149		NO	UNCHANGED

表 2.7.4.7-21 すべての重篤な有害事象の一覧（試験 11899、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {12.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Placebo	380043014	YES	CZECH REPUBLIC	WHITE	FEMALE	73	Cardiac failure	心不全			SEVERE	NO	191	1	NO	DEATH
BAY 59-7939	380044007	YES	CZECH REPUBLIC	WHITE	FEMALE	32	Metrorrhagia	不正子宮出血	20 mg	.	MODERATE	YES	126	6	YES	RESOLVED
Placebo	380073008	YES	CZECH REPUBLIC	WHITE	FEMALE	85	Bronchitis	気管支炎			MODERATE	YES	159	7	NO	RESOLVED
Placebo	380073008	YES	CZECH REPUBLIC	WHITE	FEMALE	85	Respiratory failure	呼吸不全			MODERATE	YES	159	7	NO	RESOLVED
Placebo	380074005	YES	CZECH REPUBLIC	WHITE	MALE	64	Supraventricular tachycardia	上室性頻脈			MODERATE	YES	207	1	NO	RESOLVED
Placebo	380085004	YES	CZECH REPUBLIC	WHITE	MALE	70	Bronchitis	気管支炎			MILD	YES	48	8	NO	RESOLVED
BAY 59-7939	380085010	YES	CZECH REPUBLIC	WHITE	MALE	64	Dyspnoea	呼吸困難	20 mg	I	MODERATE	YES	7	4	NO	RESOLVED
BAY 59-7939	380085010	YES	CZECH REPUBLIC	WHITE	MALE	64	Bronchospasm	気管支痙攣	20 mg	I	MODERATE	YES	7	4	NO	RESOLVED
BAY 59-7939	380085010	YES	CZECH REPUBLIC	WHITE	MALE	64	Dyspnoea	呼吸困難	20 mg	.	MODERATE	YES	33	6	NO	RESOLVED
BAY 59-7939	380085010	YES	CZECH REPUBLIC	WHITE	MALE	64	Hypertension	高血圧	20 mg	.	SEVERE	YES	47	3	NO	RESOLVED
BAY 59-7939	380085010	YES	CZECH REPUBLIC	WHITE	MALE	64	Acute pulmonary oedema	急性肺水腫	20 mg	.	SEVERE	YES	47	3	NO	RESOLVED
BAY 59-7939	380085010	YES	CZECH REPUBLIC	WHITE	MALE	64	Dyspnoea	呼吸困難	20 mg	.	MODERATE	YES	53	6	NO	RESOLVED

表 2.7.4.7-21 すべての重篤な有害事象の一覧（試験 11899、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {12.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
Placebo	390014003	YES	ISRAEL	WHITE	FEMALE	57	Endometrial cancer	子宮内膜癌			MODERATE	YES	131	5	NO	RESOLVED
BAY 59-7939	390014007	YES	ISRAEL	WHITE	FEMALE	81	Anaemia	貧血	20 mg	I	MODERATE	YES	102	6	YES	RESOLVED
BAY 59-7939	390014012	YES	ISRAEL	WHITE	MALE	63	Abdominal pain upper	上腹部痛	20 mg	F	MODERATE	YES	242	7	NO	RESOLVED
BAY 59-7939	390014012	YES	ISRAEL	WHITE	MALE	63	Metastases to liver	肝転移	20 mg	F	SEVERE	NO	253		NO	UNCHANGED
BAY 59-7939	390014012	YES	ISRAEL	WHITE	MALE	63	Metastases to spine	脊椎転移	20 mg	F	SEVERE	NO	253		NO	UNCHANGED
Placebo	390014020	YES	ISRAEL	WHITE	MALE	70	Sick sinus syndrome	洞不全症候群			MODERATE	YES	49	5	NO	RESOLVED
Placebo	390014020	YES	ISRAEL	WHITE	MALE	70	Syncope	失神			MODERATE	YES	49	5	NO	RESOLVED
BAY 59-7939	390015002	YES	ISRAEL	WHITE	MALE	59	Rectal haemorrhage	直腸出血	20 mg	.	MILD	YES	91	7	YES	RESOLVED
BAY 59-7939	390015003	YES	ISRAEL	WHITE	FEMALE	68	Pneumonia	肺炎	20 mg	.	MILD	YES	115	6	NO	IMPROVED
BAY 59-7939	390015003	YES	ISRAEL	WHITE	FEMALE	68	Pneumonia	肺炎	20 mg	.	MODERATE	YES	123	91	NO	RESOLVED
BAY 59-7939	390015003	YES	ISRAEL	WHITE	FEMALE	68	Lung abscess	肺膿瘍	20 mg	.	MODERATE	YES	201	13	NO	RESOLVED
Placebo	390024012	YES	ISRAEL	WHITE	FEMALE	68	Hypertension	高血圧			SEVERE	YES	200	2	NO	RESOLVED
Placebo	390033001	YES	ISRAEL	WHITE	FEMALE	67	Abdominal hernia obstructive	閉塞を伴う腹部ヘルニア			SEVERE	YES	45	2	NO	RESOLVED
Placebo	390104009	YES	ISRAEL	WHITE	MALE	85	Atrial	心房細動			MILD	NO	297	2	NO	IMPROVED

表 2.7.4.7-21 すべての重篤な有害事象の一覧（試験 11899、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {12.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
							fibrillation									
Placebo	390104020	YES	ISRAEL	WHITE	FEMALE	82	Pain in extremity	四肢痛			MILD	YES	26	3	NO	RESOLVED
Placebo	390104020	YES	ISRAEL	WHITE	FEMALE	82	Chest pain	胸痛			MILD	YES	62	2	NO	RESOLVED
BAY 59-7939	390104023	YES	ISRAEL	WHITE	MALE	78	Gastritis	胃炎	20 mg	.	MODERATE	YES	41	2	NO	RESOLVED
BAY 59-7939	390104023	YES	ISRAEL	WHITE	MALE	78	Gastritis	胃炎	20 mg	.	MODERATE	YES	46	2	NO	RESOLVED
Placebo	390113002	YES	ISRAEL	WHITE	MALE	75	Malignant melanoma in situ	表皮内悪性黒色腫			MILD	YES	72		NO	INSUFFICIENT FOLLOW-UP
Placebo	400034027	YES	AUSTRALIA	WHITE	FEMALE	71	Diverticulum	憩室			MODERATE	YES	35	9	NO	RESOLVED
BAY 59-7939	400063001	YES	AUSTRALIA	WHITE	FEMALE	57	Gastric ulcer	胃潰瘍	20 mg	.	MODERATE	YES	54	55	NO	RESOLVED
Placebo	400065002	YES	AUSTRALIA	WHITE	FEMALE	41	Anal fistula excision	痔瘻切除			MILD	YES	87	2	NO	RESOLVED
Placebo	400073018	YES	AUSTRALIA	WHITE	FEMALE	87	Colorectal cancer	結腸直腸癌			SEVERE	YES	27	10	NO	RESOLVED
Placebo	400094014	YES	AUSTRALIA	WHITE	FEMALE	59	Vaginal neoplasm	膣新生物			MODERATE	YES	15	9	NO	RESOLVED
Placebo	400094014	YES	AUSTRALIA	WHITE	FEMALE	59	Vaginal prolapse	膣脱			SEVERE	YES	15	9	NO	RESOLVED
Placebo	400094014	YES	AUSTRALIA	WHITE	FEMALE	59	Haemorrhoids	痔核			MODERATE	YES	72	12	NO	RESOLVED

表 2.7.4.7-21 すべての重篤な有害事象の一覧（試験 11899、割り付けられた被験者）（続き）

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Placebo	400113001	YES	AUSTRALIA	WHITE	FEMALE	72	Colitis ischaemic	虚血性大腸炎			MODERATE	YES	169	10	NO	RESOLVED
Placebo	400113001	YES	AUSTRALIA	WHITE	FEMALE	72	Chest pain	胸痛			MODERATE	YES	182	1	NO	RESOLVED
Placebo	400113001	YES	AUSTRALIA	WHITE	FEMALE	72	Constipation	便秘			SEVERE	YES	306	32	NO	RESOLVED
Placebo	400115001	YES	AUSTRALIA	WHITE	MALE	41	Soft tissue injury	軟部組織損傷			MODERATE	NO	364	2	NO	RESOLVED
Placebo	400123004	YES	AUSTRALIA	WHITE	FEMALE	83	Atrial fibrillation	心房細動			MODERATE	YES	33	5	NO	RESOLVED
BAY 59-7939	400123009	YES	AUSTRALIA	WHITE	MALE	75	Dyspnoea	呼吸困難	20 mg	.	MODERATE	YES	89	15	NO	RESOLVED
BAY 59-7939	400155003	YES	AUSTRALIA	WHITE	MALE	75	Squamous cell carcinoma of skin	皮膚有棘細胞癌	20 mg	.	SEVERE	YES	284	1	NO	RESOLVED
BAY 59-7939	400155003	YES	AUSTRALIA	WHITE	MALE	75	Metastatic squamous cell carcinoma	転移性扁平上皮癌	20 mg	F	SEVERE	NO	359	25	NO	RESOLVED
BAY 59-7939	400213008	YES	AUSTRALIA	WHITE	MALE	46	Cellulitis	蜂巣炎	20 mg	F	MODERATE	NO	208	10	NO	RESOLVED
Placebo	400213020	YES	AUSTRALIA	AMERICAN INDIAN OR ALASKA NATIVE	MALE	75	Osteoarthritis	骨関節炎			MODERATE	YES	171	8	NO	RESOLVED

表 2.7.4.7-21 すべての重篤な有害事象の一覧（試験 11899、割り付けられた被験者）（続き）

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Placebo	400213020	YES	AUSTRALIA	AMERICAN INDIAN OR ALASKA NATIVE	MALE	75	Joint stiffness	関節硬直			MILD	YES	253	4	NO	RESOLVED
BAY 59-7939	400215002	YES	AUSTRALIA	WHITE	FEMALE	83	Rib fracture	肋骨骨折	20 mg	.	MODERATE	YES	85	2	NO	IMPROVED
Placebo	400215005	YES	AUSTRALIA	WHITE	MALE	74	Bronchitis	気管支炎			MILD	YES	66	1	NO	IMPROVED
BAY 59-7939	400235001	YES	AUSTRALIA	WHITE	FEMALE	42	Cholelithiasis	胆石症	20 mg	.	MODERATE	YES	265	38	NO	RESOLVED
BAY 59-7939	400235001	YES	AUSTRALIA	WHITE	FEMALE	42	Cholecystitis	胆嚢炎	20 mg	.	MODERATE	YES	265	38	NO	RESOLVED
Placebo	400243003	YES	AUSTRALIA	WHITE	MALE	63	Atrial fibrillation	心房細動			MODERATE	YES	98		NO	IMPROVED
Placebo	400243003	YES	AUSTRALIA	WHITE	MALE	63	Cardiomyopathy	心筋症			MODERATE	YES	98		NO	UNCHANGED
Placebo	440025001	YES	AUSTRIA	WHITE	MALE	59	Benign vascular neoplasm	血管の良性新生物			MILD	YES	92	21	YES	RESOLVED
Placebo	440043014	YES	AUSTRIA	WHITE	MALE	50	Herpes zoster	帯状疱疹			MILD	YES	3	8	NO	IMPROVED
Placebo	440063003	YES	AUSTRIA	WHITE	MALE	65	Sleep apnoea syndrome	睡眠時無呼吸症候群			MILD	YES	147	2	NO	RESOLVED

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BAY 59-7939	440075001	YES	AUSTRIA	WHITE	MALE	65	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	20 mg	.	MILD	YES	92	59	YES	RESOLVED
BAY 59-7939	440075001	YES	AUSTRIA	WHITE	MALE	65	Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	20 mg	.	MILD	YES	92	59	YES	RESOLVED
BAY 59-7939	440075001	YES	AUSTRIA	WHITE	MALE	65	Hepatic enzyme increased	肝酵素上昇	20 mg	.	MILD	YES	92	59	YES	RESOLVED
Placebo	460034003	YES	HUNGARY	WHITE	MALE	46	Pulmonary embolism	肺塞栓症			SEVERE	YES	134	1	YES	DEATH
BAY 59-7939	460044007	YES	HUNGARY	WHITE	FEMALE	25	Pregnancy	妊娠	20 mg	.	MILD	YES	190	43	NO	RESOLVED
BAY 59-7939	460044018	YES	HUNGARY	WHITE	FEMALE	55	Angina unstable	不安定狭心症	20 mg	I	MODERATE	YES	34	5	NO	RESOLVED
BAY 59-7939	460045004	YES	HUNGARY	WHITE	MALE	66	Atrial fibrillation	心房細動	20 mg	.	MODERATE	YES	325		NO	UNCHANGED
Placebo	460054007	YES	HUNGARY	WHITE	FEMALE	45	Anaemia	貧血			MODERATE	YES	176	7	NO	RESOLVED
BAY 59-7939	460095003	YES	HUNGARY	WHITE	MALE	68	Syncope	失神	20 mg	.	MILD	YES	249	2	NO	RESOLVED
Placebo	540024005	YES	CHINA	ASIAN	FEMALE	56	Rheumatoid arthritis	関節リウマチ			MODERATE	YES	81	22	NO	RESOLVED
BAY 59-7939	600045001	YES	INDIA	ASIAN	MALE	24	Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増	20 mg	.	MILD	YES	36	71	YES	RESOLVED

表 2.7.4.7-21 すべての重篤な有害事象の一覧（試験 11899、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {12.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
								加								
BAY 59-7939	600045001	YES	INDIA	ASIAN	MALE	24	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	20 mg	.	MILD	YES	36	71	YES	RESOLVED
Placebo	600094003	YES	INDIA	ASIAN	MALE	42	Peripheral arterial occlusive disease	末梢動脈閉塞性疾患			SEVERE	YES	48	9	YES	RESOLVED
BAY 59-7939	600095003	YES	INDIA	ASIAN	MALE	49	Urinary tract infection	尿路感染	20 mg	I	SEVERE	YES	35	7	NO	RESOLVED
BAY 59-7939	600095003	YES	INDIA	ASIAN	MALE	49	Syncope	失神	20 mg	.	MILD	YES	39	1	NO	RESOLVED
BAY 59-7939	600095005	YES	INDIA	ASIAN	FEMALE	39	Thrombophlebitis	血栓性静脈炎	20 mg	F	SEVERE	YES	156	12	NO	RESOLVED
BAY 59-7939	600104001	YES	INDIA	ASIAN	FEMALE	78	Hyperglycaemia	高血糖	20 mg	F	SEVERE	NO	185	28	NO	RESOLVED
BAY 59-7939	600104001	YES	INDIA	ASIAN	FEMALE	78	Hyponatraemia	低ナトリウム血症	20 mg	F	SEVERE	NO	185	28	NO	RESOLVED
BAY 59-7939	600104001	YES	INDIA	ASIAN	FEMALE	78	Renal failure acute	急性腎不全	20 mg	F	SEVERE	NO	185	28	NO	RESOLVED
BAY 59-7939	600104001	YES	INDIA	ASIAN	FEMALE	78	Hypertension	高血圧	20 mg	F	SEVERE	NO	185	28	NO	RESOLVED
BAY 59-7939	600104001	YES	INDIA	ASIAN	FEMALE	78	Metabolic encephalopathy	代謝性脳症	20 mg	F	SEVERE	NO	185	28	NO	RESOLVED
BAY 59-7939	670015001	YES	PHILIPPINES	ASIAN	FEMALE	82	Gastroenteritis	胃腸炎	20 mg	.	MODERATE	YES	13	2	NO	RESOLVED

表 2.7.4.7-21 すべての重篤な有害事象の一覧（試験 11899、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {12.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
BAY 59-7939	670015002	YES	PHILIPPINES	ASIAN	FEMALE	38	Abortion missed	稽留流産	20 mg	F	SEVERE	NO	92	3	NO	RESOLVED
BAY 59-7939	680015003	YES	SINGAPORE	ASIAN	MALE	51	Haematuria	血尿	20 mg	F	MODERATE	YES	45	3	YES	RESOLVED
BAY 59-7939	700015002	YES	NEW ZEALAND	WHITE	MALE	62	Angina unstable	不安定狭心症	20 mg	.	SEVERE	YES	110	5	NO	RESOLVED
Placebo	700025002	YES	NEW ZEALAND	WHITE	MALE	63	Non-cardiac chest pain	非心臓性胸痛			MODERATE	YES	76	15	NO	RESOLVED
Placebo	700025006	YES	NEW ZEALAND	ASIAN	MALE	51	Cellulitis	蜂巣炎			MODERATE	YES	58	11	NO	RESOLVED
BAY 59-7939	700025008	YES	NEW ZEALAND	WHITE	MALE	86	Circulatory collapse	循環虚脱	20 mg	.	SEVERE	YES	4	1	YES	RESOLVED
BAY 59-7939	700025008	YES	NEW ZEALAND	WHITE	MALE	86	Atrial fibrillation	心房細動	20 mg	.	SEVERE	YES	4	1	NO	RESOLVED
Placebo	700025009	YES	NEW ZEALAND	WHITE	MALE	45	Liver function test abnormal	肝機能検査異常			MILD	YES	93	7	YES	IMPROVED
Placebo	700035002	YES	NEW ZEALAND	WHITE	MALE	77	Musculoskeletal chest pain	筋骨格系胸痛			MILD	YES	181	2	NO	RESOLVED
Placebo	700035007	YES	NEW ZEALAND	WHITE	MALE	77	Inguinal hernia	鼠径ヘルニア			MODERATE	YES	7	42	NO	RESOLVED
BAY 59-7939	700035009	YES	NEW ZEALAND	WHITE	FEMALE	76	Atrial fibrillation	心房細動	20 mg	.	MILD	YES	34		NO	IMPROVED
BAY 59-7939	700055005	YES	NEW ZEALAND	WHITE	FEMALE	74	Respiratory tract infection	気道感染	20 mg	.	SEVERE	YES	33	12	NO	RESOLVED

表 2.7.4.7-21 すべての重篤な有害事象の一覧（試験 11899、割り付けられた被験者）（続き）

Treatment group	Subject ID	Safety population	Country	Race	Sex	Age	Adverse Events (AE) Preferred term (MedDRA version {12.0})		Dose on AE onset	Dose status on AE onset	Intensity	TE	Relative Day of AE	Duration of AE	Related to study drug	Outcome of AE
BAY 59-7939	700055005	YES	NEW ZEALAND	WHITE	FEMALE	74	Chest pain	胸痛	20 mg	.	MODERATE	YES	33	12	NO	RESOLVED
BAY 59-7939	700065002	YES	NEW ZEALAND	WHITE	MALE	48	Antiphospholipid syndrome	抗リン脂質抗体症候群	20 mg	.	MODERATE	YES	17		NO	UNCHANGED
BAY 59-7939	710024001	YES	THAILAND	ASIAN	MALE	79	Cardiac failure congestive	うっ血性心不全	20 mg	.	MODERATE	YES	129	14	NO	IMPROVED

Only All serious AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is (onset day of AE minus medication day) plus 1 day.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, I will be listed. If AE onset is after treatment phase, F will be listed.

表 2.7.4.7-22 重篤な TEAE（試験 11702_DVT、安全性解析対象集団）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
ANY EVENT		207 (12.0%)	233 (13.6%)
Blood and lymphatic system disorders	血液およびリンパ系障害	15 (0.9%)	9 (0.5%)
Anaemia	貧血	10 (0.6%)	7 (0.4%)
Autoimmune thrombocytopenia	自己免疫性血小板減少症	0	1 (<0.1%)
Febrile neutropenia	発熱性好中球減少症	1 (<0.1%)	0
Lymphadenopathy mediastinal	縦隔リンパ節腫脹	0	1 (<0.1%)
Microcytic anaemia	小球性貧血	1 (<0.1%)	0
Spontaneous haematoma	特発性血腫	1 (<0.1%)	0
Thrombocytopenia	血小板減少症	2 (0.1%)	0
Cardiac disorders	心臓障害	15 (0.9%)	17 (1.0%)
Acute coronary syndrome	急性冠動脈症候群	1 (<0.1%)	0
Acute myocardial infarction	急性心筋梗塞	4 (0.2%)	1 (<0.1%)
Angina unstable	不安定狭心症	1 (<0.1%)	3 (0.2%)
Aortic valve disease	大動脈弁疾患	0	1 (<0.1%)
Arrhythmia	不整脈	1 (<0.1%)	0
Atrial fibrillation	心房細動	1 (<0.1%)	3 (0.2%)
Atrial flutter	心房粗動	1 (<0.1%)	0
Atrioventricular block second degree	第二度房室ブロック	1 (<0.1%)	0
Cardiac arrest	心停止	0	1 (<0.1%)
Cardiac disorder	心障害	1 (<0.1%)	0
Cardiac failure	心不全	1 (<0.1%)	1 (<0.1%)
Cardiac failure chronic	慢性心不全	0	1 (<0.1%)
Cardiac failure congestive	うっ血性心不全	0	2 (0.1%)
Myocardial infarction	心筋梗塞	0	1 (<0.1%)
Myocardial ischaemia	心筋虚血	0	1 (<0.1%)
Pericarditis	心膜炎	1 (<0.1%)	0
Right ventricular failure	右室不全	1 (<0.1%)	0
Sick sinus syndrome	洞不全症候群	0	1 (<0.1%)
Sinus arrhythmia	洞性不整脈	0	1 (<0.1%)
Tachyarrhythmia	頻脈性不整脈	1 (<0.1%)	0
Tachycardia	頻脈	1 (<0.1%)	0
Ventricular tachycardia	心室性頻脈	0	1 (<0.1%)
Congenital, familial and genetic disorders	先天性、家族性および遺伝性障害	0	1 (<0.1%)

表 2.7.4.7-22 重篤な TEAE（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Phimosis	包茎	0	1 (<0.1%)
Ear and labyrinth disorders	耳および迷路障害	2 (0.1%)	2 (0.1%)
Ear haemorrhage	耳出血	0	1 (<0.1%)
Vertigo	回転性めまい	2 (0.1%)	1 (<0.1%)
Endocrine disorders	内分泌障害	2 (0.1%)	0
Basedow's disease	バセドウ病	1 (<0.1%)	0
Goitre	甲状腺腫	1 (<0.1%)	0
Eye disorders	眼障害	3 (0.2%)	4 (0.2%)
Blepharochalasis	眼瞼皮膚弛緩症	0	1 (<0.1%)
Conjunctival haemorrhage	結膜出血	0	2 (0.1%)
Eye haemorrhage	眼出血	1 (<0.1%)	0
Hyphaema	前房出血	1 (<0.1%)	0
Retinal detachment	網膜剥離	1 (<0.1%)	0
Vitreous detachment	硝子体剥離	1 (<0.1%)	0
Vitreous haemorrhage	硝子体出血	0	1 (<0.1%)
Gastrointestinal disorders	胃腸障害	27 (1.6%)	31 (1.8%)
Abdominal discomfort	腹部不快感	0	1 (<0.1%)
Abdominal pain	腹痛	3 (0.2%)	0
Abdominal pain upper	上腹部痛	1 (<0.1%)	0
Abdominal wall cyst	腹壁嚢胞	1 (<0.1%)	0
Ascites	腹水	1 (<0.1%)	0
Colitis ulcerative	潰瘍性大腸炎	1 (<0.1%)	1 (<0.1%)
Colonic polyp	結腸ポリープ	0	2 (0.1%)
Constipation	便秘	1 (<0.1%)	0
Crohn's disease	クローン病	0	4 (0.2%)
Diarrhoea	下痢	1 (<0.1%)	0
Duodenal ulcer	十二指腸潰瘍	0	1 (<0.1%)
Enterocutaneous fistula	腸管皮膚瘻	2 (0.1%)	0
Food poisoning	食中毒	0	1 (<0.1%)
Gastric ulcer perforation	穿孔性胃潰瘍	0	1 (<0.1%)
Gastritis	胃炎	1 (<0.1%)	1 (<0.1%)
Gastrointestinal haemorrhage	胃腸出血	4 (0.2%)	0
Gingival bleeding	歯肉出血	0	1 (<0.1%)

表 2.7.4.7-22 重篤な TEAE（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Haematemesis	吐血	1 (<0.1%)	3 (0.2%)
Haematochezia	血便排泄	0	2 (0.1%)
Haemorrhoidal haemorrhage	痔出血	0	1 (<0.1%)
Haemorrhoids	痔核	0	1 (<0.1%)
Inguinal hernia, obstructive	閉塞性鼠径ヘルニア	0	1 (<0.1%)
Intestinal dilatation	腸管拡張症	1 (<0.1%)	0
Intestinal haemorrhage	腸出血	0	1 (<0.1%)
Intestinal obstruction	腸閉塞	1 (<0.1%)	1 (<0.1%)
Intestinal perforation	腸管穿孔	1 (<0.1%)	0
Large intestine perforation	大腸穿孔	0	1 (<0.1%)
Melaena	メレナ	1 (<0.1%)	1 (<0.1%)
Nausea	悪心	1 (<0.1%)	0
Oesophageal ulcer haemorrhage	食道潰瘍出血	0	1 (<0.1%)
Oesophagitis	食道炎	0	1 (<0.1%)
Pancreatitis	膵炎	1 (<0.1%)	1 (<0.1%)
Pancreatitis acute	急性膵炎	0	1 (<0.1%)
Rectal haemorrhage	直腸出血	4 (0.2%)	4 (0.2%)
Rectal polyp	直腸ポリープ	1 (<0.1%)	0
Reflux oesophagitis	逆流性食道炎	0	1 (<0.1%)
Retroperitoneal fibrosis	後腹膜線維症	0	1 (<0.1%)
Small intestinal obstruction	小腸閉塞	0	1 (<0.1%)
Vomiting	嘔吐	1 (<0.1%)	0
General disorders and administration site conditions	全身障害および投与局所様態	15 (0.9%)	10 (0.6%)
Chest pain	胸痛	3 (0.2%)	1 (<0.1%)
Death	死亡	0	1 (<0.1%)
Device occlusion	医療機器閉塞	1 (<0.1%)	0
Generalised oedema	全身性浮腫	1 (<0.1%)	0
Impaired healing	治癒不良	0	1 (<0.1%)
Malaise	倦怠感	1 (<0.1%)	1 (<0.1%)
Medical device complication	医療機器合併症	0	1 (<0.1%)
Multi-organ failure	多臓器不全	3 (0.2%)	1 (<0.1%)
Oedema peripheral	末梢性浮腫	3 (0.2%)	0
Pelvic mass	骨盤腔内腫瘤	0	1 (<0.1%)

表 2.7.4.7-22 重篤な TEAE（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Pyrexia	発熱	3 (0.2%)	2 (0.1%)
Sudden cardiac death	心突然死	1 (<0.1%)	0
Sudden death	突然死	0	1 (<0.1%)
Hepatobiliary disorders	肝胆道系障害	4 (0.2%)	5 (0.3%)
Biliary colic	胆道仙痛	0	1 (<0.1%)
Cholangitis	胆管炎	1 (<0.1%)	0
Cholecystitis	胆嚢炎	0	1 (<0.1%)
Cholecystitis acute	急性胆嚢炎	0	1 (<0.1%)
Cholelithiasis	胆石症	1 (<0.1%)	0
Hepatic mass	肝腫瘤	1 (<0.1%)	0
Hepatic steatosis	脂肪肝	0	1 (<0.1%)
Hepatitis acute	急性肝炎	1 (<0.1%)	0
Jaundice cholestatic	胆汁うっ滞性黄疸	0	1 (<0.1%)
Immune system disorders	免疫系障害	0	1 (<0.1%)
Liver transplant rejection	肝移植拒絶反応	0	1 (<0.1%)
Infections and infestations	感染症および寄生虫症	28 (1.6%)	48 (2.8%)
Abdominal abscess	腹部膿瘍	0	1 (<0.1%)
Abscess	膿瘍	1 (<0.1%)	0
Abscess limb	四肢膿瘍	0	1 (<0.1%)
Anal abscess	肛門膿瘍	0	1 (<0.1%)
Appendicitis	虫垂炎	0	1 (<0.1%)
Bacteraemia	菌血症	1 (<0.1%)	0
Bacterial sepsis	細菌性敗血症	0	1 (<0.1%)
Bronchitis	気管支炎	1 (<0.1%)	0
Bronchopneumonia	気管支肺炎	3 (0.2%)	1 (<0.1%)
Cardiac valve vegetation	心臓弁疣贅	0	1 (<0.1%)
Cellulitis	蜂巣炎	3 (0.2%)	4 (0.2%)
Cerebral toxoplasmosis	脳トキソプラズマ症	0	1 (<0.1%)
Dengue fever	デング熱	0	1 (<0.1%)
Device related infection	医療機器関連感染	0	1 (<0.1%)
Endocarditis staphylococcal	ブドウ球菌性心内膜炎	0	1 (<0.1%)
Epiglottitis	喉頭蓋炎	0	1 (<0.1%)
Erysipelas	丹毒	0	2 (0.1%)

表 2.7.4.7-22 重篤な TEAE（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Gastroenteritis	胃腸炎	0	4 (0.2%)
Incision site abscess	切開部位膿瘍	1 (<0.1%)	0
Incision site infection	切開部位感染	0	1 (<0.1%)
Infective aneurysm	感染性動脈瘤	1 (<0.1%)	0
Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪	0	1 (<0.1%)
Influenza	インフルエンザ	0	1 (<0.1%)
Lobar pneumonia	大葉性肺炎	1 (<0.1%)	1 (<0.1%)
Lower respiratory tract infection	下気道感染	0	1 (<0.1%)
Mastitis	乳腺炎	0	1 (<0.1%)
Paronychia	爪囲炎	0	1 (<0.1%)
Pneumonia	肺炎	4 (0.2%)	10 (0.6%)
Pneumonia bacterial	細菌性肺炎	0	2 (0.1%)
Post procedural sepsis	処置後敗血症	0	1 (<0.1%)
Postoperative wound infection	術後創感染	1 (<0.1%)	1 (<0.1%)
Pulmonary sepsis	肺敗血症	0	1 (<0.1%)
Pulmonary tuberculosis	肺結核	0	1 (<0.1%)
Pyelonephritis	腎盂腎炎	1 (<0.1%)	0
Respiratory tract infection	気道感染	1 (<0.1%)	2 (0.1%)
Sepsis	敗血症	2 (0.1%)	4 (0.2%)
Septic shock	敗血症性ショック	1 (<0.1%)	1 (<0.1%)
Tracheobronchitis	気管気管支炎	1 (<0.1%)	0
Urinary tract infection	尿路感染	5 (0.3%)	3 (0.2%)
Viral infection	ウイルス感染	1 (<0.1%)	0
Wound abscess	創部膿瘍	1 (<0.1%)	0
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	13 (0.8%)	17 (1.0%)
Accident	事故	0	1 (<0.1%)
Alcohol poisoning	アルコール中毒	0	1 (<0.1%)
Ankle fracture	足関節部骨折	0	1 (<0.1%)
Cartilage injury	軟骨損傷	0	1 (<0.1%)
Contusion	挫傷	2 (0.1%)	1 (<0.1%)
Drug toxicity	薬物毒性	1 (<0.1%)	0
Femoral neck fracture	大腿骨頚部骨折	0	2 (0.1%)

表 2.7.4.7-22 重篤な TEAE（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Femur fracture	大腿骨骨折	0	1 (<0.1%)
Humerus fracture	上腕骨骨折	1 (<0.1%)	0
Induced abortion haemorrhage	人工流産による出血	1 (<0.1%)	0
Joint dislocation	関節脱臼	0	1 (<0.1%)
Ligament injury	靭帯損傷	0	1 (<0.1%)
Overdose	過量投与	1 (<0.1%)	1 (<0.1%)
Post procedural haematuria	処置後血尿	1 (<0.1%)	0
Post procedural haemorrhage	処置後出血	1 (<0.1%)	1 (<0.1%)
Radius fracture	橈骨骨折	0	1 (<0.1%)
Rib fracture	肋骨骨折	1 (<0.1%)	0
Skin laceration	皮膚裂傷	1 (<0.1%)	1 (<0.1%)
Spinal compression fracture	脊椎圧迫骨折	1 (<0.1%)	1 (<0.1%)
Therapeutic agent toxicity	治療薬毒性	0	2 (0.1%)
Thoracic vertebral fracture	胸椎骨折	0	1 (<0.1%)
Traumatic haemorrhage	外傷性出血	1 (<0.1%)	0
Ulna fracture	尺骨骨折	0	1 (<0.1%)
Vascular pseudoaneurysm	血管偽動脈瘤	1 (<0.1%)	0
Wound dehiscence	創し開	1 (<0.1%)	0
Investigations	臨床検査	8 (0.5%)	20 (1.2%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2 (0.1%)	6 (0.4%)
Blood bilirubin increased	血中ビリルビン増加	1 (<0.1%)	0
Chest X-ray abnormal	胸部Ｘ線異常	0	1 (<0.1%)
Hepatic enzyme increased	肝酵素上昇	1 (<0.1%)	5 (0.3%)
International normalised ratio fluctuation	ＩＮＲ変動	0	1 (<0.1%)
International normalised ratio increased	ＩＮＲ増加	0	4 (0.2%)
Liver function test abnormal	肝機能検査異常	2 (0.1%)	4 (0.2%)
Transaminases increased	トランスアミナーゼ上昇	2 (0.1%)	0
Weight decreased	体重減少	1 (<0.1%)	0
Metabolism and nutrition disorders	代謝および栄養障害	3 (0.2%)	4 (0.2%)
Dehydration	脱水	0	1 (<0.1%)
Diabetic foot	糖尿病性足病変	0	1 (<0.1%)
Diabetic ketoacidosis	糖尿病性ケトアシドーシス	1 (<0.1%)	0
Hypoglycaemia	低血糖症	0	1 (<0.1%)

表 2.7.4.7-22 重篤な TEAE（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Hypoproteinaemia	低蛋白血症	1 (<0.1%)	0
Metabolic disorder	代謝障害	0	1 (<0.1%)
Tetany	テタニー	1 (<0.1%)	0
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	11 (0.6%)	15 (0.9%)
Arthralgia	関節痛	1 (<0.1%)	0
Arthritis	関節炎	0	2 (0.1%)
Back pain	背部痛	2 (0.1%)	2 (0.1%)
Bursitis	滑液包炎	1 (<0.1%)	0
Foot deformity	足変形	0	1 (<0.1%)
Haemarthrosis	出血性関節症	0	1 (<0.1%)
Intervertebral disc protrusion	椎間板突出	0	1 (<0.1%)
Joint range of motion decreased	関節可動域減少	1 (<0.1%)	0
Juvenile arthritis	若年性関節炎	0	1 (<0.1%)
Muscle haemorrhage	筋肉内出血	0	3 (0.2%)
Musculoskeletal chest pain	筋骨格系胸痛	0	1 (<0.1%)
Musculoskeletal pain	筋骨格痛	1 (<0.1%)	0
Myalgia	筋肉痛	1 (<0.1%)	0
Osteoarthritis	変形性関節症	1 (<0.1%)	0
Osteoporosis	骨粗鬆症	1 (<0.1%)	0
Pain in extremity	四肢痛	0	1 (<0.1%)
Pathological fracture	病的骨折	1 (<0.1%)	0
Rotator cuff syndrome	肩回旋筋腱板症候群	0	1 (<0.1%)
Synovitis	滑膜炎	0	1 (<0.1%)
Systemic lupus erythematosus	全身性エリテマトーデス	1 (<0.1%)	0
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）	47 (2.7%)	42 (2.5%)
Acute leukaemia	急性白血病	0	1 (<0.1%)
Basal cell carcinoma	基底細胞癌	0	1 (<0.1%)
Bladder cancer	膀胱癌	2 (0.1%)	0
Bladder transitional cell carcinoma stage I	膀胱移行上皮癌第１期	0	1 (<0.1%)
Breast cancer	乳癌	3 (0.2%)	1 (<0.1%)
Breast cancer metastatic	転移性乳癌	1 (<0.1%)	0
Cervix cancer metastatic	転移性子宮頚部癌	1 (<0.1%)	0

表 2.7.4.7-22　重篤な TEAE（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Cervix carcinoma	子宮頚部癌	2 (0.1%)	5 (0.3%)
Cervix carcinoma stage III	子宮頚部癌第３期	1 (<0.1%)	0
Colon cancer	結腸癌	2 (0.1%)	4 (0.2%)
Colorectal cancer	結腸直腸癌	2 (0.1%)	0
Ear neoplasm malignant	耳の悪性新生物	0	1 (<0.1%)
Endometrial cancer	子宮内膜癌	1 (<0.1%)	1 (<0.1%)
Gastric cancer	胃癌	1 (<0.1%)	1 (<0.1%)
Gastric cancer recurrent	再発胃癌	1 (<0.1%)	0
Hepatic cancer metastatic	転移性肝癌	1 (<0.1%)	0
Hepatic neoplasm malignant	肝の悪性新生物	2 (0.1%)	2 (0.1%)
Large cell carcinoma of the respiratory tract stage unspecified	呼吸器大細胞癌、病期不明	0	1 (<0.1%)
Large intestine carcinoma	大腸癌	1 (<0.1%)	0
Lung adenocarcinoma	肺腺癌	0	3 (0.2%)
Lung cancer metastatic	転移性肺癌	1 (<0.1%)	0
Lung carcinoma cell type unspecified recurrent	再発肺癌、細胞タイプ不明	1 (<0.1%)	0
Lung neoplasm	肺新生物	1 (<0.1%)	1 (<0.1%)
Lung neoplasm malignant	肺の悪性新生物	2 (0.1%)	2 (0.1%)
Lymphoma	リンパ腫	3 (0.2%)	0
Lymphoma cutis	皮膚型リンパ腫	1 (<0.1%)	0
Malignant melanoma	悪性黒色腫	1 (<0.1%)	0
Meningioma	髄膜腫	0	1 (<0.1%)
Metastases to central nervous system	中枢神経系転移	1 (<0.1%)	0
Metastases to liver	肝転移	2 (0.1%)	3 (0.2%)
Metastases to lung	肺転移	1 (<0.1%)	1 (<0.1%)
Metastases to lymph nodes	リンパ節転移	2 (0.1%)	1 (<0.1%)
Metastatic neoplasm	転移性新生物	2 (0.1%)	0
Metastatic squamous cell carcinoma	転移性扁平上皮癌	0	1 (<0.1%)
Non-Hodgkin's lymphoma	非ホジキンリンパ腫	2 (0.1%)	0
Oesophageal adenocarcinoma	食道腺癌	1 (<0.1%)	0
Oesophageal carcinoma	食道癌	0	1 (<0.1%)
Ovarian cancer	卵巣癌	1 (<0.1%)	2 (0.1%)
Ovarian cancer metastatic	転移性卵巣癌	0	1 (<0.1%)

表 2.7.4.7-22 重篤な TEAE（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Ovarian cancer recurrent	再発卵巣癌	0	1 (<0.1%)
Ovarian epithelial cancer	卵巣上皮癌	0	1 (<0.1%)
Pancreatic carcinoma	膵癌	2 (0.1%)	0
Pelvic neoplasm	骨盤新生物	1 (<0.1%)	0
Penis carcinoma	陰茎癌	0	1 (<0.1%)
Prostate cancer	前立腺癌	1 (<0.1%)	1 (<0.1%)
Prostate cancer metastatic	転移性前立腺癌	0	1 (<0.1%)
Rectal cancer	直腸癌	1 (<0.1%)	2 (0.1%)
Rectal cancer recurrent	再発直腸癌	1 (<0.1%)	0
Renal cell carcinoma	腎細胞癌	1 (<0.1%)	0
Renal cell carcinoma recurrent	再発腎細胞癌	0	1 (<0.1%)
Renal neoplasm	腎新生物	0	1 (<0.1%)
Retroperitoneal neoplasm	後腹膜新生物	0	1 (<0.1%)
Rhabdomyosarcoma	横紋筋肉腫	1 (<0.1%)	0
Small cell lung cancer metastatic	転移性小細胞肺癌	1 (<0.1%)	0
Waldenstrom's macroglobulinaemia	ワルデンストローム・マクログロブリン血症	1 (<0.1%)	0
Nervous system disorders	神経系障害	18 (1.0%)	17 (1.0%)
Cerebral arteriosclerosis	脳動脈硬化症	1 (<0.1%)	0
Cerebral haemorrhage	脳出血	1 (<0.1%)	1 (<0.1%)
Cognitive disorder	認知障害	1 (<0.1%)	0
Complex regional pain syndrome	複合性局所疼痛症候群	0	1 (<0.1%)
Dizziness	浮動性めまい	0	1 (<0.1%)
Epilepsy	てんかん	1 (<0.1%)	0
Haemorrhage intracranial	頭蓋内出血	1 (<0.1%)	1 (<0.1%)
Headache	頭痛	1 (<0.1%)	1 (<0.1%)
Hypoglycaemic coma	低血糖昏睡	1 (<0.1%)	0
IIIrd nerve paresis	第３脳神経不全麻痺	0	1 (<0.1%)
Ischaemic stroke	虚血性脳卒中	3 (0.2%)	5 (0.3%)
Metabolic encephalopathy	代謝性脳症	1 (<0.1%)	0
Migraine	片頭痛	1 (<0.1%)	0
Mononeuritis	単神経炎	1 (<0.1%)	0
Multiple sclerosis	多発性硬化症	1 (<0.1%)	0
Neuralgia	神経痛	0	1 (<0.1%)

表 2.7.4.7-22 重篤な TEAE（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Parkinson's disease	パーキンソン病	1 (<0.1%)	0
Presyncope	失神寸前の状態	1 (<0.1%)	0
Syncope	失神	1 (<0.1%)	2 (0.1%)
Transient ischaemic attack	一過性脳虚血発作	1 (<0.1%)	4 (0.2%)
Psychiatric disorders	精神障害	5 (0.3%)	7 (0.4%)
Acute psychosis	急性精神病	0	1 (<0.1%)
Alcohol abuse	アルコール乱用	0	1 (<0.1%)
Completed suicide	自殺既遂	0	1 (<0.1%)
Confusional state	錯乱状態	0	1 (<0.1%)
Depression	うつ病	3 (0.2%)	2 (0.1%)
Major depression	大うつ病	1 (<0.1%)	0
Panic attack	パニック発作	1 (<0.1%)	1 (<0.1%)
Psychotic disorder	精神病性障害	1 (<0.1%)	0
Suicide attempt	自殺企図	1 (<0.1%)	0
Renal and urinary disorders	腎および尿路障害	9 (0.5%)	10 (0.6%)
Anuria	無尿	1 (<0.1%)	0
Calculus ureteric	尿管結石	1 (<0.1%)	0
Cystitis haemorrhagic	出血性膀胱炎	1 (<0.1%)	0
Haematuria	血尿	3 (0.2%)	6 (0.4%)
Hydronephrosis	水腎症	0	1 (<0.1%)
Nephrolithiasis	腎結石症	0	1 (<0.1%)
Nephrotic syndrome	ネフローゼ症候群	1 (<0.1%)	0
Renal colic	腎仙痛	0	1 (<0.1%)
Renal failure	腎不全	1 (<0.1%)	0
Renal failure acute	急性腎不全	1 (<0.1%)	2 (0.1%)
Reproductive system and breast disorders	生殖系および乳房障害	13 (0.8%)	3 (0.2%)
Haemorrhagic ovarian cyst	出血性卵巣嚢胞	1 (<0.1%)	0
Menorrhagia	月経過多	5 (0.3%)	1 (<0.1%)
Ovarian cyst	卵巣嚢胞	1 (<0.1%)	0
Penile swelling	陰茎腫脹	0	1 (<0.1%)
Postmenopausal haemorrhage	閉経後出血	1 (<0.1%)	0
Prostatitis	前立腺炎	1 (<0.1%)	0
Scrotal swelling	陰嚢腫脹	0	1 (<0.1%)

表 2.7.4.7-22 重篤な TEAE（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Uterine polyp	子宮ポリープ	1 (<0.1%)	0
Vaginal haemorrhage	膣出血	3 (0.2%)	1 (<0.1%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	16 (0.9%)	17 (1.0%)
Asthma	喘息	1 (<0.1%)	3 (0.2%)
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	2 (0.1%)	2 (0.1%)
Cough	咳嗽	2 (0.1%)	0
Dyspnoea	呼吸困難	2 (0.1%)	4 (0.2%)
Dyspnoea at rest	安静時呼吸困難	1 (<0.1%)	0
Epistaxis	鼻出血	1 (<0.1%)	1 (<0.1%)
Haemoptysis	喀血	1 (<0.1%)	2 (0.1%)
Haemothorax	血胸	0	1 (<0.1%)
Interstitial lung disease	間質性肺疾患	0	1 (<0.1%)
Lung disorder	肺障害	1 (<0.1%)	0
Pleural effusion	胸水	1 (<0.1%)	1 (<0.1%)
Pulmonary embolism	肺塞栓症	1 (<0.1%)	1 (<0.1%)
Pulmonary fibrosis	肺線維症	1 (<0.1%)	0
Pulmonary mass	肺腫瘤	1 (<0.1%)	0
Pulmonary oedema	肺水腫	0	1 (<0.1%)
Respiratory distress	呼吸窮迫	0	1 (<0.1%)
Respiratory failure	呼吸不全	1 (<0.1%)	0
Sputum retention	痰貯留	1 (<0.1%)	0
Tachypnoea	頻呼吸	0	1 (<0.1%)
Wegener's granulomatosis	ウェゲナー肉芽腫症	1 (<0.1%)	0
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	0	5 (0.3%)
Dermatitis exfoliative	剥脱性皮膚炎	0	1 (<0.1%)
Drug eruption	薬疹	0	1 (<0.1%)
Henoch-Schonlein purpura	ヘノッホ・シェーンライン紫斑病	0	1 (<0.1%)
Leukocytoclastic vasculitis	白血球破砕性血管炎	0	1 (<0.1%)
Scar	瘢痕	0	1 (<0.1%)
Skin ulcer	皮膚潰瘍	0	1 (<0.1%)
Surgical and medical procedures	外科および内科処置	2 (0.1%)	2 (0.1%)
Abortion induced	人工流産	0	1 (<0.1%)
Bladder catheter removal	膀胱カテーテル除去	1 (<0.1%)	0

表 2.7.4.7-22 重篤な TEAE（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Ileostomy closure	回腸瘻閉鎖	1 (<0.1%)	0
Uterine polypectomy	子宮ポリープ切除	0	1 (<0.1%)
Vascular disorders	血管障害	10 (0.6%)	19 (1.1%)
Aortic aneurysm	大動脈瘤	0	1 (<0.1%)
Arterial haemorrhage	動脈出血	0	1 (<0.1%)
Arterial thrombosis limb	四肢動脈血栓症	1 (<0.1%)	1 (<0.1%)
Arteriosclerosis	動脈硬化症	0	2 (0.1%)
Circulatory collapse	循環虚脱	1 (<0.1%)	0
Extremity necrosis	四肢壊死	0	1 (<0.1%)
Femoral artery occlusion	大腿動脈閉塞	1 (<0.1%)	0
Haematoma	血腫	1 (<0.1%)	4 (0.2%)
Hypertension	高血圧	2 (0.1%)	0
Hypertensive crisis	高血圧クリーゼ	0	1 (<0.1%)
Iliac artery stenosis	腸骨動脈狭窄	0	1 (<0.1%)
Jugular vein thrombosis	頚静脈血栓症	0	1 (<0.1%)
Lymphoedema	リンパ浮腫	1 (<0.1%)	0
May-Thurner syndrome	マイ・トゥルナー症候群	0	1 (<0.1%)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	2 (0.1%)	0
Peripheral artery aneurysm	末梢動脈瘤	1 (<0.1%)	0
Peripheral embolism	末梢血管塞栓症	0	1 (<0.1%)
Peripheral ischaemia	末梢性虚血	1 (<0.1%)	1 (<0.1%)
Peripheral vascular disorder	末梢血管障害	0	1 (<0.1%)
Post thrombotic syndrome	血栓後症候群	0	1 (<0.1%)
Shock haemorrhagic	出血性ショック	0	1 (<0.1%)
Thrombophlebitis superficial	表在性血栓性静脈炎	0	1 (<0.1%)
Thrombosis	血栓症	0	1 (<0.1%)

Note: SOC = System Organ Class
Note: Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more clinical AEs, the subject is counted only once in a category. The same subject may appear in different categories.
Note: Percentages calculated with the number of subjects in each group as denominator. Sorted first by SOC (alphab. order) then by preferred term (alphab. order).
Note: Treatment-emergent AE is defined as the AE occurred after randomization and up to the respective time window after the last dose of study drug.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_dvt/stat/prod/pgms/t-ae-incidence-1.sas gcwer 15SEP2010 15:42
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表 2.7.4.7-23 重篤な TEAE（試験 11702_PE、安全性解析対象集団）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
ANY EVENT		471 (19.5%)	463 (19.3%)
Blood and lymphatic system disorders	血液およびリンパ系障害	20 (0.8%)	13 (0.5%)
Anaemia	貧血	12 (0.5%)	5 (0.2%)
Anaemia folate deficiency	葉酸欠乏性貧血	1 (<0.1%)	0
Coagulopathy	凝血異常	0	2 (<0.1%)
Eosinophilia	好酸球増加症	0	1 (<0.1%)
Haemolytic anaemia	溶血性貧血	1 (<0.1%)	0
Haemorrhagic anaemia	出血性貧血	1 (<0.1%)	2 (<0.1%)
Hypercoagulation	凝固亢進	1 (<0.1%)	0
Idiopathic thrombocytopenic purpura	特発性血小板減少性紫斑病	0	1 (<0.1%)
Leukopenia	白血球減少症	0	1 (<0.1%)
Lymphadenopathy	リンパ節症	1 (<0.1%)	1 (<0.1%)
Neutropenia	好中球減少症	0	1 (<0.1%)
Pernicious anaemia	悪性貧血	1 (<0.1%)	0
Splenic haemorrhage	脾臓出血	0	1 (<0.1%)
Splenic infarction	脾臓梗塞	0	1 (<0.1%)
Thrombocytopenia	血小板減少症	2 (<0.1%)	0
Cardiac disorders	心臓障害	56 (2.3%)	58 (2.4%)
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	5 (0.2%)	9 (0.4%)
Angina pectoris	狭心症	2 (<0.1%)	4 (0.2%)
Angina unstable	不安定狭心症	6 (0.2%)	2 (<0.1%)
Arrhythmia	不整脈	1 (<0.1%)	1 (<0.1%)
Atrial fibrillation	心房細動	7 (0.3%)	9 (0.4%)
Atrial flutter	心房粗動	1 (<0.1%)	1 (<0.1%)
Atrioventricular block	房室ブロック	0	1 (<0.1%)
Cardiac failure	心不全	8 (0.3%)	6 (0.2%)
Cardiac failure acute	急性心不全	2 (<0.1%)	2 (<0.1%)
Cardiac failure congestive	うっ血性心不全	4 (0.2%)	4 (0.2%)
Cardio-respiratory arrest	心肺停止	1 (<0.1%)	0
Congestive cardiomyopathy	うっ血性心筋症	2 (<0.1%)	0
Cor pulmonale	肺性心	3 (0.1%)	1 (<0.1%)

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
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	1 (<0.1%)	8 (0.3%)
Coronary artery dissection	冠動脈解離	0	1 (<0.1%)
Coronary artery stenosis	冠動脈狭窄	0	1 (<0.1%)
Left ventricular failure	左室不全	1 (<0.1%)	0
Mitral valve incompetence	僧帽弁閉鎖不全症	1 (<0.1%)	0
Myocardial infarction	心筋梗塞	0	1 (<0.1%)
Myocardial ischaemia	心筋虚血	0	2 (<0.1%)
Myocarditis	心筋炎	0	1 (<0.1%)
Palpitations	動悸	2 (<0.1%)	2 (<0.1%)
Pericardial effusion	心嚢液貯留	1 (<0.1%)	0
Pericardial haemorrhage	心嚢内出血	0	2 (<0.1%)
Pericarditis	心膜炎	2 (<0.1%)	0
Right ventricular failure	右室不全	3 (0.1%)	0
Sick sinus syndrome	洞不全症候群	0	1 (<0.1%)
Sinus tachycardia	洞性頻脈	0	2 (<0.1%)
Supraventricular tachycardia	上室性頻脈	1 (<0.1%)	4 (0.2%)
Tachycardia	頻脈	1 (<0.1%)	2 (<0.1%)
Ventricular tachycardia	心室性頻脈	3 (0.1%)	1 (<0.1%)
Congenital, familial and genetic disorders	先天性、家族性および遺伝性障害	2 (<0.1%)	1 (<0.1%)
Atrial septal defect	心房中隔欠損症	1 (<0.1%)	0
Hydrocele	陰嚢水瘤	1 (<0.1%)	0
Phimosis	包茎	0	1 (<0.1%)
Ear and labyrinth disorders	耳および迷路障害	5 (0.2%)	6 (0.2%)
Deafness unilateral	片耳難聴	0	1 (<0.1%)
Sudden hearing loss	突発難聴	1 (<0.1%)	1 (<0.1%)
Vertigo	回転性めまい	3 (0.1%)	4 (0.2%)
Vertigo positional	頭位性回転性めまい	1 (<0.1%)	0
Endocrine disorders	内分泌障害	1 (<0.1%)	4 (0.2%)
Addison's disease	アジソン病	1 (<0.1%)	0
Adrenal haemorrhage	副腎出血	1 (<0.1%)	1 (<0.1%)
Diabetes insipidus	尿崩症	0	1 (<0.1%)

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Goitre	甲状腺腫	0	1 (<0.1%)
Hyperthyroidism	甲状腺機能亢進症	0	1 (<0.1%)
Eye disorders	眼障害	2 (<0.1%)	8 (0.3%)
Age-related macular degeneration	加齢黄斑変性	0	1 (<0.1%)
Amaurosis	黒内障	0	1 (<0.1%)
Cataract	白内障	0	1 (<0.1%)
Diplopia	複視	1 (<0.1%)	0
Eye haemorrhage	眼出血	0	3 (0.1%)
Eye pain	眼痛	0	1 (<0.1%)
Optic ischaemic neuropathy	虚血性視神経症	1 (<0.1%)	0
Retinal degeneration	網膜変性	0	1 (<0.1%)
Retinal haemorrhage	網膜出血	0	1 (<0.1%)
Vision blurred	霧視	0	1 (<0.1%)
Gastrointestinal disorders	胃腸障害	55 (2.3%)	56 (2.3%)
Abdominal hernia	腹部ヘルニア	1 (<0.1%)	0
Abdominal pain	腹痛	1 (<0.1%)	4 (0.2%)
Abdominal pain upper	上腹部痛	1 (<0.1%)	3 (0.1%)
Abdominal wall haematoma	腹壁血腫	0	2 (<0.1%)
Anorectal disorder	肛門直腸障害	0	1 (<0.1%)
Ascites	腹水	0	1 (<0.1%)
Colitis	大腸炎	1 (<0.1%)	1 (<0.1%)
Colitis ischaemic	虚血性大腸炎	1 (<0.1%)	0
Colonic polyp	結腸ポリープ	2 (<0.1%)	0
Colonic stenosis	結腸狭窄	1 (<0.1%)	0
Dental caries	齲歯	1 (<0.1%)	0
Diarrhoea	下痢	1 (<0.1%)	0
Diarrhoea haemorrhagic	血性下痢	1 (<0.1%)	0
Diverticulum	憩室	0	1 (<0.1%)
Diverticulum intestinal	腸憩室	1 (<0.1%)	0
Duodenal ulcer	十二指腸潰瘍	2 (<0.1%)	0
Dyspepsia	消化不良	2 (<0.1%)	0
Dysphagia	嚥下障害	1 (<0.1%)	0
Gastric haemorrhage	胃出血	0	1 (<0.1%)

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Gastric perforation	胃穿孔	1 (<0.1%)	0
Gastric ulcer	胃潰瘍	1 (<0.1%)	0
Gastric ulcer haemorrhage	出血性胃潰瘍	1 (<0.1%)	1 (<0.1%)
Gastritis	胃炎	1 (<0.1%)	2 (<0.1%)
Gastritis haemorrhagic	出血性胃炎	1 (<0.1%)	1 (<0.1%)
Gastrointestinal dysplasia	胃腸異形成	1 (<0.1%)	0
Gastrointestinal haemorrhage	胃腸出血	6 (0.2%)	4 (0.2%)
Gastrooesophageal reflux disease	胃食道逆流性疾患	1 (<0.1%)	1 (<0.1%)
Haematemesis	吐血	4 (0.2%)	2 (<0.1%)
Haematochezia	血便排泄	0	1 (<0.1%)
Haemorrhoidal haemorrhage	痔出血	1 (<0.1%)	2 (<0.1%)
Haemorrhoids	痔核	1 (<0.1%)	0
Hiatus hernia	裂孔ヘルニア	1 (<0.1%)	0
Ileus	イレウス	0	1 (<0.1%)
Inguinal hernia	鼠径ヘルニア	1 (<0.1%)	0
Intestinal haemorrhage	腸出血	1 (<0.1%)	3 (0.1%)
Intestinal infarction	腸梗塞	1 (<0.1%)	0
Intestinal obstruction	腸閉塞	0	1 (<0.1%)
Intestinal polyp	腸管ポリープ	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%)
Lower gastrointestinal haemorrhage	下部消化管出血	2 (<0.1%)	3 (0.1%)
Melaena	メレナ	2 (<0.1%)	5 (0.2%)
Nausea	悪心	2 (<0.1%)	0
Oesophageal ulcer	食道潰瘍	1 (<0.1%)	0
Oesophageal ulcer haemorrhage	食道潰瘍出血	0	1 (<0.1%)
Pancreatitis	膵炎	0	1 (<0.1%)
Pancreatitis acute	急性膵炎	0	1 (<0.1%)
Rectal haemorrhage	直腸出血	6 (0.2%)	6 (0.2%)
Retroperitoneal haematoma	後腹膜血腫	0	2 (<0.1%)
Small intestinal obstruction	小腸閉塞	1 (<0.1%)	1 (<0.1%)
Subileus	亜イレウス	1 (<0.1%)	1 (<0.1%)
Tooth loss	歯の脱落	1 (<0.1%)	0

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Umbilical hernia	臍ヘルニア	1 (<0.1%)	0
Upper gastrointestinal haemorrhage	上部消化管出血	2 (<0.1%)	2 (<0.1%)
Vomiting	嘔吐	3 (0.1%)	3 (0.1%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	45 (1.9%)	43 (1.8%)
Adverse drug reaction	医薬品副作用	0	1 (<0.1%)
Asthenia	無力症	1 (<0.1%)	0
Chest discomfort	胸部不快感	1 (<0.1%)	0
Chest pain	胸痛	20 (0.8%)	27 (1.1%)
Cyst	嚢胞	0	1 (<0.1%)
Death	死亡	4 (0.2%)	2 (<0.1%)
Device deposit issue	医療機器沈着物の問題	0	1 (<0.1%)
Drug intolerance	薬物不耐性	0	1 (<0.1%)
Fatigue	疲労	1 (<0.1%)	0
Gait disturbance	歩行障害	1 (<0.1%)	0
General physical health deterioration	全身健康状態低下	3 (0.1%)	1 (<0.1%)
Granuloma	肉芽腫	0	1 (<0.1%)
Implant site thrombosis	埋込み部位血栓	0	1 (<0.1%)
Malaise	倦怠感	1 (<0.1%)	0
Non-cardiac chest pain	非心臓性胸痛	5 (0.2%)	3 (0.1%)
Oedema peripheral	末梢性浮腫	1 (<0.1%)	2 (<0.1%)
Pyrexia	発熱	4 (0.2%)	2 (<0.1%)
Sudden death	突然死	3 (0.1%)	1 (<0.1%)
Hepatobiliary disorders	肝胆道系障害	15 (0.6%)	11 (0.5%)
Bile duct stone	胆管結石	1 (<0.1%)	1 (<0.1%)
Biliary colic	胆道仙痛	1 (<0.1%)	0
Cholangitis	胆管炎	1 (<0.1%)	0
Cholecystitis	胆嚢炎	2 (<0.1%)	1 (<0.1%)
Cholecystitis acute	急性胆嚢炎	0	1 (<0.1%)
Cholelithiasis	胆石症	4 (0.2%)	5 (0.2%)
Cytolytic hepatitis	肝細胞融解性肝炎	1 (<0.1%)	0
Hepatic failure	肝不全	1 (<0.1%)	1 (<0.1%)
Hepatic function abnormal	肝機能異常	0	1 (<0.1%)
Hepatic pain	肝臓痛	1 (<0.1%)	0

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Hepatitis	肝炎	0	1 (<0.1%)
Hepatitis acute	急性肝炎	1 (<0.1%)	0
Hepatitis chronic active	慢性活動性肝炎	1 (<0.1%)	0
Ischaemic hepatitis	虚血性肝炎	1 (<0.1%)	0
Jaundice	黄疸	1 (<0.1%)	0
Immune system disorders	免疫系障害	3 (0.1%)	2 (<0.1%)
Antiphospholipid syndrome	抗リン脂質抗体症候群	1 (<0.1%)	1 (<0.1%)
Drug hypersensitivity	薬物過敏症	0	1 (<0.1%)
Hypersensitivity	過敏症	1 (<0.1%)	0
Sarcoidosis	サルコイドーシス	1 (<0.1%)	0
Infections and infestations	感染症および寄生虫症	72 (3.0%)	69 (2.9%)
Abscess limb	四肢膿瘍	0	1 (<0.1%)
Abscess soft tissue	軟部組織膿瘍	1 (<0.1%)	0
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%)
Bacteraemia	菌血症	0	1 (<0.1%)
Biliary sepsis	胆道性敗血症	0	1 (<0.1%)
Bronchitis	気管支炎	5 (0.2%)	8 (0.3%)
Bronchopneumonia	気管支肺炎	3 (0.1%)	4 (0.2%)
Bronchopulmonary aspergillosis	気管支肺アスペルギルス症	1 (<0.1%)	0
Cellulitis	蜂巣炎	3 (0.1%)	5 (0.2%)
Cystitis	膀胱炎	0	1 (<0.1%)
Diverticulitis	憩室炎	1 (<0.1%)	0
Endocarditis	心内膜炎	1 (<0.1%)	0
Endocarditis bacterial	細菌性心内膜炎	1 (<0.1%)	0
Gastroenteritis	胃腸炎	3 (0.1%)	0
Gastroenteritis salmonella	サルモネラ菌性胃腸炎	1 (<0.1%)	0
Groin abscess	鼠径部膿瘍	0	1 (<0.1%)
Hepatitis A	A型肝炎	0	1 (<0.1%)
Herpes zoster	帯状疱疹	0	2 (<0.1%)
Infectious peritonitis	感染性腹膜炎	3 (0.1%)	0

表 2.7.4.7-23 重篤な TEAE（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}		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	1 (<0.1%)	2 (<0.1%)
Intervertebral discitis	椎間板炎	1 (<0.1%)	0
Joint abscess	関節膿瘍	1 (<0.1%)	0
Lobar pneumonia	大葉性肺炎	3 (0.1%)	0
Localised infection	限局性感染	0	1 (<0.1%)
Lower respiratory tract infection	下気道感染	2 (<0.1%)	4 (0.2%)
Lung infection	肺感染	3 (0.1%)	3 (0.1%)
Mastitis	乳腺炎	1 (<0.1%)	0
Osteomyelitis	骨髄炎	0	2 (<0.1%)
Pneumonia	肺炎	19 (0.8%)	19 (0.8%)
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%)
Postoperative wound infection	術後創感染	0	1 (<0.1%)
Prostate infection	前立腺感染	0	1 (<0.1%)
Pyelonephritis	腎盂腎炎	3 (0.1%)	2 (<0.1%)
Pyelonephritis acute	急性腎盂腎炎	0	1 (<0.1%)
Respiratory tract infection	気道感染	1 (<0.1%)	2 (<0.1%)
Sepsis	敗血症	8 (0.3%)	1 (<0.1%)
Sinusitis	副鼻腔炎	1 (<0.1%)	0
Skin bacterial infection	皮膚細菌感染	0	1 (<0.1%)
Skin infection	皮膚感染	0	1 (<0.1%)
Subdiaphragmatic abscess	横隔膜下膿瘍	1 (<0.1%)	0
Urinary tract infection	尿路感染	5 (0.2%)	3 (0.1%)
Urosepsis	尿路性敗血症	2 (<0.1%)	1 (<0.1%)
Viral rash	ウイルス性発疹	0	1 (<0.1%)
Wound infection	創傷感染	2 (<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	29 (1.2%)	35 (1.5%)
Alcohol poisoning	アルコール中毒	1 (<0.1%)	0
Anaemia postoperative	術後貧血	0	1 (<0.1%)
Ankle fracture	足関節部骨折	3 (0.1%)	0

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Brain contusion	脳挫傷	0	1 (<0.1%)
Cardiac valve replacement complication	心臓弁置換合併症	0	1 (<0.1%)
Cerebral haemorrhage traumatic	外傷性脳出血	1 (<0.1%)	0
Cervical vertebral fracture	頚椎骨折	0	1 (<0.1%)
Chest injury	胸部損傷	0	1 (<0.1%)
Concussion	脳振盪	1 (<0.1%)	0
Contusion	挫傷	1 (<0.1%)	0
Craniocerebral injury	頭蓋脳損傷	0	1 (<0.1%)
Facial bones fracture	顔面骨骨折	2 (<0.1%)	0
Fall	転倒	4 (0.2%)	1 (<0.1%)
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	0	1 (<0.1%)
Hip fracture	股関節部骨折	1 (<0.1%)	0
Humerus fracture	上腕骨骨折	0	2 (<0.1%)
Incision site haemorrhage	切開部位出血	0	1 (<0.1%)
Joint dislocation	関節脱臼	0	1 (<0.1%)
Joint injury	関節損傷	2 (<0.1%)	0
Kidney rupture	腎臓破裂	0	1 (<0.1%)
Limb injury	四肢損傷	1 (<0.1%)	0
Lumbar vertebral fracture	腰椎骨折	1 (<0.1%)	0
Multiple injuries	多発性外傷	0	1 (<0.1%)
Operative haemorrhage	術中出血	1 (<0.1%)	0
Overdose	過量投与	1 (<0.1%)	2 (<0.1%)
Perirenal haematoma	腎周囲血腫	0	1 (<0.1%)
Post procedural haemorrhage	処置後出血	2 (<0.1%)	2 (<0.1%)
Postoperative ileus	術後イレウス	1 (<0.1%)	0
Rib fracture	肋骨骨折	1 (<0.1%)	0
Road traffic accident	交通事故	0	1 (<0.1%)
Soft tissue injury	軟部組織損傷	0	2 (<0.1%)
Spinal compression fracture	脊椎圧迫骨折	1 (<0.1%)	0
Splenic haematoma	脾血腫	0	1 (<0.1%)

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Sternal fracture	胸骨骨折	0	1 (<0.1%)
Subcutaneous haematoma	皮下血腫	1 (<0.1%)	3 (0.1%)
Subdural haematoma	硬膜下血腫	1 (<0.1%)	3 (0.1%)
Subdural haemorrhage	硬膜下出血	0	2 (<0.1%)
Tendon rupture	腱断裂	1 (<0.1%)	0
Thoracic vertebral fracture	胸椎骨折	0	2 (<0.1%)
Tibia fracture	脛骨骨折	1 (<0.1%)	0
Toxicity to various agents	各種物質毒性	0	1 (<0.1%)
Traumatic haematoma	外傷性血腫	0	2 (<0.1%)
Upper limb fracture	上肢骨折	1 (<0.1%)	1 (<0.1%)
Vascular pseudoaneurysm	血管偽動脈瘤	0	1 (<0.1%)
Investigations	臨床検査	22 (0.9%)	31 (1.3%)
Activated partial thromboplastin time prolonged	活性化部分トロンボプラスチン時間延長	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	5 (0.2%)	9 (0.4%)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	0	1 (<0.1%)
Blood amylase increased	血中アミラーゼ増加	1 (<0.1%)	0
Blood potassium increased	血中カリウム増加	1 (<0.1%)	0
C-reactive protein increased	Ｃ－反応性蛋白増加	0	1 (<0.1%)
Coagulation time prolonged	凝固時間延長	0	1 (<0.1%)
Coagulation time shortened	凝固時間短縮	0	1 (<0.1%)
Ejection fraction decreased	駆出率減少	0	1 (<0.1%)
Haemoglobin decreased	ヘモグロビン減少	1 (<0.1%)	0
Hepatic enzyme increased	肝酵素上昇	3 (0.1%)	1 (<0.1%)
International normalised ratio abnormal	ＩＮＲ異常	0	1 (<0.1%)
International normalised ratio increased	ＩＮＲ増加	1 (<0.1%)	4 (0.2%)
Liver function test abnormal	肝機能検査異常	4 (0.2%)	9 (0.4%)
Medical observation	医学的観察	1 (<0.1%)	0
Prostatic specific antigen increased	前立腺特異性抗原増加	1 (<0.1%)	1 (<0.1%)
Transaminases increased	トランスアミナーゼ上昇	2 (<0.1%)	2 (<0.1%)
Ultrasound liver abnormal	肝超音波検査異常	1 (<0.1%)	0
Metabolism and nutrition disorders	代謝および栄養障害	11 (0.5%)	14 (0.6%)
Acidosis	アシドーシス	1 (<0.1%)	0
Decreased appetite	食欲減退	1 (<0.1%)	1 (<0.1%)

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Dehydration	脱水	1 (<0.1%)	2 (<0.1%)
Diabetes mellitus	糖尿病	1 (<0.1%)	0
Failure to thrive	成長障害	0	1 (<0.1%)
Gout	痛風	0	1 (<0.1%)
Hypercalcaemia	高カルシウム血症	0	1 (<0.1%)
Hyperglycaemia	高血糖	1 (<0.1%)	0
Hyperkalaemia	高カリウム血症	0	1 (<0.1%)
Hypoalbuminaemia	低アルブミン血症	0	1 (<0.1%)
Hypoglycaemia	低血糖症	2 (<0.1%)	0
Hypokalaemia	低カリウム血症	0	1 (<0.1%)
Hyponatraemia	低ナトリウム血症	1 (<0.1%)	2 (<0.1%)
Hypovolaemia	血液量減少症	0	1 (<0.1%)
Malnutrition	栄養障害	0	1 (<0.1%)
Metabolic disorder	代謝障害	0	1 (<0.1%)
Shock hypoglycaemic	低血糖ショック	1 (<0.1%)	0
Type 2 diabetes mellitus	２型糖尿病	2 (<0.1%)	0
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	34 (1.4%)	37 (1.5%)
Arthralgia	関節痛	2 (<0.1%)	2 (<0.1%)
Back pain	背部痛	5 (0.2%)	5 (0.2%)
Bone pain	骨痛	0	3 (0.1%)
Cervical spinal stenosis	頚部脊柱管狭窄症	1 (<0.1%)	0
Groin pain	鼠径部痛	1 (<0.1%)	0
Haemarthrosis	出血性関節症	0	1 (<0.1%)
Intervertebral disc compression	椎間板圧迫	0	1 (<0.1%)
Intervertebral disc degeneration	椎間板変性症	0	1 (<0.1%)
Intervertebral disc disorder	椎間板障害	1 (<0.1%)	0
Joint stiffness	関節硬直	0	1 (<0.1%)
Muscle haemorrhage	筋肉内出血	1 (<0.1%)	9 (0.4%)
Muscular weakness	筋力低下	4 (0.2%)	3 (0.1%)
Musculoskeletal chest pain	筋骨格系胸痛	2 (<0.1%)	1 (<0.1%)
Musculoskeletal pain	筋骨格痛	3 (0.1%)	1 (<0.1%)
Myalgia	筋肉痛	2 (<0.1%)	0
Osteoarthritis	変形性関節症	4 (0.2%)	5 (0.2%)

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Osteolysis	骨溶解	1 (<0.1%)	0
Osteonecrosis	骨壊死	1 (<0.1%)	1 (<0.1%)
Pain in extremity	四肢痛	3 (0.1%)	1 (<0.1%)
Pseudarthrosis	偽関節	0	1 (<0.1%)
Rheumatoid arthritis	関節リウマチ	1 (<0.1%)	0
Rotator cuff syndrome	肩回旋筋腱板症候群	2 (<0.1%)	0
Scoliosis	側弯症	0	1 (<0.1%)
Spinal column stenosis	脊柱管狭窄症	0	1 (<0.1%)
Spinal disorder	脊椎障害	1 (<0.1%)	0
Spinal osteoarthritis	変形性脊椎症	0	1 (<0.1%)
Systemic lupus erythematosus	全身性エリテマトーデス	0	1 (<0.1%)
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）	63 (2.6%)	62 (2.6%)
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 neoplasm	副腎新生物	0	1 (<0.1%)
B-cell lymphoma	Ｂ細胞性リンパ腫	1 (<0.1%)	0
Basal cell carcinoma	基底細胞癌	0	1 (<0.1%)
Benign oesophageal neoplasm	食道の良性新生物	1 (<0.1%)	0
Bile duct cancer non-resectable	切除不能な胆管癌	0	1 (<0.1%)
Bladder cancer	膀胱癌	0	2 (<0.1%)
Bladder neoplasm	膀胱新生物	0	2 (<0.1%)
Brain neoplasm	脳新生物	2 (<0.1%)	0
Breast cancer	乳癌	1 (<0.1%)	0
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%)
Colon cancer	結腸癌	5 (0.2%)	0
Colon cancer metastatic	転移性結腸癌	0	1 (<0.1%)
Colon neoplasm	結腸新生物	1 (<0.1%)	0
Colorectal cancer	結腸直腸癌	2 (<0.1%)	0

表 2.7.4.7-23　重篤な TEAE（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}		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
Gallbladder cancer	胆嚢癌	1 (<0.1%)	0
Gastric cancer	胃癌	3 (0.1%)	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%)
Histiocytosis haematophagic	貪食細胞性組織球症	1 (<0.1%)	0
Inflammatory pseudotumour	炎症性偽腫瘍	1 (<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	0	2 (<0.1%)
Lung neoplasm malignant	肺の悪性新生物	5 (0.2%)	3 (0.1%)
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	1 (<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%)
Meningioma	髄膜腫	1 (<0.1%)	0
Mesothelioma malignant	悪性中皮腫	0	1 (<0.1%)
Metastases to central nervous system	中枢神経系転移	0	1 (<0.1%)
Metastases to liver	肝転移	2 (<0.1%)	4 (0.2%)
Metastases to lung	肺転移	0	1 (<0.1%)
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	1 (<0.1%)
Metastatic gastric cancer	転移性胃癌	0	1 (<0.1%)
Metastatic neoplasm	転移性新生物	0	2 (<0.1%)
Multiple myeloma	多発性骨髄腫	1 (<0.1%)	1 (<0.1%)
Myelodysplastic syndrome	骨髄異形成症候群	0	1 (<0.1%)
Neoplasm malignant	悪性新生物	0	1 (<0.1%)

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Neoplasm prostate	前立腺新生物	1 (<0.1%)	0
Non-small cell lung cancer	非小細胞肺癌	1 (<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
Parathyroid tumour benign	良性副甲状腺腫瘍	0	1 (<0.1%)
Pelvic neoplasm	骨盤新生物	0	1 (<0.1%)
Polycythaemia vera	真性多血症	0	1 (<0.1%)
Prostate cancer	前立腺癌	3 (0.1%)	7 (0.3%)
Prostate cancer recurrent	再発前立腺癌	0	1 (<0.1%)
Prostatic adenoma	前立腺腺腫	2 (<0.1%)	2 (<0.1%)
Rectal cancer	直腸癌	2 (<0.1%)	0
Rectal cancer metastatic	転移性直腸癌	0	1 (<0.1%)
Rectal neoplasm	直腸新生物	1 (<0.1%)	0
Renal cancer	腎癌	1 (<0.1%)	0
Renal cell carcinoma	腎細胞癌	1 (<0.1%)	0
Renal neoplasm	腎新生物	1 (<0.1%)	1 (<0.1%)
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0	1 (<0.1%)
T-cell lymphoma	Ｔ細胞性リンパ腫	1 (<0.1%)	0
Thyroid cancer	甲状腺癌	0	2 (<0.1%)
Tumour haemorrhage	腫瘍出血	0	1 (<0.1%)
Uterine leiomyoma	子宮平滑筋腫	4 (0.2%)	2 (<0.1%)
Nervous system disorders	神経系障害	44 (1.8%)	35 (1.5%)
Altered state of consciousness	意識変容状態	1 (<0.1%)	0
Ataxia	運動失調	0	1 (<0.1%)
Balance disorder	平衡障害	1 (<0.1%)	0
Carotid artery stenosis	頚動脈狭窄	0	1 (<0.1%)
Cauda equina syndrome	馬尾症候群	1 (<0.1%)	0
Cerebellar haemorrhage	小脳出血	1 (<0.1%)	0
Cerebral haemorrhage	脳出血	0	4 (0.2%)
Cerebral infarction	脳梗塞	0	1 (<0.1%)
Cerebrovascular accident	脳血管発作	1 (<0.1%)	0

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Clumsiness	不器用	1 (<0.1%)	0
Complex regional pain syndrome	複合性局所疼痛症候群	0	1 (<0.1%)
Convulsion	痙攣	1 (<0.1%)	2 (<0.1%)
Dementia Alzheimer's type	アルツハイマー型認知症	0	1 (<0.1%)
Depressed level of consciousness	意識レベルの低下	1 (<0.1%)	0
Dizziness	浮動性めまい	3 (0.1%)	2 (<0.1%)
Encephalopathy	脳症	0	1 (<0.1%)
Epilepsy	てんかん	2 (<0.1%)	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	0	2 (<0.1%)
Haemorrhagic transformation stroke	卒中の出血性変化	1 (<0.1%)	0
Headache	頭痛	2 (<0.1%)	4 (0.2%)
Hepatic encephalopathy	肝性脳症	1 (<0.1%)	0
Ischaemic stroke	虚血性脳卒中	11 (0.5%)	4 (0.2%)
Lacunar infarction	ラクナ梗塞	0	1 (<0.1%)
Leukoencephalopathy	白質脳症	1 (<0.1%)	0
Loss of consciousness	意識消失	0	1 (<0.1%)
Migraine	片頭痛	0	1 (<0.1%)
Nervous system disorder	神経系障害	1 (<0.1%)	0
Neuropathy peripheral	末梢性ニューロパチー	2 (<0.1%)	0
Parkinson's disease	パーキンソン病	1 (<0.1%)	0
Parkinsonism	パーキンソニズム	1 (<0.1%)	0
Presyncope	失神寸前の状態	0	1 (<0.1%)
Radicular pain	神経根痛	1 (<0.1%)	0
Sciatica	坐骨神経痛	2 (<0.1%)	1 (<0.1%)
Spinal cord compression	脊髄圧迫	0	1 (<0.1%)
Subarachnoid haemorrhage	くも膜下出血	0	1 (<0.1%)
Syncope	失神	7 (0.3%)	3 (0.1%)
Tension headache	緊張性頭痛	0	1 (<0.1%)
Transient ischaemic attack	一過性脳虚血発作	3 (0.1%)	3 (0.1%)
VIIth nerve paralysis	第７脳神経麻痺	0	1 (<0.1%)
Pregnancy, puerperium and perinatal conditions	妊娠、産褥および周産期の状態	0	2 (<0.1%)
Post abortion haemorrhage	流産後の出血	0	1 (<0.1%)

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Pregnancy	妊娠	0	2 (<0.1%)
Psychiatric disorders	精神障害	15 (0.6%)	12 (0.5%)
Alcohol abuse	アルコール乱用	0	1 (<0.1%)
Alcoholism	アルコール症	0	1 (<0.1%)
Anxiety	不安	5 (0.2%)	3 (0.1%)
Bipolar I disorder	双極１型障害	1 (<0.1%)	1 (<0.1%)
Confusional state	錯乱状態	0	1 (<0.1%)
Delusion	妄想	1 (<0.1%)	0
Depression	うつ病	4 (0.2%)	2 (<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	0	1 (<0.1%)
Panic attack	パニック発作	1 (<0.1%)	0
Somatoform disorder	身体表現性障害	1 (<0.1%)	0
Suicide attempt	自殺企図	1 (<0.1%)	1 (<0.1%)
Renal and urinary disorders	腎および尿路障害	19 (0.8%)	25 (1.0%)
Acute prerenal failure	急性腎前性腎不全	1 (<0.1%)	0
Anuria	無尿	0	1 (<0.1%)
Bladder dilatation	膀胱拡大	0	1 (<0.1%)
Dysuria	排尿困難	1 (<0.1%)	0
Glomerulonephritis membranous	膜性糸球体腎炎	1 (<0.1%)	0
Haematuria	血尿	8 (0.3%)	11 (0.5%)
Nephritis	腎炎	1 (<0.1%)	0
Nephrolithiasis	腎結石症	0	3 (0.1%)
Nephropathy toxic	中毒性ネフロパシー	0	1 (<0.1%)
Nephrotic syndrome	ネフローゼ症候群	1 (<0.1%)	0
Renal colic	腎仙痛	0	3 (0.1%)
Renal cyst	腎嚢胞	0	1 (<0.1%)
Renal failure acute	急性腎不全	1 (<0.1%)	4 (0.2%)
Renal impairment	腎機能障害	1 (<0.1%)	1 (<0.1%)
Urethral stenosis	尿道狭窄	0	1 (<0.1%)
Urinary bladder polyp	膀胱ポリープ	1 (<0.1%)	0

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Urinary retention	尿閉	2 (<0.1%)	0
Urinary tract disorder	尿路障害	1 (<0.1%)	0
Reproductive system and breast disorders	生殖系および乳房障害	20 (0.8%)	10 (0.4%)
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	0	1 (<0.1%)
Dysfunctional uterine bleeding	機能障害性子宮出血	1 (<0.1%)	0
Genital haemorrhage	性器出血	1 (<0.1%)	0
Menorrhagia	月経過多	9 (0.4%)	2 (<0.1%)
Metrorrhagia	不正子宮出血	4 (0.2%)	1 (<0.1%)
Ovarian cyst	卵巣嚢胞	0	1 (<0.1%)
Priapism	持続勃起症	0	1 (<0.1%)
Prostatic mass	前立腺腫瘤	0	1 (<0.1%)
Prostatitis	前立腺炎	0	1 (<0.1%)
Uterine polyp	子宮ポリープ	0	1 (<0.1%)
Uterine prolapse	子宮脱	1 (<0.1%)	0
Vaginal haemorrhage	膣出血	3 (0.1%)	0
Vulval disorder	外陰部障害	1 (<0.1%)	0
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	74 (3.1%)	74 (3.1%)
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	1 (<0.1%)	1 (<0.1%)
Acute respiratory failure	急性呼吸不全	1 (<0.1%)	0
Asthma	喘息	4 (0.2%)	0
Bronchial obstruction	気管支閉塞	0	1 (<0.1%)
Bronchiectasis	気管支拡張症	0	1 (<0.1%)
Bronchospasm	気管支痙攣	0	1 (<0.1%)
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	8 (0.3%)	5 (0.2%)
Cough	咳嗽	1 (<0.1%)	0
Dyspnoea	呼吸困難	16 (0.7%)	13 (0.5%)
Emphysema	肺気腫	1 (<0.1%)	0
Epistaxis	鼻出血	3 (0.1%)	2 (<0.1%)
Haemoptysis	喀血	6 (0.2%)	7 (0.3%)
Haemothorax	血胸	1 (<0.1%)	2 (<0.1%)
Hyperventilation	過換気	0	1 (<0.1%)

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Interstitial lung disease	間質性肺疾患	1 (<0.1%)	0
Lung disorder	肺障害	2 (<0.1%)	2 (<0.1%)
Mediastinal haemorrhage	縦隔出血	0	1 (<0.1%)
Pharyngeal cyst	咽頭嚢腫	0	1 (<0.1%)
Pleural effusion	胸水	8 (0.3%)	11 (0.5%)
Pleurisy	胸膜炎	0	4 (0.2%)
Pleuritic pain	胸膜痛	4 (0.2%)	8 (0.3%)
Pneumothorax	気胸	1 (<0.1%)	3 (0.1%)
Pulmonary congestion	肺うっ血	1 (<0.1%)	1 (<0.1%)
Pulmonary embolism	肺塞栓症	4 (0.2%)	1 (<0.1%)
Pulmonary fibrosis	肺線維症	0	1 (<0.1%)
Pulmonary haemorrhage	肺出血	2 (<0.1%)	0
Pulmonary hypertension	肺高血圧症	3 (0.1%)	1 (<0.1%)
Pulmonary infarction	肺梗塞	3 (0.1%)	2 (<0.1%)
Pulmonary oedema	肺水腫	1 (<0.1%)	1 (<0.1%)
Pulmonary venous thrombosis	肺静脈血栓症	1 (<0.1%)	0
Respiratory arrest	呼吸停止	1 (<0.1%)	1 (<0.1%)
Respiratory failure	呼吸不全	3 (0.1%)	3 (0.1%)
Sleep apnoea syndrome	睡眠時無呼吸症候群	0	1 (<0.1%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	9 (0.4%)	6 (0.2%)
Angioedema	血管浮腫	1 (<0.1%)	1 (<0.1%)
Dermatitis	皮膚炎	0	1 (<0.1%)
Dermatitis exfoliative	剥脱性皮膚炎	1 (<0.1%)	0
Dermatomyositis	皮膚筋炎	1 (<0.1%)	0
Drug eruption	薬疹	0	1 (<0.1%)
Haemorrhage subcutaneous	皮下出血	0	1 (<0.1%)
Lichen planus	扁平苔癬	1 (<0.1%)	0
Purpura	紫斑	1 (<0.1%)	0
Rash morbilliform	麻疹様発疹	1 (<0.1%)	0
Skin lesion	皮膚病変	0	1 (<0.1%)
Skin necrosis	皮膚壊死	0	1 (<0.1%)
Skin ulcer	皮膚潰瘍	1 (<0.1%)	1 (<0.1%)
Urticaria	蕁麻疹	2 (<0.1%)	0

表 2.7.4.7-23 重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Social circumstances	社会環境	1 (<0.1%)	0
Miscarriage of partner	パートナーの自然流産	1 (<0.1%)	0
Surgical and medical procedures	外科および内科処置	2 (<0.1%)	3 (0.1%)
Abortion induced	人工流産	2 (<0.1%)	3 (0.1%)
Vascular disorders	血管障害	17 (0.7%)	18 (0.7%)
Aortic aneurysm	大動脈瘤	1 (<0.1%)	2 (<0.1%)
Aortic aneurysm rupture	大動脈瘤破裂	0	1 (<0.1%)
Aortic dissection	大動脈解離	1 (<0.1%)	0
Aortic thrombosis	大動脈血栓症	0	1 (<0.1%)
Circulatory collapse	循環虚脱	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%)
Haematoma	血腫	3 (0.1%)	3 (0.1%)
Hypertension	高血圧	1 (<0.1%)	3 (0.1%)
Hypertensive crisis	高血圧クリーゼ	0	1 (<0.1%)
Hypotension	低血圧	3 (0.1%)	1 (<0.1%)
Iliac artery thrombosis	腸骨動脈血栓症	0	1 (<0.1%)
Intra-abdominal haematoma	腹腔内血腫	0	1 (<0.1%)
Intra-abdominal haemorrhage	腹腔内出血	1 (<0.1%)	2 (<0.1%)
Lymphocele	リンパ嚢腫	1 (<0.1%)	0
Orthostatic hypotension	起立性低血圧	1 (<0.1%)	0
Paradoxical embolism	奇異性塞栓症	1 (<0.1%)	0
Peripheral ischaemia	末梢性虚血	1 (<0.1%)	0
Temporal arteritis	側頭動脈炎	0	1 (<0.1%)
Thrombophlebitis superficial	表在性血栓性静脈炎	1 (<0.1%)	0
Vena cava thrombosis	大静脈血栓症	1 (<0.1%)	0

Note: SOC = System Organ Class
Note: Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more clinical AEs, the subject is counted only once in a category. The same subject may appear in different categories.
Note: Percentages calculated with the number of subjects in each group as denominator. Sorted first by SOC (alphab. order) then by preferred term (alphab. order).
Note: Treatment-emergent AE is defined as the AE occurred after randomization and up to the respective time window after the last dose of study drug.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_pe/stat/prod/pgms/t-ae-incidence-1.sas sgqaz 12MAR2012 19:23
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表 2.7.4.7-24 重篤な TEAE（試験 11899、安全性解析対象集団）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
ANY EVENT		46 (7.8%)	52 (8.7%)
Blood and lymphatic system disorders	血液およびリンパ系障害	1 (0.2%)	1 (0.2%)
Anaemia	貧血	1 (0.2%)	1 (0.2%)
Cardiac disorders	心臓障害	7 (1.2%)	9 (1.5%)
Acute myocardial infarction	急性心筋梗塞	1 (0.2%)	0
Angina unstable	不安定狭心症	0	3 (0.5%)
Atrial fibrillation	心房細動	3 (0.5%)	3 (0.5%)
Bradycardia	徐脈	1 (0.2%)	1 (0.2%)
Cardiac arrest	心停止	0	1 (0.2%)
Cardiac failure congestive	うっ血性心不全	0	1 (0.2%)
Cardiomyopathy	心筋症	1 (0.2%)	0
Sick sinus syndrome	洞不全症候群	1 (0.2%)	0
Supraventricular tachycardia	上室性頻脈	1 (0.2%)	0
Gastrointestinal disorders	胃腸障害	6 (1.0%)	10 (1.7%)
Abdominal hernia obstructive	閉塞を伴う腹部ヘルニア	1 (0.2%)	0
Abdominal pain	腹痛	1 (0.2%)	1 (0.2%)
Abdominal pain upper	上腹部痛	0	2 (0.3%)
Colitis ischaemic	虚血性大腸炎	1 (0.2%)	0
Constipation	便秘	1 (0.2%)	0
Diverticulum	憩室	1 (0.2%)	0
Gastric ulcer	胃潰瘍	0	1 (0.2%)
Gastritis	胃炎	0	1 (0.2%)
Gastrointestinal haemorrhage	胃腸出血	0	2 (0.3%)
Haemorrhoids	痔核	1 (0.2%)	0
Inguinal hernia	鼠径ヘルニア	1 (0.2%)	0
Intestinal obstruction	腸閉塞	0	1 (0.2%)
Melaena	メレナ	0	1 (0.2%)
Rectal haemorrhage	直腸出血	0	1 (0.2%)
General disorders and administration site conditions	全身障害および投与局所様態	4 (0.7%)	2 (0.3%)
Asthenia	無力症	1 (0.2%)	0
Chest pain	胸痛	2 (0.3%)	2 (0.3%)
Non-cardiac chest pain	非心臓性胸痛	1 (0.2%)	0
Hepatobiliary disorders	肝胆道系障害	1 (0.2%)	1 (0.2%)

表 2.7.4.7-24 重篤な TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Cholecystitis	胆嚢炎	1 (0.2%)	1 (0.2%)
Cholelithiasis	胆石症	0	1 (0.2%)
Immune system disorders	免疫系障害	0	1 (0.2%)
Antiphospholipid syndrome	抗リン脂質抗体症候群	0	1 (0.2%)
Infections and infestations	感染症および寄生虫症	7 (1.2%)	8 (1.3%)
Abdominal abscess	腹部膿瘍	0	1 (0.2%)
Appendicitis	虫垂炎	0	1 (0.2%)
Bronchitis	気管支炎	3 (0.5%)	0
Cellulitis	蜂巣炎	1 (0.2%)	0
Gastroenteritis	胃腸炎	0	2 (0.3%)
Herpes zoster	帯状疱疹	1 (0.2%)	0
Intestinal gangrene	腸壊疽	1 (0.2%)	0
Localised infection	限局性感染	0	1 (0.2%)
Lung abscess	肺膿瘍	0	1 (0.2%)
Pneumonia	肺炎	0	2 (0.3%)
Postoperative abscess	術後膿瘍	0	1 (0.2%)
Respiratory tract infection	気道感染	0	1 (0.2%)
Urinary tract infection	尿路感染	1 (0.2%)	1 (0.2%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	2 (0.3%)	3 (0.5%)
Drug exposure during pregnancy	妊娠時の薬物曝露	1 (0.2%)	0
Joint dislocation	関節脱臼	0	1 (0.2%)
Rib fracture	肋骨骨折	0	1 (0.2%)
Skull fracture	頭蓋骨骨折	0	1 (0.2%)
Traumatic fracture	外傷性骨折	1 (0.2%)	0
Investigations	臨床検査	1 (0.2%)	3 (0.5%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	0	2 (0.3%)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	0	2 (0.3%)
Hepatic enzyme increased	肝酵素上昇	0	2 (0.3%)
Liver function test abnormal	肝機能検査異常	1 (0.2%)	0
Metabolism and nutrition disorders	代謝および栄養障害	1 (0.2%)	0
Diabetic ketoacidosis	糖尿病性ケトアシドーシス	1 (0.2%)	0
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	4 (0.7%)	3 (0.5%)
Joint stiffness	関節硬直	1 (0.2%)	0

表 2.7.4.7-24 重篤な TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Musculoskeletal chest pain	筋骨格系胸痛	1 (0.2%)	0
Osteoarthritis	骨関節炎	1 (0.2%)	1 (0.2%)
Pain in extremity	四肢痛	1 (0.2%)	1 (0.2%)
Rheumatoid arthritis	関節リウマチ	1 (0.2%)	1 (0.2%)
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）	6 (1.0%)	2 (0.3%)
Benign vascular neoplasm	血管の良性新生物	1 (0.2%)	0
Colon cancer	結腸癌	1 (0.2%)	0
Colorectal cancer	結腸直腸癌	1 (0.2%)	0
Endometrial cancer	子宮内膜癌	1 (0.2%)	0
Malignant melanoma in situ	表皮内悪性黒色腫	1 (0.2%)	0
Oesophageal neoplasm	食道新生物	0	1 (0.2%)
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0	1 (0.2%)
Vaginal neoplasm	膣新生物	1 (0.2%)	0
Nervous system disorders	神経系障害	3 (0.5%)	3 (0.5%)
Epilepsy	てんかん	1 (0.2%)	1 (0.2%)
Ischaemic stroke	虚血性脳卒中	1 (0.2%)	0
Syncope	失神	1 (0.2%)	2 (0.3%)
Transient ischaemic attack	一過性脳虚血発作	0	1 (0.2%)
Pregnancy, puerperium and perinatal conditions	妊娠、産褥および周産期の状態	0	1 (0.2%)
Pregnancy	妊娠	0	1 (0.2%)
Psychiatric disorders	精神障害	1 (0.2%)	1 (0.2%)
Anxiety	不安	1 (0.2%)	0
Depression	うつ病	0	1 (0.2%)
Renal and urinary disorders	腎および尿路障害	1 (0.2%)	1 (0.2%)
Haematuria	血尿	0	1 (0.2%)
Hydronephrosis	水腎症	1 (0.2%)	0
Reproductive system and breast disorders	生殖系および乳房障害	1 (0.2%)	2 (0.3%)
Menometrorrhagia	機能性子宮出血	0	1 (0.2%)
Metrorrhagia	不正子宮出血	0	1 (0.2%)
Vaginal prolapse	膣脱	1 (0.2%)	0
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	3 (0.5%)	5 (0.8%)
Acute pulmonary oedema	急性肺水腫	0	1 (0.2%)

表 2.7.4.7-24 重篤な TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
Bronchospasm	気管支痙攣	0	1 (0.2%)
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	0	3 (0.5%)
Dyspnoea	呼吸困難	0	2 (0.3%)
Pulmonary embolism	肺塞栓症	1 (0.2%)	0
Respiratory failure	呼吸不全	1 (0.2%)	0
Sleep apnoea syndrome	睡眠時無呼吸症候群	1 (0.2%)	0
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	1 (0.2%)	0
Stevens-Johnson syndrome	スティーブンス・ジョンソン症候群	1 (0.2%)	0
Surgical and medical procedures	外科および内科処置	1 (0.2%)	2 (0.3%)
Anal fistula excision	痔瘻切除	1 (0.2%)	0
Appendicectomy	虫垂切除	0	1 (0.2%)
Bladder calculus removal	膀胱結石除去	0	1 (0.2%)
Vascular disorders	血管障害	3 (0.5%)	3 (0.5%)
Circulatory collapse	循環虚脱	0	1 (0.2%)
Haematoma	血腫	1 (0.2%)	0
Hypertension	高血圧	1 (0.2%)	1 (0.2%)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	1 (0.2%)	0
Thrombophlebitis	血栓性静脈炎	0	1 (0.2%)

Note: SOC = System Organ Class
Note: Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more clinical AEs, the subject is counted only once in a category. The same subject may appear in different categories.
Note: Percentages calculated with the number of subjects in each group as denominator.
Note: Sorted first by System Organ Class (alphab. order) then by Preferred Term (alphab. order).
Note: Treatment-emergent AE is defined as the AE occurred after the first dose and up to 2 days after the last dose of study drug.
Global Biostatistics: /by-sasp/patdb/projects/597939/11899/stat/prod/pgms/t-ae-incidence-1.sas sgqaz 03MAY2010 23:14
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表 2.7.4.7-25　治験薬との因果関係が否定できない重篤な TEAE（試験 11702_DVT、安全性解析対象集団）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
ANY EVENT		42 (2.4%)	51 (3.0%)
Blood and lymphatic system disorders	血液およびリンパ系障害	11 (0.6%)	4 (0.2%)
Anaemia	貧血	7 (0.4%)	4 (0.2%)
Microcytic anaemia	小球性貧血	1 (<0.1%)	0
Spontaneous haematoma	特発性血腫	1 (<0.1%)	0
Thrombocytopenia	血小板減少症	2 (0.1%)	0
Ear and labyrinth disorders	耳および迷路障害	0	1 (<0.1%)
Ear haemorrhage	耳出血	0	1 (<0.1%)
Eye disorders	眼障害	2 (0.1%)	1 (<0.1%)
Conjunctival haemorrhage	結膜出血	0	1 (<0.1%)
Eye haemorrhage	眼出血	1 (<0.1%)	0
Hyphaema	前房出血	1 (<0.1%)	0
Vitreous detachment	硝子体剥離	1 (<0.1%)	0
Gastrointestinal disorders	胃腸障害	7 (0.4%)	9 (0.5%)
Gastrointestinal haemorrhage	胃腸出血	3 (0.2%)	0
Gingival bleeding	歯肉出血	0	1 (<0.1%)
Haematemesis	吐血	1 (<0.1%)	2 (0.1%)
Haematochezia	血便排泄	0	2 (0.1%)
Intestinal haemorrhage	腸出血	0	1 (<0.1%)
Melaena	メレナ	1 (<0.1%)	1 (<0.1%)
Rectal haemorrhage	直腸出血	2 (0.1%)	2 (0.1%)
Hepatobiliary disorders	肝胆道系障害	1 (<0.1%)	0
Hepatitis acute	急性肝炎	1 (<0.1%)	0
Infections and infestations	感染症および寄生虫症	1 (<0.1%)	0
Urinary tract infection	尿路感染	1 (<0.1%)	0
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	3 (0.2%)	3 (0.2%)
Drug toxicity	薬物毒性	1 (<0.1%)	0
Overdose	過量投与	0	1 (<0.1%)
Post procedural haematuria	処置後血尿	1 (<0.1%)	0
Post procedural haemorrhage	処置後出血	1 (<0.1%)	0
Therapeutic agent toxicity	治療薬毒性	0	2 (0.1%)

表 2.7.4.7-25　治験薬との因果関係が否定できない重篤な TEAE（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Investigations	臨床検査	5 (0.3%)	13 (0.8%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2 (0.1%)	4 (0.2%)
Hepatic enzyme increased	肝酵素上昇	0	4 (0.2%)
International normalised ratio fluctuation	ＩＮＲ変動	0	1 (<0.1%)
International normalised ratio increased	ＩＮＲ増加	0	4 (0.2%)
Liver function test abnormal	肝機能検査異常	2 (0.1%)	0
Transaminases increased	トランスアミナーゼ上昇	1 (<0.1%)	0
Metabolism and nutrition disorders	代謝および栄養障害	1 (<0.1%)	0
Tetany	テタニー	1 (<0.1%)	0
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	0	5 (0.3%)
Haemarthrosis	出血性関節症	0	1 (<0.1%)
Muscle haemorrhage	筋肉内出血	0	3 (0.2%)
Pain in extremity	四肢痛	0	1 (<0.1%)
Nervous system disorders	神経系障害	2 (0.1%)	3 (0.2%)
Cerebral haemorrhage	脳出血	1 (<0.1%)	1 (<0.1%)
Haemorrhage intracranial	頭蓋内出血	1 (<0.1%)	1 (<0.1%)
Ischaemic stroke	虚血性脳卒中	0	1 (<0.1%)
Renal and urinary disorders	腎および尿路障害	3 (0.2%)	5 (0.3%)
Haematuria	血尿	3 (0.2%)	5 (0.3%)
Reproductive system and breast disorders	生殖系および乳房障害	6 (0.3%)	2 (0.1%)
Menorrhagia	月経過多	3 (0.2%)	1 (<0.1%)
Vaginal haemorrhage	膣出血	3 (0.2%)	1 (<0.1%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	2 (0.1%)	4 (0.2%)
Epistaxis	鼻出血	1 (<0.1%)	1 (<0.1%)
Haemoptysis	喀血	1 (<0.1%)	2 (0.1%)
Haemothorax	血胸	0	1 (<0.1%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	0	1 (<0.1%)
Leukocytoclastic vasculitis	白血球破砕性血管炎	0	1 (<0.1%)
Skin ulcer	皮膚潰瘍	0	1 (<0.1%)

表 2.7.4.7-25 治験薬との因果関係が否定できない重篤な TEAE（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{13.0}		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Vascular disorders	血管障害	2 (0.1%)	5 (0.3%)
Arterial thrombosis limb	四肢動脈血栓症	0	1 (<0.1%)
Circulatory collapse	循環虚脱	1 (<0.1%)	0
Haematoma	血腫	1 (<0.1%)	3 (0.2%)
Shock haemorrhagic	出血性ショック	0	1 (<0.1%)

Note: SOC = System Organ Class
Note: Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more clinical AEs, the subject is counted only once in a category. The same subject may appear in different categories.
Note: Percentages calculated with the number of subjects in each group as denominator. Sorted first by SOC (alphab. order) then by preferred term (alphab. order).
Note: Treatment-emergent AE is defined as the AE occurred after randomization and up to the respective time window after the last dose of study drug.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_dvt/stat/prod/pgms/t-ae-incidence-1.sas gcwer 15SEP2010 15:42
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表 2.7.4.7-26 治験薬との因果関係が否定できない重篤な TEAE（試験 11702_PE、安全性解析対象集団）

Primary System Organ Class / Preferred Term MedDRA version{14.1}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
ANY EVENT		112 (4.6%)	118 (4.9%)
Blood and lymphatic system disorders	血液およびリンパ系障害	9 (0.4%)	5 (0.2%)
Anaemia	貧血	7 (0.3%)	2 (<0.1%)
Coagulopathy	凝血異常	0	2 (<0.1%)
Haemorrhagic anaemia	出血性貧血	1 (<0.1%)	2 (<0.1%)
Splenic haemorrhage	脾臓出血	0	1 (<0.1%)
Thrombocytopenia	血小板減少症	1 (<0.1%)	0
Cardiac disorders	心臓障害	4 (0.2%)	3 (0.1%)
Angina unstable	不安定狭心症	1 (<0.1%)	0
Cardiac failure acute	急性心不全	1 (<0.1%)	0
Cardiac failure congestive	うっ血性心不全	1 (<0.1%)	0
Congestive cardiomyopathy	うっ血性心筋症	1 (<0.1%)	0
Coronary artery disease	冠動脈疾患	0	1 (<0.1%)
Pericardial haemorrhage	心嚢内出血	0	2 (<0.1%)
Right ventricular failure	右室不全	1 (<0.1%)	0
Endocrine disorders	内分泌障害	1 (<0.1%)	1 (<0.1%)
Addison's disease	アジソン病	1 (<0.1%)	0
Adrenal haemorrhage	副腎出血	1 (<0.1%)	1 (<0.1%)
Eye disorders	眼障害	0	3 (0.1%)
Eye haemorrhage	眼出血	0	2 (<0.1%)
Retinal haemorrhage	網膜出血	0	1 (<0.1%)
Gastrointestinal disorders	胃腸障害	24 (1.0%)	31 (1.3%)
Abdominal wall haematoma	腹壁血腫	0	2 (<0.1%)
Gastric haemorrhage	胃出血	0	1 (<0.1%)
Gastric ulcer haemorrhage	出血性胃潰瘍	1 (<0.1%)	1 (<0.1%)
Gastritis	胃炎	0	1 (<0.1%)
Gastritis haemorrhagic	出血性胃炎	1 (<0.1%)	1 (<0.1%)
Gastrointestinal haemorrhage	胃腸出血	6 (0.2%)	4 (0.2%)
Haematemesis	吐血	3 (0.1%)	2 (<0.1%)
Haemorrhoidal haemorrhage	痔出血	1 (<0.1%)	1 (<0.1%)
Intestinal haemorrhage	腸出血	1 (<0.1%)	3 (0.1%)
Lower gastrointestinal haemorrhage	下部消化管出血	0	3 (0.1%)
Melaena	メレナ	1 (<0.1%)	5 (0.2%)

表 2.7.4.7-26 治験薬との因果関係が否定できない重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Nausea	悪心	1 (<0.1%)	0
Oesophageal ulcer	食道潰瘍	1 (<0.1%)	0
Oesophageal ulcer haemorrhage	食道潰瘍出血	0	1 (<0.1%)
Rectal haemorrhage	直腸出血	6 (0.2%)	5 (0.2%)
Retroperitoneal haematoma	後腹膜血腫	0	2 (<0.1%)
Upper gastrointestinal haemorrhage	上部消化管出血	2 (<0.1%)	1 (<0.1%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	6 (0.2%)	3 (0.1%)
Asthenia	無力症	1 (<0.1%)	0
Chest pain	胸痛	1 (<0.1%)	0
Death	死亡	1 (<0.1%)	2 (<0.1%)
Drug intolerance	薬物不耐性	0	1 (<0.1%)
Malaise	倦怠感	1 (<0.1%)	0
Sudden death	突然死	2 (<0.1%)	0
Hepatobiliary disorders	肝胆道系障害	4 (0.2%)	2 (<0.1%)
Cholecystitis	胆嚢炎	1 (<0.1%)	0
Cytolytic hepatitis	肝細胞融解性肝炎	1 (<0.1%)	0
Hepatic function abnormal	肝機能異常	0	1 (<0.1%)
Hepatitis	肝炎	0	1 (<0.1%)
Hepatitis acute	急性肝炎	1 (<0.1%)	0
Hepatitis chronic active	慢性活動性肝炎	1 (<0.1%)	0
Immune system disorders	免疫系障害	0	1 (<0.1%)
Drug hypersensitivity	薬物過敏症	0	1 (<0.1%)
Infections and infestations	感染症および寄生虫症	0	1 (<0.1%)
Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪	0	1 (<0.1%)
Pneumonia	肺炎	0	1 (<0.1%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	5 (0.2%)	13 (0.5%)
Cerebral haemorrhage traumatic	外傷性脳出血	1 (<0.1%)	0
Kidney rupture	腎臓破裂	0	1 (<0.1%)
Operative haemorrhage	術中出血	1 (<0.1%)	0
Overdose	過量投与	0	2 (<0.1%)
Perirenal haematoma	腎周囲血腫	0	1 (<0.1%)
Post procedural haemorrhage	処置後出血	1 (<0.1%)	1 (<0.1%)

表 2.7.4.7-26　治験薬との因果関係が否定できない重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Splenic haematoma	脾血腫	0	1 (<0.1%)
Subcutaneous haematoma	皮下血腫	1 (<0.1%)	2 (<0.1%)
Subdural haematoma	硬膜下血腫	1 (<0.1%)	2 (<0.1%)
Subdural haemorrhage	硬膜下出血	0	1 (<0.1%)
Traumatic haematoma	外傷性血腫	0	1 (<0.1%)
Vascular pseudoaneurysm	血管偽動脈瘤	0	1 (<0.1%)
Investigations	臨床検査	12 (0.5%)	17 (0.7%)
Activated partial thromboplastin time prolonged	活性化部分トロンボプラスチン時間延長	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	3 (0.1%)	4 (0.2%)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	0	1 (<0.1%)
Coagulation time prolonged	凝固時間延長	0	1 (<0.1%)
Hepatic enzyme increased	肝酵素上昇	2 (<0.1%)	1 (<0.1%)
International normalised ratio abnormal	ＩＮＲ異常	0	1 (<0.1%)
International normalised ratio increased	ＩＮＲ増加	1 (<0.1%)	4 (0.2%)
Liver function test abnormal	肝機能検査異常	2 (<0.1%)	5 (0.2%)
Transaminases increased	トランスアミナーゼ上昇	2 (<0.1%)	1 (<0.1%)
Ultrasound liver abnormal	肝超音波検査異常	1 (<0.1%)	0
Metabolism and nutrition disorders	代謝および栄養障害	0	2 (<0.1%)
Gout	痛風	0	1 (<0.1%)
Hypovolaemia	血液量減少症	0	1 (<0.1%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1 (<0.1%)	10 (0.4%)
Haemarthrosis	出血性関節症	0	1 (<0.1%)
Muscle haemorrhage	筋肉内出血	1 (<0.1%)	9 (0.4%)
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）	0	1 (<0.1%)
Lung neoplasm	肺新生物	0	1 (<0.1%)
Nervous system disorders	神経系障害	7 (0.3%)	7 (0.3%)
Cerebellar haemorrhage	小脳出血	1 (<0.1%)	0
Cerebral haemorrhage	脳出血	0	3 (0.1%)
Cerebrovascular accident	脳血管発作	1 (<0.1%)	0
Clumsiness	不器用	1 (<0.1%)	0
Convulsion	痙攣	1 (<0.1%)	0
Haemorrhage intracranial	頭蓋内出血	0	2 (<0.1%)

表 2.7.4.7-26　治験薬との因果関係が否定できない重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Headache	頭痛	1 (<0.1%)	0
Hepatic encephalopathy	肝性脳症	1 (<0.1%)	0
Ischaemic stroke	虚血性脳卒中	0	1 (<0.1%)
Subarachnoid haemorrhage	くも膜下出血	0	1 (<0.1%)
Syncope	失神	1 (<0.1%)	0
Tension headache	緊張性頭痛	0	1 (<0.1%)
Renal and urinary disorders	腎および尿路障害	8 (0.3%)	11 (0.5%)
Haematuria	血尿	8 (0.3%)	10 (0.4%)
Renal failure acute	急性腎不全	0	1 (<0.1%)
Reproductive system and breast disorders	生殖系および乳房障害	17 (0.7%)	4 (0.2%)
Dysfunctional uterine bleeding	機能障害性子宮出血	1 (<0.1%)	0
Menorrhagia	月経過多	9 (0.4%)	2 (<0.1%)
Metrorrhagia	不正子宮出血	4 (0.2%)	1 (<0.1%)
Priapism	持続勃起症	0	1 (<0.1%)
Vaginal haemorrhage	膣出血	3 (0.1%)	0
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	13 (0.5%)	9 (0.4%)
Dyspnoea	呼吸困難	0	1 (<0.1%)
Epistaxis	鼻出血	3 (0.1%)	1 (<0.1%)
Haemoptysis	喀血	4 (0.2%)	5 (0.2%)
Haemothorax	血胸	1 (<0.1%)	1 (<0.1%)
Pulmonary congestion	肺うっ血	0	1 (<0.1%)
Pulmonary embolism	肺塞栓症	1 (<0.1%)	0
Pulmonary haemorrhage	肺出血	1 (<0.1%)	0
Pulmonary infarction	肺梗塞	1 (<0.1%)	0
Pulmonary venous thrombosis	肺静脈血栓症	1 (<0.1%)	0
Respiratory failure	呼吸不全	1 (<0.1%)	0
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	4 (0.2%)	2 (<0.1%)
Haemorrhage subcutaneous	皮下出血	0	1 (<0.1%)
Purpura	紫斑	1 (<0.1%)	0
Rash morbilliform	麻疹様発疹	1 (<0.1%)	0
Skin necrosis	皮膚壊死	0	1 (<0.1%)
Urticaria	蕁麻疹	2 (<0.1%)	0
Social circumstances	社会環境	1 (<0.1%)	0

表 2.7.4.7-26 治験薬との因果関係が否定できない重篤な TEAE（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}		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Miscarriage of partner	パートナーの自然流産	1 (<0.1%)	0
Vascular disorders	血管障害	4 (0.2%)	5 (0.2%)
Haematoma	血腫	3 (0.1%)	3 (0.1%)
Hypertension	高血圧	0	1 (<0.1%)
Intra-abdominal haematoma	腹腔内血腫	0	1 (<0.1%)
Intra-abdominal haemorrhage	腹腔内出血	1 (<0.1%)	0

Note: SOC = System Organ Class
Note: Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more clinical AEs, the subject is counted only once in a category. The same subject may appear in different categories.
Note: Percentages calculated with the number of subjects in each group as denominator. Sorted first by SOC (alphab. order) then by preferred term (alphab. order).
Note: Treatment-emergent AE is defined as the AE occurred after randomization and up to the respective time window after the last dose of study drug.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_pe/stat/prod/pgms/t-ae-incidence-1.sas sgqaz 12MAR2012 19:23
End of table

表 2.7.4.7-27 治験薬との因果関係が否定できない重篤な TEAE（試験 11899、安全性解析対象集団）

Primary System Organ Class / Preferred Term MedDRA version{12.0}		Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)
ANY EVENT		5 (0.8%)	12 (2.0%)
Blood and lymphatic system disorders	血液およびリンパ系障害	0	1 (0.2%)
Anaemia	貧血	0	1 (0.2%)
Gastrointestinal disorders	胃腸障害	0	5 (0.8%)
Abdominal pain upper	上腹部痛	0	1 (0.2%)
Gastrointestinal haemorrhage	胃腸出血	0	2 (0.3%)
Melaena	メレナ	0	1 (0.2%)
Rectal haemorrhage	直腸出血	0	1 (0.2%)
Investigations	臨床検査	1 (0.2%)	2 (0.3%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	0	2 (0.3%)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	0	2 (0.3%)
Hepatic enzyme increased	肝酵素上昇	0	1 (0.2%)
Liver function test abnormal	肝機能検査異常	1 (0.2%)	0
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）	1 (0.2%)	0
Benign vascular neoplasm	血管の良性新生物	1 (0.2%)	0
Renal and urinary disorders	腎および尿路障害	0	1 (0.2%)
Haematuria	血尿	0	1 (0.2%)
Reproductive system and breast disorders	生殖系および乳房障害	0	2 (0.3%)
Menometrorrhagia	機能性子宮出血	0	1 (0.2%)
Metrorrhagia	不正子宮出血	0	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	1 (0.2%)	0
Pulmonary embolism	肺塞栓症	1 (0.2%)	0
Vascular disorders	血管障害	2 (0.3%)	1 (0.2%)
Circulatory collapse	循環虚脱	0	1 (0.2%)
Haematoma	血腫	1 (0.2%)	0
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	1 (0.2%)	0

表 2.7.4.7-27 治験薬との因果関係が否定できない重篤な TEAE（試験 11899、安全性解析対象集団）（続き）

Primary System Organ Class / Preferred Term MedDRA version{12.0}	Placebo N=590 (100%)	BAY 59-7939 N=598 (100%)

Note: SOC = System Organ Class
Note: Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more clinical AEs, the subject is counted only once in a category. The same subject may appear in different categories.
Note: Percentages calculated with the number of subjects in each group as denominator.
Note: Sorted first by System Organ Class (alphab. order) then by Preferred Term (alphab. order).
Note: Treatment-emergent AE is defined as the AE occurred after the first dose and up to 2 days after the last dose of study drug.
Global Biostatistics: /by-sasp/patdb/projects/597939/11899/stat/prod/pgms/t-ae-incidence-1.sas sgqaz 03MAY2010 23:14
End of table

表 2.7.4.7-28 死亡に至った有害事象（試験 11702_DVT、安全性解析対象集団）

Primary System Organ Class Preferred Term MedDRA version{13.0} Cause of death by CIAC		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
ANY EVENT		41 (2.4%)	52 (3.0%)
!Not in the AE database	AE として集計していない事象	1 (<0.1%)	2 (0.1%)
CANCER	悪性腫瘍	1 (<0.1%)	2 (0.1%)
Cardiac disorders	心臓障害	2 (0.1%)	4 (0.2%)
Cardiac arrest	心停止	0	3 (0.2%)
UNEXPLAINED PE AND PE CANNOT BE RULED OUT	PE の可能性が否定できない原因不明の死亡	0	1 (<0.1%)
ISCHEMIC STROKE	虚血性脳卒中	0	2 (0.1%)
Cardiac failure	心不全	1 (<0.1%)	0
OTHER VASCULAR EVENT	その他の心血管事象	1 (<0.1%)	0
Cardio-respiratory arrest	心肺停止	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Myocardial infarction	心筋梗塞	0	1 (<0.1%)
UNEXPLAINED PE AND PE CANNOT BE RULED OUT	PE の可能性が否定できない原因不明の死亡	0	1 (<0.1%)
Gastrointestinal disorders	胃腸障害	2 (0.1%)	1 (<0.1%)
Haematemesis	吐血	1 (<0.1%)	1 (<0.1%)
BLEEDING	出血	1 (<0.1%)	1 (<0.1%)
Large intestine perforation	大腸穿孔	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
General disorders and administration site conditions	全身障害および投与局所様態	6 (0.3%)	5 (0.3%)
Death	死亡	2 (0.1%)	1 (<0.1%)
CANCER	悪性腫瘍	1 (<0.1%)	0
UNEXPLAINED PE AND PE CANNOT BE RULED OUT	PE の可能性が否定できない原因不明の死亡	1 (<0.1%)	1 (<0.1%)
General physical health deterioration	全身健康状態低下	0	1 (<0.1%)
ISCHEMIC STROKE	虚血性脳卒中	0	1 (<0.1%)
Multi-organ failure	多臓器不全	2 (0.1%)	2 (0.1%)
BLEEDING	出血	0	1 (<0.1%)
CANCER	悪性腫瘍	1 (<0.1%)	0
INFECTIOUS DISEASE	感染症	1 (<0.1%)	1 (<0.1%)
Sudden cardiac death	心突然死	1 (<0.1%)	0
UNEXPLAINED PE AND PE CANNOT BE RULED OUT	PE の可能性が否定できない原因不明の死亡	1 (<0.1%)	0
Sudden death	突然死	0	1 (<0.1%)
UNEXPLAINED PE AND PE CANNOT BE RULED OUT	PE の可能性が否定できない原因不明の死亡	0	1 (<0.1%)

表 2.7.4.7-28　死亡に至った有害事象（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0} Cause of death by CIAC		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Systemic inflammatory response syndrome	全身性炎症反応症候群	1 (<0.1%)	0
BLEEDING	出血	1 (<0.1%)	0
Hepatobiliary disorders	肝胆道系障害	0	1 (<0.1%)
Hepatic failure	肝不全	0	1 (<0.1%)
LIVER DISEASE	肝疾患	0	1 (<0.1%)
Infections and infestations	感染症および寄生虫症	4 (0.2%)	13 (0.8%)
Bronchopneumonia	気管支肺炎	1 (<0.1%)	0
INFECTIOUS DISEASE	感染症	1 (<0.1%)	0
Cerebral toxoplasmosis	脳トキソプラズマ症	0	1 (<0.1%)
INFECTIOUS DISEASE	感染症	0	1 (<0.1%)
Escherichia sepsis	大腸菌性敗血症	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Lung infection	肺感染	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Pneumonia	肺炎	2 (0.1%)	2 (0.1%)
UNEXPLAINED PE AND PE CANNOT BE RULED OUT	PE の可能性が否定できない原因不明の死亡	1 (<0.1%)	0
INFECTIOUS DISEASE	感染症	1 (<0.1%)	2 (0.1%)
Pneumonia bacterial	細菌性肺炎	0	1 (<0.1%)
OTHER RESPIRATORY FAILURE	その他の呼吸不全	0	1 (<0.1%)
Respiratory tract infection	気道感染	0	1 (<0.1%)
INFECTIOUS DISEASE	感染症	0	1 (<0.1%)
Sepsis	敗血症	0	2 (0.1%)
SEPTICAEMIA	敗血症	0	1 (<0.1%)
OTHER VASCULAR EVENT	その他の心血管事象	0	1 (<0.1%)
Septic shock	敗血症性ショック	1 (<0.1%)	4 (0.2%)
CANCER	悪性腫瘍	1 (<0.1%)	0
INFECTIOUS DISEASE	感染症	0	4 (0.2%)
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）	19 (1.1%)	17 (1.0%)
Breast cancer	乳癌	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Cervix cancer metastatic	転移性子宮頚部癌	1 (<0.1%)	0

表 2.7.4.7-28 死亡に至った有害事象（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0} Cause of death by CIAC		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
CANCER	悪性腫瘍	1 (<0.1%)	0
Cervix carcinoma	子宮頚部癌	2 (0.1%)	6 (0.4%)
CANCER	悪性腫瘍	2 (0.1%)	6 (0.4%)
Cervix carcinoma stage III	子宮頚部癌第３期	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Colorectal cancer	結腸直腸癌	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Endometrial cancer	子宮内膜癌	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Hepatic cancer metastatic	転移性肝癌	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Hepatic neoplasm malignant	肝の悪性新生物	1 (<0.1%)	2 (0.1%)
CANCER	悪性腫瘍	1 (<0.1%)	2 (0.1%)
Large cell carcinoma of the respiratory tract stage unspecified	呼吸器大細胞癌、病期不明	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Lung neoplasm	肺新生物	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Lung neoplasm malignant	肺の悪性新生物	1 (<0.1%)	2 (0.1%)
CANCER	悪性腫瘍	1 (<0.1%)	2 (0.1%)
Metastases to liver	肝転移	1 (<0.1%)	1 (<0.1%)
CANCER	悪性腫瘍	1 (<0.1%)	1 (<0.1%)
Metastases to lung	肺転移	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Metastatic neoplasm	転移性新生物	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Oesophageal adenocarcinoma	食道腺癌	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Ovarian cancer	卵巣癌	0	1 (<0.1%)
Not adjudicated	判定なし	0	1 (<0.1%)
Pancreatic carcinoma	膵癌	2 (0.1%)	0
CANCER	悪性腫瘍	2 (0.1%)	0

表 2.7.4.7-28 死亡に至った有害事象（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0} Cause of death by CIAC		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Pancreatic carcinoma metastatic	転移性膵癌	0	2 (0.1%)
CANCER	悪性腫瘍	0	2 (0.1%)
Rectal cancer recurrent	再発直腸癌	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Retroperitoneal neoplasm	後腹膜新生物	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Rhabdomyosarcoma	横紋筋肉腫	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Small cell lung cancer metastatic	転移性小細胞肺癌	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Nervous system disorders	神経系障害	3 (0.2%)	3 (0.2%)
Cerebral haemorrhage	脳出血	0	1 (<0.1%)
BLEEDING	出血	0	1 (<0.1%)
Haemorrhage intracranial	頭蓋内出血	0	1 (<0.1%)
BLEEDING	出血	0	1 (<0.1%)
Hypoglycaemic coma	低血糖昏睡	1 (<0.1%)	0
DIABETIC COMA	糖尿病性昏睡	1 (<0.1%)	0
Ischaemic stroke	虚血性脳卒中	1 (<0.1%)	1 (<0.1%)
ISCHEMIC STROKE	虚血性脳卒中	1 (<0.1%)	1 (<0.1%)
Metabolic encephalopathy	代謝性脳症	1 (<0.1%)	0
CACHEXIA	悪液質	1 (<0.1%)	0
Psychiatric disorders	精神障害	0	1 (<0.1%)
Completed suicide	自殺既遂	0	1 (<0.1%)
SUICIDE	自殺	0	1 (<0.1%)
Renal and urinary disorders	腎および尿路障害	2 (0.1%)	0
Renal failure	腎不全	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Renal failure acute	急性腎不全	1 (<0.1%)	0
RENAL FAILURE	腎不全	1 (<0.1%)	0
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	2 (0.1%)	4 (0.2%)
Haemothorax	血胸	0	1 (<0.1%)
BLEEDING	出血	0	1 (<0.1%)

表 2.7.4.7-28 死亡に至った有害事象（試験 11702_DVT、安全性解析対象集団）（続き）

Primary System Organ Class Preferred Term MedDRA version{13.0} Cause of death by CIAC		Rivaroxaban N=1718 (100%)	Enoxaparin/VKA N=1711 (100%)
Interstitial lung disease	間質性肺疾患	0	1 (<0.1%)
PNEUMONIA	肺炎	0	1 (<0.1%)
Pulmonary embolism	肺塞栓症	1 (<0.1%)	2 (0.1%)
PULMONARY EMBOLISM	肺塞栓症	1 (<0.1%)	0
UNEXPLAINED PE AND PE CANNOT BE RULED OUT	PE の可能性が否定できない原因不明の死亡	0	2 (0.1%)
Respiratory failure	呼吸不全	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Vascular disorders	血管障害	0	1 (<0.1%)
Shock	ショック	0	1 (<0.1%)
SEPTICAEMIA	敗血症	0	1 (<0.1%)

Note: SOC = System Organ Class
Note: Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more clinical AEs, the subject is counted only once in a category. The same subject may appear in different categories.
Note: Percentages calculated with the number of subjects in each group as denominator. Sorted first by SOC (alphab. order) then by preferred term (alphab. order).
Note: CIAC: Central Independent Adjudication Committee.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_dvt/stat/prod/pgms/t-ae-incidence-1.sas gcwer 15SEP2010 15:42
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表 2.7.4.7-29 死亡に至った有害事象（試験 11702_PE、安全性解析対象集団）

Primary System Organ Class Preferred Term MedDRA version{14.1} Cause of death by CIAC		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
ANY EVENT		63 (2.6%)	51 (2.1%)
!Not in the AE database	AEとして集計していない事象	0	2 (<0.1%)
CANCER	悪性腫瘍	0	2 (<0.1%)
Cardiac disorders	心臓障害	11 (0.5%)	2 (<0.1%)
Acute myocardial infarction	急性心筋梗塞	1 (<0.1%)	1 (<0.1%)
MYOCARDIAL INFARCTION	心筋梗塞	1 (<0.1%)	1 (<0.1%)
Arrhythmia	不整脈	1 (<0.1%)	0
OTHER VASCULAR EVENT	その他の心血管事象	1 (<0.1%)	0
Atrioventricular block	房室ブロック	0	1 (<0.1%)
OTHER CARDIAC DEATH	その他の心臓死	0	1 (<0.1%)
Cardiac arrest	心停止	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Cardiac failure	心不全	3 (0.1%)	0
MULTIPLE ORGAN FAILURE	多臓器不全	1 (<0.1%)	0
HEART FAILURE	心不全	2 (<0.1%)	0
Cardiac failure acute	急性心不全	1 (<0.1%)	0
HEART FAILURE	心不全	1 (<0.1%)	0
Cardiac failure congestive	うっ血性心不全	1 (<0.1%)	0
HEART FAILURE	心不全	1 (<0.1%)	0
Cardio-respiratory arrest	心肺停止	1 (<0.1%)	0
INFECTIOUS DISEASE	感染症	1 (<0.1%)	0
Cardiogenic shock	心原性ショック	1 (<0.1%)	0
BLEEDING	出血	1 (<0.1%)	0
Congestive cardiomyopathy	うっ血性心筋症	1 (<0.1%)	0
HEART FAILURE	心不全	1 (<0.1%)	0
Right ventricular failure	右室不全	1 (<0.1%)	0
INFLAMMATORY DISEASE	炎症性疾患	1 (<0.1%)	0
Ventricular fibrillation	心室細動	1 (<0.1%)	0
INFECTIOUS DISEASE	感染症	1 (<0.1%)	0
Gastrointestinal disorders	胃腸障害	3 (0.1%)	2 (<0.1%)
Abdominal wall haematoma	腹壁血腫	0	1 (<0.1%)
BLEEDING	出血	0	1 (<0.1%)

表 2.7.4.7-29 死亡に至った有害事象（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} Cause of death by CIAC		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Acute abdomen	急性腹症	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Duodenal ulcer	十二指腸潰瘍	1 (<0.1%)	0
SEPTICAEMIA	敗血症	1 (<0.1%)	0
Intestinal fistula	腸管瘻	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Intestinal infarction	腸梗塞	1 (<0.1%)	0
OTHER VASCULAR EVENT	その他の心血管事象	1 (<0.1%)	0
General disorders and administration site conditions	一般・全身障害および投与部位の状態	8 (0.3%)	4 (0.2%)
Death	死亡	4 (0.2%)	2 (<0.1%)
CANCER	悪性腫瘍	1 (<0.1%)	0
UNEXPLAINED DEATH AND PE CANNOT BE RULED OUT	PE の可能性が否定できない原因不明の死亡	3 (0.1%)	2 (<0.1%)
General physical health deterioration	全身健康状態低下	0	1 (<0.1%)
ISCHEMIC STROKE	虚血性脳卒中	0	1 (<0.1%)
Multi-organ failure	多臓器不全	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Sudden death	突然死	3 (0.1%)	1 (<0.1%)
UNEXPLAINED DEATH AND PE CANNOT BE RULED OUT	PE の可能性が否定できない原因不明の死亡	3 (0.1%)	1 (<0.1%)
Hepatobiliary disorders	肝胆道系障害	1 (<0.1%)	0
Ischaemic hepatitis	虚血性肝炎	1 (<0.1%)	0
HEART FAILURE	心不全	1 (<0.1%)	0
Infections and infestations	感染症および寄生虫症	10 (0.4%)	4 (0.2%)
Bronchopulmonary aspergillosis	気管支肺アスペルギルス症	1 (<0.1%)	0
INFECTIOUS DISEASE	感染症	1 (<0.1%)	0
Endocarditis	心内膜炎	1 (<0.1%)	0
INFECTIOUS DISEASE	感染症	1 (<0.1%)	0
Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪	0	1 (<0.1%)
INFECTIOUS DISEASE	感染症	0	1 (<0.1%)
Lobar pneumonia	大葉性肺炎	0	1 (<0.1%)
INFECTIOUS DISEASE	感染症	0	1 (<0.1%)
Pneumonia	肺炎	2 (<0.1%)	2 (<0.1%)

表 2.7.4.7-29 死亡に至った有害事象（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} Cause of death by CIAC		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
CANCER	悪性腫瘍	1 (<0.1%)	0
INFECTIOUS DISEASE	感染症	1 (<0.1%)	2 (<0.1%)
Sepsis	敗血症	7 (0.3%)	0
CANCER	悪性腫瘍	3 (0.1%)	0
OTHER VASCULAR EVENT	その他の心血管事象	1 (<0.1%)	0
INFECTIOUS DISEASE	感染症	3 (0.1%)	0
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	2 (<0.1%)	1 (<0.1%)
Cerebral haemorrhage traumatic	外傷性脳出血	1 (<0.1%)	0
BLEEDING	出血	1 (<0.1%)	0
Multiple injuries	多発性外傷	0	1 (<0.1%)
POLYTRAUMA	多発性外傷	0	1 (<0.1%)
Subdural haematoma	硬膜下血腫	1 (<0.1%)	0
BLEEDING	出血	1 (<0.1%)	0
Metabolism and nutrition disorders	代謝および栄養障害	0	1 (<0.1%)
Failure to thrive	成長障害	0	1 (<0.1%)
ADVANCED AGE	高齢	0	1 (<0.1%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1 (<0.1%)	0
Rheumatoid arthritis	関節リウマチ	1 (<0.1%)	0
INFLAMMATORY DISEASE	炎症性疾患	1 (<0.1%)	0
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）	14 (0.6%)	17 (0.7%)
Bile duct cancer non-resectable	切除不能な胆管癌	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Brain neoplasm	脳新生物	1 (<0.1%)	0
BLEEDING	出血	1 (<0.1%)	0
Breast cancer metastatic	転移性乳癌	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Cervix carcinoma	子宮頚部癌	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Colon cancer	結腸癌	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Colon cancer metastatic	転移性結腸癌	0	1 (<0.1%)

表 2.7.4.7-29 死亡に至った有害事象（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} Cause of death by CIAC		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Gallbladder cancer	胆嚢癌	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Gastric cancer	胃癌	2 (<0.1%)	0
CANCER	悪性腫瘍	2 (<0.1%)	0
Gastric neoplasm	胃新生物	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Lung adenocarcinoma	肺腺癌	1 (<0.1%)	2 (<0.1%)
Not adjudicated	判定なし	0	1 (<0.1%)
CANCER	悪性腫瘍	1 (<0.1%)	1 (<0.1%)
Lung cancer metastatic	転移性肺癌	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Lung neoplasm malignant	肺の悪性新生物	3 (0.1%)	1 (<0.1%)
CANCER	悪性腫瘍	3 (0.1%)	1 (<0.1%)
Malignant ascites	悪性腹水	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Metastases to central nervous system	中枢神経系転移	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Metastases to liver	肝転移	2 (<0.1%)	0
CANCER	悪性腫瘍	2 (<0.1%)	0
Metastases to pleura	胸膜転移	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Metastatic neoplasm	転移性新生物	0	2 (<0.1%)
CANCER	悪性腫瘍	0	2 (<0.1%)
Myelodysplastic syndrome	骨髄異形成症候群	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Neoplasm malignant	悪性新生物	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Neoplasm prostate	前立腺新生物	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Ovarian cancer	卵巣癌	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0

表 2.7.4.7-29 死亡に至った有害事象（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} Cause of death by CIAC		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Pancreatic carcinoma metastatic	転移性膵癌	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Pelvic neoplasm	骨盤新生物	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Rectal cancer	直腸癌	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Rectal cancer metastatic	転移性直腸癌	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Tumour haemorrhage	腫瘍出血	1 (<0.1%)	0
BLEEDING	出血	1 (<0.1%)	0
Nervous system disorders	神経系障害	5 (0.2%)	4 (0.2%)
Amyotrophic lateral sclerosis	筋萎縮性側索硬化症	0	1 (<0.1%)
AMYOTHROPHIC LATERAL SCLEROSIS	筋萎縮性側索硬化症	0	1 (<0.1%)
Cerebellar haemorrhage	小脳出血	1 (<0.1%)	0
BLEEDING	出血	1 (<0.1%)	0
Cerebral haemorrhage	脳出血	0	2 (<0.1%)
BLEEDING	出血	0	2 (<0.1%)
Coma	昏睡	1 (<0.1%)	0
SEPTICAEMIA	敗血症	1 (<0.1%)	0
Haemorrhage intracranial	頭蓋内出血	0	1 (<0.1%)
BLEEDING	出血	0	1 (<0.1%)
Haemorrhagic transformation stroke	卒中の出血性変化	1 (<0.1%)	0
ISCHEMIC STROKE	虚血性脳卒中	1 (<0.1%)	0
Ischaemic stroke	虚血性脳卒中	2 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
ISCHEMIC STROKE	虚血性脳卒中	1 (<0.1%)	0
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	12 (0.5%)	14 (0.6%)
Acute pulmonary oedema	急性肺水腫	1 (<0.1%)	0
MYOCARDIAL INFARCTION	心筋梗塞	1 (<0.1%)	0
Acute respiratory distress syndrome	急性呼吸窮迫症候群	2 (<0.1%)	1 (<0.1%)
CANCER	悪性腫瘍	1 (<0.1%)	0
INFECTIOUS DISEASE	感染症	1 (<0.1%)	1 (<0.1%)

表 2.7.4.7-29 死亡に至った有害事象（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} Cause of death by CIAC		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
Acute respiratory failure	急性呼吸不全	0	3 (0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
OTHER RESPIRATORY FAILURE	その他の呼吸不全	0	1 (<0.1%)
CACHEXIA	悪液質	0	1 (<0.1%)
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	0	1 (<0.1%)
OTHER RESPIRATORY FAILURE	その他の呼吸不全	0	1 (<0.1%)
Dyspnoea	呼吸困難	1 (<0.1%)	0
CANCER	悪性腫瘍	1 (<0.1%)	0
Interstitial lung disease	間質性肺疾患	1 (<0.1%)	0
INFECTIOUS DISEASE	感染症	1 (<0.1%)	0
Pleural effusion	胸水	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Pleurisy	胸膜炎	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)
Pulmonary embolism	肺塞栓症	6 (0.2%)	1 (<0.1%)
PULMONARY EMBOLISM	肺塞栓症	3 (0.1%)	1 (<0.1%)
UNEXPLAINED DEATH AND PE CANNOT BE RULED OUT	PE の可能性が否定できない原因不明の死亡	2 (<0.1%)	0
OTHER VASCULAR EVENT	その他の心血管事象	1 (<0.1%)	0
Pulmonary haemorrhage	肺出血	1 (<0.1%)	0
INFECTIOUS DISEASE	感染症	1 (<0.1%)	0
Respiratory arrest	呼吸停止	0	1 (<0.1%)
UNEXPLAINED DEATH AND PE CANNOT BE RULED OUT	PE の可能性が否定できない原因不明の死亡	0	1 (<0.1%)
Respiratory failure	呼吸不全	0	5 (0.2%)
CANCER	悪性腫瘍	0	1 (<0.1%)
UNEXPLAINED DEATH AND PE CANNOT BE RULED OUT	PE の可能性が否定できない原因不明の死亡	0	2 (<0.1%)
INFECTIOUS DISEASE	感染症	0	1 (<0.1%)
OTHER RESPIRATORY FAILURE	その他の呼吸不全	0	1 (<0.1%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	1 (<0.1%)	0
Dermatomyositis	皮膚筋炎	1 (<0.1%)	0
INFLAMMATORY DISEASE	炎症性疾患	1 (<0.1%)	0
Vascular disorders	血管障害	1 (<0.1%)	1 (<0.1%)
Circulatory collapse	循環虚脱	1 (<0.1%)	0

表 2.7.4.7-29 死亡に至った有害事象（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} Cause of death by CIAC		Rivaroxaban N=2412 (100%)	Enoxaparin/VKA N=2405 (100%)
HEART FAILURE	心不全	1 (<0.1%)	0
Hypovolaemic shock	血液量減少性ショック	0	1 (<0.1%)
CANCER	悪性腫瘍	0	1 (<0.1%)

Note: SOC = System Organ Class
Note: Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more clinical AEs, the subject is counted only once in a category. The same subject may appear in different categories.
Note: The AEs include all AEs with outcome of death.
Note: Percentages calculated with the number of subjects in each group as denominator. Sorted first by SOC (alphab. order) then by preferred term (alphab. order).
Note: CIAC: Central Independent Adjudication Committee.
Global Biostatistics: /by-sasp/patdb/projects/597939/11702_pe/stat/prod/pgms/t-ae-incidence-1.sas sgqaz 12MAR2012 19:23
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表 2.7.4.7-30　治験薬投与後のその他の抗凝固療法（試験 11702_DVT、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）

ANTICOAGULANT MEDICATION	Rivaroxaban N=1260 (100%)	Enoxaparin/VKA N=1214 (100%)	Total N=2474 (100%)
Any medication	230 (18.3%)	414 (34.1%)	644 (26.0%)
VKA	195 (15.5%)	384 (31.6%)	579 (23.4%)
UFH	8 (0.6%)	3 (0.2%)	11 (0.4%)
LMWH	104 (8.3%)	47 (3.9%)	151 (6.1%)
Fondaparinux	12 (1.0%)	1 (<0.1%)	13 (0.5%)

Anticoagulant drugs are selected by ATC codes (see additional SAP).
If the above drugs meet the following condition, these drugs are treated as taken after study medication.
End date of study treatment < end date of the above concomitant medication drugs or end date of study treatment < start date of the above concomitant medication drugs.
Ongoing status at subject's last visit will be also considered.
The patients who completed' means the patients completed intended treatment duration without primary efficacy outcome, death (scope: intended treatment duration) and/or termination by sponsor.
GB: .../projects/597939/11702_meta/stat/prod_query41/pgms/t-adsl-pmda-posthoc-other-anticoagulant.sas　erjli　06MAR2014 17:24
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引用元：5.3.5.1.43 Additional_22/Table/23

表 2.7.4.7-31　治験薬投与後のその他の抗凝固療法（試験 11702_PE、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）

ANTICOAGULANT MEDICATION	Rivaroxaban N=2003 (100%)	Enoxaparin/VKA N=1997 (100%)	Total N=4000 (100%)
Any medication	537 (26.8%)	839 (42.0%)	1376 (34.4%)
VKA	453 (22.6%)	764 (38.3%)	1217 (30.4%)
UFH	12 (0.6%)	14 (0.7%)	26 (0.7%)
LMWH	227 (11.3%)	107 (5.4%)	334 (8.4%)
Fondaparinux	46 (2.3%)	6 (0.3%)	52 (1.3%)

Anticoagulant drugs are selected by ATC codes (see additional SAP).
If the above drugs meet the following condition, these drugs are treated as taken after study medication.
End date of study treatment < end date of the above concomitant medication drugs or end date of study treatment < start date of the above concomitant medication drugs.
Ongoing status at subject's last visit will be also considered.
The patients who completed' means the patients completed intended treatment duration without primary efficacy outcome, death (scope: intended treatment duration) and/or termination by sponsor.
GB: .../projects/597939/11702_meta/stat/prod_query41/pgms/t-adsl-pmda-posthoc-other-anticoagulant.sas　erjli　06MAR2014 17:24
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引用元：5.3.5.1.43 Additional_22/Table/24

表 2.7.4.7-32　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_DVT、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）

Other anticoagulant medication after stopping study: NO			
	Rivaroxaban	Enoxaparin/VKA	Total
Sex			
N	1030 (100.0%)	800 (100.0%)	1830 (100.0%)
MALE	576 (55.9%)	452 (56.5%)	1028 (56.2%)
FEMALE	454 (44.1%)	348 (43.5%)	802 (43.8%)
Race			
N	1030 (100.0%)	800 (100.0%)	1830 (100.0%)
WHITE	778 (75.5%)	611 (76.4%)	1389 (75.9%)
BLACK	22 (2.1%)	15 (1.9%)	37 (2.0%)
ASIAN	152 (14.8%)	109 (13.6%)	261 (14.3%)
AMERICAN INDIAN OR ALASKA NATIVE	1 (<0.1%)	2 (0.3%)	3 (0.2%)
HISPANIC	6 (0.6%)	6 (0.8%)	12 (0.7%)
UNCODABLE	3 (0.3%)	1 (0.1%)	4 (0.2%)
N.A.	68 (6.6%)	56 (7.0%)	124 (6.8%)
Other anticoagulant medication after stopping study: YES			
Sex			
N	230 (100.0%)	414 (100.0%)	644 (100.0%)
MALE	142 (61.7%)	248 (59.9%)	390 (60.6%)
FEMALE	88 (38.3%)	166 (40.1%)	254 (39.4%)
Race			
N	230 (100.0%)	414 (100.0%)	644 (100.0%)
WHITE	190 (82.6%)	343 (82.9%)	533 (82.8%)
BLACK	2 (0.9%)	9 (2.2%)	11 (1.7%)
ASIAN	15 (6.5%)	31 (7.5%)	46 (7.1%)
AMERICAN INDIAN OR ALASKA NATIVE	0	0	0
HISPANIC	0	2 (0.5%)	2 (0.3%)
UNCODABLE	1 (0.4%)	1 (0.2%)	2 (0.3%)
N.A.	22 (9.6%)	28 (6.8%)	50 (7.8%)

表 2.7.4.7-32 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_DVT、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: NO			
	Rivaroxaban	Enoxaparin/VKA	Total
Calculated age at enrollment			
n	1030	800	1830
Nmiss	0	0	0
Mean	55.0	55.8	55.4
SD	16.5	16.3	16.4
Min	18	19	18
Q1	43.0	43.0	43.0
Median	56.0	57.0	56.0
Q3	68.0	69.0	68.0
Max	89	91	91
Age groups 1			
N	1030 (100.0%)	800 (100.0%)	1830 (100.0%)
missing	0	0	0
<18 years	0	0	0
18 - <40 years	198 (19.2%)	132 (16.5%)	330 (18.0%)
40 - <60 years	386 (37.5%)	318 (39.8%)	704 (38.5%)
60 - <75 years	309 (30.0%)	232 (29.0%)	541 (29.6%)
>=75 years	137 (13.3%)	118 (14.8%)	255 (13.9%)
Age groups 2			
N	1030 (100.0%)	800 (100.0%)	1830 (100.0%)
missing	0	0	0
<65 years	702 (68.2%)	534 (66.8%)	1236 (67.5%)
65 - 75 years	210 (20.4%)	163 (20.4%)	373 (20.4%)
>75 years	118 (11.5%)	103 (12.9%)	221 (12.1%)

表 2.7.4.7-32 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_DVT、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: NO			
	Rivaroxaban	Enoxaparin/VKA	Total
Weight (kg)			
n	1029	800	1829
Nmiss	1	0	1
Mean	81.54	81.63	81.58
SD	18.61	18.79	18.69
Min	33.0	41.0	33.0
Q1	69.00	69.25	69.00
Median	80.00	80.00	80.00
Q3	92.40	92.00	92.10
Max	192.8	163.5	192.8
Weight Group (multiple groups)			
N	1030 (100.0%)	800 (100.0%)	1830 (100.0%)
missing	1 (<0.1%)	0	1 (<0.1%)
<=50 kg	26 (2.5%)	26 (3.3%)	52 (2.8%)
>50-60 kg	111 (10.8%)	78 (9.8%)	189 (10.3%)
>60-70 kg	163 (15.8%)	129 (16.1%)	292 (16.0%)
>70-80 kg	235 (22.8%)	195 (24.4%)	430 (23.5%)
>80-90 kg	208 (20.2%)	153 (19.1%)	361 (19.7%)
>90-100 kg	152 (14.8%)	105 (13.1%)	257 (14.0%)
>100-110 kg	65 (6.3%)	61 (7.6%)	126 (6.9%)
>110 kg	69 (6.7%)	53 (6.6%)	122 (6.7%)
Height (cm)			
n	1026	796	1822
Nmiss	4	4	8
Mean	171.2	171.0	171.1
SD	10.4	9.9	10.1
Min	140	140	140
Q1	164.0	165.0	165.0
Median	171.0	170.2	170.8
Q3	178.0	178.0	178.0
Max	205	202	205

表 2.7.4.7-32 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_DVT、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: NO			
	Rivaroxaban	Enoxaparin/VKA	Total
Body Mass Index Calculated In House (kg/m2)			
n	1025	796	1821
Nmiss	5	4	9
Mean	27.72	27.81	27.76
SD	5.42	5.48	5.45
Min	14.9	16.5	14.9
Q1	23.90	24.10	24.00
Median	27.10	27.20	27.10
Q3	30.60	30.70	30.60
Max	56.8	61.9	61.9
BMI Group (multiple groups)			
N	1030 (100.0%)	800 (100.0%)	1830 (100.0%)
missing	5 (0.5%)	4 (0.5%)	9 (0.5%)
< 18.5 kg/m²	15 (1.5%)	9 (1.1%)	24 (1.3%)
18.5 - < 25 kg/m²	316 (30.7%)	253 (31.6%)	569 (31.1%)
25 - < 30 kg/m²	395 (38.3%)	298 (37.3%)	693 (37.9%)
30 - < 35 kg/m²	208 (20.2%)	158 (19.8%)	366 (20.0%)
35 - < 40 kg/m²	60 (5.8%)	55 (6.9%)	115 (6.3%)
>= 40 kg/m²	31 (3.0%)	23 (2.9%)	54 (3.0%)
Creatinine Clearance (Group multiple groups)			
N	1030 (100.0%)	800 (100.0%)	1830 (100.0%)
missing	10 (1.0%)	5 (0.6%)	15 (0.8%)
< 30 ml/min	2 (0.2%)	4 (0.5%)	6 (0.3%)
30 - < 50 ml/min	60 (5.8%)	47 (5.9%)	107 (5.8%)
50 - < 80 ml/min	232 (22.5%)	177 (22.1%)	409 (22.3%)
>= 80 ml/min	726 (70.5%)	567 (70.9%)	1293 (70.7%)

表 2.7.4.7-32　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_DVT、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: NO			
	Rivaroxaban	Enoxaparin/VKA	Total
Systolic Blood Pressure (mmHg)			
n	1027	789	1816
Nmiss	3	11	14
Mean	130.5	131.9	131.1
SD	16.3	16.3	16.3
Min	82	94	82
Q1	120.0	120.0	120.0
Median	130.0	130.0	130.0
Q3	140.0	140.0	140.0
Max	192	184	192
Diastolic Blood Pressure (mmHg)			
n	1027	788	1815
Nmiss	3	12	15
Mean	77.9	78.9	78.3
SD	9.9	10.4	10.1
Min	49	50	49
Q1	70.0	70.0	70.0
Median	80.0	80.0	80.0
Q3	84.0	85.0	85.0
Max	112	120	120

表 2.7.4.7-32　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_DVT、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: YES			
	Rivaroxaban	Enoxaparin/VKA	Total
Calculated age at enrollment			
n	230	414	644
Nmiss	0	0	0
Mean	57.0	56.6	56.7
SD	16.5	16.6	16.5
Min	18	19	18
Q1	45.0	45.0	45.0
Median	59.0	58.0	58.0
Q3	71.0	70.0	70.0
Max	92	92	92
Age groups 1			
N	230 (100.0%)	414 (100.0%)	644 (100.0%)
missing	0	0	0
<18 years	0	0	0
18 - <40 years	35 (15.2%)	71 (17.1%)	106 (16.5%)
40 - <60 years	83 (36.1%)	153 (37.0%)	236 (36.6%)
60 - <75 years	82 (35.7%)	128 (30.9%)	210 (32.6%)
>=75 years	30 (13.0%)	62 (15.0%)	92 (14.3%)
Age groups 2			
N	230 (100.0%)	414 (100.0%)	644 (100.0%)
missing	0	0	0
<65 years	144 (62.6%)	258 (62.3%)	402 (62.4%)
65 - 75 years	61 (26.5%)	99 (23.9%)	160 (24.8%)
>75 years	25 (10.9%)	57 (13.8%)	82 (12.7%)

表 2.7.4.7-32 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_DVT、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: YES			
	Rivaroxaban	Enoxaparin/VKA	Total
Weight (kg)			
n	229	414	643
Nmiss	1	0	1
Mean	83.49	83.16	83.28
SD	17.35	19.10	18.49
Min	48.0	34.1	34.1
Q1	71.00	70.00	70.00
Median	82.00	80.00	80.29
Q3	93.00	94.00	94.00
Max	150.0	162.0	162.0
Weight Group (multiple groups)			
N	230 (100.0%)	414 (100.0%)	644 (100.0%)
missing	1 (0.4%)	0	1 (0.2%)
<=50 kg	1 (0.4%)	4 (1.0%)	5 (0.8%)
>50-60 kg	16 (7.0%)	37 (8.9%)	53 (8.2%)
>60-70 kg	40 (17.4%)	77 (18.6%)	117 (18.2%)
>70-80 kg	50 (21.7%)	96 (23.2%)	146 (22.7%)
>80-90 kg	57 (24.8%)	74 (17.9%)	131 (20.3%)
>90-100 kg	26 (11.3%)	63 (15.2%)	89 (13.8%)
>100-110 kg	25 (10.9%)	32 (7.7%)	57 (8.9%)
>110 kg	14 (6.1%)	31 (7.5%)	45 (7.0%)
Height (cm)			
n	229	413	642
Nmiss	1	1	2
Mean	172.7	172.2	172.3
SD	9.9	9.8	9.8
Min	152	148	148
Q1	165.0	165.0	165.0
Median	173.0	172.0	172.0
Q3	179.0	180.0	180.0
Max	204	198	204

表 2.7.4.7-32 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_DVT、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: YES			
	Rivaroxaban	Enoxaparin/VKA	Total
Body Mass Index Calculated In House (kg/m2)			
n	228	413	641
Nmiss	2	1	3
Mean	27.95	27.95	27.95
SD	5.06	5.50	5.35
Min	18.0	13.3	13.3
Q1	24.20	24.30	24.20
Median	27.55	27.30	27.30
Q3	30.70	30.40	30.50
Max	50.1	64.9	64.9
BMI Group (multiple groups)			
N	230 (100.0%)	414 (100.0%)	644 (100.0%)
missing	2 (0.9%)	1 (0.2%)	3 (0.5%)
< 18.5 kg/m²	1 (0.4%)	4 (1.0%)	5 (0.8%)
18.5 - < 25 kg/m²	71 (30.9%)	130 (31.4%)	201 (31.2%)
25 - < 30 kg/m²	88 (38.3%)	162 (39.1%)	250 (38.8%)
30 - < 35 kg/m²	50 (21.7%)	75 (18.1%)	125 (19.4%)
35 - < 40 kg/m²	11 (4.8%)	31 (7.5%)	42 (6.5%)
>= 40 kg/m²	7 (3.0%)	11 (2.7%)	18 (2.8%)
Creatinine Clearance (Group multiple groups)			
N	230 (100.0%)	414 (100.0%)	644 (100.0%)
missing	4 (1.7%)	7 (1.7%)	11 (1.7%)
< 30 ml/min	1 (0.4%)	0	1 (0.2%)
30 - < 50 ml/min	13 (5.7%)	33 (8.0%)	46 (7.1%)
50 - < 80 ml/min	50 (21.7%)	99 (23.9%)	149 (23.1%)
>= 80 ml/min	162 (70.4%)	275 (66.4%)	437 (67.9%)

表 2.7.4.7-32 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_DVT、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: YES			
	Rivaroxaban	Enoxaparin/VKA	Total
Systolic Blood Pressure (mmHg)			
n	228	412	640
Nmiss	2	2	4
Mean	131.9	131.9	131.9
SD	17.4	16.8	17.0
Min	80	91	80
Q1	120.0	120.0	120.0
Median	130.0	130.0	130.0
Q3	141.0	140.0	140.0
Max	180	200	200
Diastolic Blood Pressure (mmHg)			
n	228	412	640
Nmiss	2	2	4
Mean	78.3	78.2	78.3
SD	10.5	10.4	10.4
Min	50	46	46
Q1	70.0	70.0	70.0
Median	80.0	80.0	80.0
Q3	85.0	85.0	85.0
Max	110	110	110

表 2.7.4.7-32 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_DVT、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

	Rivaroxaban	Enoxaparin/VKA	Total
Other anticoagulant medication after stopping study: NO			
N	1030 (100.0%)	800 (100.0%)	1830 (100.0%)
Any elevated LFT as defined in protocol			
missing	686 (66.6%)	496 (62.0%)	1182 (64.6%)
NO	305 (29.6%)	241 (30.1%)	546 (29.8%)
YES	39 (3.8%)	63 (7.9%)	102 (5.6%)
missing	0	0	0
N.A.	1 (<0.1%)	1 (0.1%)	2 (0.1%)
ABSTINENT	15 (1.5%)	22 (2.8%)	37 (2.0%)
LIGHT ALCOHOL CONSUMPTION	17 (1.7%)	27 (3.4%)	44 (2.4%)
MODERATE ALCOHOL CONSUMPTION	5 (0.5%)	8 (1.0%)	13 (0.7%)
HEAVY ALCOHOL CONSUMPTION	1 (<0.1%)	5 (0.6%)	6 (0.3%)
Other anticoagulant medication after stopping study: YES			
N	230 (100.0%)	414 (100.0%)	644 (100.0%)
Any elevated LFT as defined in protocol			
missing	140 (60.9%)	257 (62.1%)	397 (61.6%)
NO	73 (31.7%)	124 (30.0%)	197 (30.6%)
YES	17 (7.4%)	33 (8.0%)	50 (7.8%)
missing	0	0	0
N.A.	1 (0.4%)	1 (0.2%)	2 (0.3%)
ABSTINENT	5 (2.2%)	14 (3.4%)	19 (3.0%)
LIGHT ALCOHOL CONSUMPTION	9 (3.9%)	17 (4.1%)	26 (4.0%)
MODERATE ALCOHOL CONSUMPTION	1 (0.4%)	1 (0.2%)	2 (0.3%)
HEAVY ALCOHOL CONSUMPTION	1 (0.4%)	0	1 (0.2%)

Note: Creatinine clearance levels were calculated using the equation of Cockroft and Gault, using the last value up to the day of randomization.
Note: Percentages are calculated including missing values.
Note: N.A. in race is not answered due to legal reasons.
Note: Q1 = 25th percentile, Q3 = 75th percentile.
Note: Treatment groups for the safety population are displayed as study treatment administered (not as randomized).
Note: Anticoagulant drugs are selected by ATC codes (see additional SAP). If the above drugs meet the following condition, these drugs are treated as taken after study medication. End date of study treatment < end date of the above concomitant medication drugs or end date of study treatment < start date of the above concomitant medication drugs. Ongoing status at subject's last visit will be also considered.
The patients who completed' means the patients completed intended treatment duration without primary efficacy outcome, death (scope: intended treatment duration) and/or termination by sponsor.
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表 2.7.4.7-33 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_PE、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）

Other anticoagulant medication after stopping study: NO			
	Rivaroxaban	Enoxaparin/VKA	Total
Sex			
N	1466 (100.0%)	1158 (100.0%)	2624 (100.0%)
MALE	763 (52.0%)	586 (50.6%)	1349 (51.4%)
FEMALE	703 (48.0%)	572 (49.4%)	1275 (48.6%)
Race			
N	1466 (100.0%)	1158 (100.0%)	2624 (100.0%)
WHITE	956 (65.2%)	733 (63.3%)	1689 (64.4%)
BLACK	42 (2.9%)	43 (3.7%)	85 (3.2%)
ASIAN	99 (6.8%)	81 (7.0%)	180 (6.9%)
HISPANIC	5 (0.3%)	9 (0.8%)	14 (0.5%)
NATIVE HAWAIIAN OR OTH. PACIFIC ISLANDER	0	2 (0.2%)	2 (<0.1%)
UNCODABLE	3 (0.2%)	1 (<0.1%)	4 (0.2%)
N.A.	361 (24.6%)	289 (25.0%)	650 (24.8%)
Other anticoagulant medication after stopping study: YES			
Sex			
N	537 (100.0%)	839 (100.0%)	1376 (100.0%)
MALE	296 (55.1%)	442 (52.7%)	738 (53.6%)
FEMALE	241 (44.9%)	397 (47.3%)	638 (46.4%)
Race			
N	537 (100.0%)	839 (100.0%)	1376 (100.0%)
WHITE	350 (65.2%)	555 (66.2%)	905 (65.8%)
BLACK	11 (2.0%)	10 (1.2%)	21 (1.5%)
ASIAN	32 (6.0%)	46 (5.5%)	78 (5.7%)
HISPANIC	3 (0.6%)	1 (0.1%)	4 (0.3%)
NATIVE HAWAIIAN OR OTH. PACIFIC ISLANDER	3 (0.6%)	0	3 (0.2%)
UNCODABLE	1 (0.2%)	2 (0.2%)	3 (0.2%)
N.A.	137 (25.5%)	225 (26.8%)	362 (26.3%)

表 2.7.4.7-33 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_PE、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: NO			
	Rivaroxaban	Enoxaparin/VKA	Total
Calculated age at enrollment			
n	1466	1158	2624
Nmiss	0	0	0
Mean	56.9	55.8	56.4
SD	17.3	17.2	17.2
Min	18	18	18
Q1	45.0	43.0	44.0
Median	58.0	58.0	58.0
Q3	71.0	70.0	70.0
Max	92	93	93
Age groups 1			
N	1466 (100.0%)	1158 (100.0%)	2624 (100.0%)
missing	0	0	0
<18 years	0	0	0
18 - <40 years	263 (17.9%)	241 (20.8%)	504 (19.2%)
40 - <60 years	513 (35.0%)	384 (33.2%)	897 (34.2%)
60 - <75 years	422 (28.8%)	351 (30.3%)	773 (29.5%)
>=75 years	268 (18.3%)	182 (15.7%)	450 (17.1%)
Age groups 2			
N	1466 (100.0%)	1158 (100.0%)	2624 (100.0%)
missing	0	0	0
<65 years	937 (63.9%)	758 (65.5%)	1695 (64.6%)
65 - 75 years	284 (19.4%)	236 (20.4%)	520 (19.8%)
>75 years	245 (16.7%)	164 (14.2%)	409 (15.6%)

表 2.7.4.7-33 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_PE、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: NO			
	Rivaroxaban	Enoxaparin/VKA	Total
Weight (kg)			
n	1464	1158	2622
Nmiss	2	0	2
Mean	82.36	82.67	82.49
SD	18.83	18.28	18.59
Min	40.0	40.0	40.0
Q1	70.00	70.00	70.00
Median	80.00	80.00	80.00
Q3	92.00	92.00	92.00
Max	180.0	172.0	180.0
Weight Group (multiple groups)			
N	1466 (100.0%)	1158 (100.0%)	2624 (100.0%)
missing	2 (0.1%)	0	2 (<0.1%)
<=50 kg	23 (1.6%)	16 (1.4%)	39 (1.5%)
>50-60 kg	124 (8.5%)	92 (7.9%)	216 (8.2%)
>60-70 kg	267 (18.2%)	196 (16.9%)	463 (17.6%)
>70-80 kg	335 (22.9%)	290 (25.0%)	625 (23.8%)
>80-90 kg	316 (21.6%)	246 (21.2%)	562 (21.4%)
>90-100 kg	207 (14.1%)	151 (13.0%)	358 (13.6%)
>100-110 kg	87 (5.9%)	94 (8.1%)	181 (6.9%)
>110 kg	105 (7.2%)	73 (6.3%)	178 (6.8%)
Height (cm)			
n	1460	1152	2612
Nmiss	6	6	12
Mean	171.0	171.2	171.1
SD	9.6	10.3	9.9
Min	140	140	140
Q1	164.0	164.0	164.0
Median	170.0	170.0	170.0
Q3	178.0	179.0	178.0
Max	203	205	205

表 2.7.4.7-33 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_PE、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: NO			
	Rivaroxaban	Enoxaparin/VKA	Total
Body Mass Index Calculated In House (kg/m2)			
n	1460	1152	2612
Nmiss	6	6	12
Mean	28.116	28.198	28.152
SD	5.771	5.672	5.727
Min	16.30	15.90	15.90
Q1	24.300	24.700	24.500
Median	27.200	27.100	27.200
Q3	30.700	30.900	30.800
Max	60.60	63.30	63.30
BMI Group (multiple groups)			
N	1466 (100.0%)	1158 (100.0%)	2624 (100.0%)
missing	6 (0.4%)	6 (0.5%)	12 (0.5%)
< 18.5 kg/m²	15 (1.0%)	14 (1.2%)	29 (1.1%)
18.5 - < 25 kg/m²	426 (29.1%)	301 (26.0%)	727 (27.7%)
25 - < 30 kg/m²	581 (39.6%)	491 (42.4%)	1072 (40.9%)
30 - < 35 kg/m²	282 (19.2%)	225 (19.4%)	507 (19.3%)
35 - < 40 kg/m²	96 (6.5%)	78 (6.7%)	174 (6.6%)
>= 40 kg/m²	60 (4.1%)	43 (3.7%)	103 (3.9%)
Creatinine Clearance (Group multiple groups)			
N	1466 (100.0%)	1158 (100.0%)	2624 (100.0%)
missing	10 (0.7%)	3 (0.3%)	13 (0.5%)
< 30 ml/min	3 (0.2%)	0	3 (0.1%)
30 - < 50 ml/min	118 (8.0%)	78 (6.7%)	196 (7.5%)
50 - < 80 ml/min	360 (24.6%)	276 (23.8%)	636 (24.2%)
>= 80 ml/min	975 (66.5%)	801 (69.2%)	1776 (67.7%)

表 2.7.4.7-33　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_PE、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: NO			
	Rivaroxaban	Enoxaparin/VKA	Total
Systolic Blood Pressure (mmHg)			
n	1462	1157	2619
Nmiss	4	1	5
Mean	128.9	129.5	129.2
SD	17.2	17.2	17.2
Min	84	80	80
Q1	118.0	119.0	118.0
Median	128.0	130.0	130.0
Q3	140.0	140.0	140.0
Max	180	180	180
Diastolic Blood Pressure (mmHg)			
n	1462	1157	2619
Nmiss	4	1	5
Mean	76.4	76.2	76.3
SD	11.7	11.1	11.4
Min	43	36	36
Q1	70.0	70.0	70.0
Median	78.0	77.0	77.0
Q3	84.0	82.0	83.0
Max	120	110	120

表 2.7.4.7-33　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_PE、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: YES			
	Rivaroxaban	Enoxaparin/VKA	Total
Calculated age at enrollment			
n	537	839	1376
Nmiss	0	0	0
Mean	59.4	58.6	58.9
SD	17.1	16.8	16.9
Min	18	18	18
Q1	47.0	47.0	47.0
Median	62.0	60.0	61.0
Q3	72.0	72.0	72.0
Max	97	95	97
Age groups 1			
N	537 (100.0%)	839 (100.0%)	1376 (100.0%)
missing	0	0	0
<18 years	0	0	0
18 - <40 years	84 (15.6%)	130 (15.5%)	214 (15.6%)
40 - <60 years	154 (28.7%)	271 (32.3%)	425 (30.9%)
60 - <75 years	190 (35.4%)	274 (32.7%)	464 (33.7%)
>=75 years	109 (20.3%)	164 (19.5%)	273 (19.8%)
Age groups 2			
N	537 (100.0%)	839 (100.0%)	1376 (100.0%)
missing	0	0	0
<65 years	289 (53.8%)	493 (58.8%)	782 (56.8%)
65 - 75 years	146 (27.2%)	199 (23.7%)	345 (25.1%)
>75 years	102 (19.0%)	147 (17.5%)	249 (18.1%)

表 2.7.4.7-33 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_PE、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: YES			
	Rivaroxaban	Enoxaparin/VKA	Total
Weight (kg)			
n	537	839	1376
Nmiss	0	0	0
Mean	84.81	84.09	84.37
SD	20.11	18.69	19.25
Min	38.1	41.2	38.1
Q1	71.00	71.00	71.00
Median	81.20	82.00	82.00
Q3	95.00	95.00	95.00
Max	169.9	166.0	169.9
Weight Group (multiple groups)			
N	537 (100.0%)	839 (100.0%)	1376 (100.0%)
missing	0	0	0
<=50 kg	7 (1.3%)	13 (1.5%)	20 (1.5%)
>50-60 kg	34 (6.3%)	59 (7.0%)	93 (6.8%)
>60-70 kg	85 (15.8%)	133 (15.9%)	218 (15.8%)
>70-80 kg	138 (25.7%)	186 (22.2%)	324 (23.5%)
>80-90 kg	100 (18.6%)	201 (24.0%)	301 (21.9%)
>90-100 kg	82 (15.3%)	113 (13.5%)	195 (14.2%)
>100-110 kg	44 (8.2%)	66 (7.9%)	110 (8.0%)
>110 kg	47 (8.8%)	68 (8.1%)	115 (8.4%)
Height (cm)			
n	534	836	1370
Nmiss	3	3	6
Mean	171.2	171.2	171.2
SD	10.0	9.7	9.9
Min	140	147	140
Q1	164.0	164.0	164.0
Median	170.1	171.0	170.2
Q3	178.0	178.0	178.0
Max	203	198	203

表 2.7.4.7-33 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_PE、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: YES			
	Rivaroxaban	Enoxaparin/VKA	Total
Body Mass Index Calculated In House (kg/m2)			
n	534	836	1370
Nmiss	3	3	6
Mean	28.89	28.65	28.74
SD	6.19	5.69	5.89
Min	17.3	16.1	16.1
Q1	24.70	24.80	24.80
Median	27.65	27.95	27.80
Q3	31.60	31.20	31.30
Max	58.0	54.9	58.0
BMI Group (multiple groups)			
N	537 (100.0%)	839 (100.0%)	1376 (100.0%)
missing	3 (0.6%)	3 (0.4%)	6 (0.4%)
< 18.5 kg/m²	1 (0.2%)	8 (1.0%)	9 (0.7%)
18.5 - < 25 kg/m²	147 (27.4%)	207 (24.7%)	354 (25.7%)
25 - < 30 kg/m²	200 (37.2%)	341 (40.6%)	541 (39.3%)
30 - < 35 kg/m²	112 (20.9%)	184 (21.9%)	296 (21.5%)
35 - < 40 kg/m²	47 (8.8%)	56 (6.7%)	103 (7.5%)
>= 40 kg/m²	27 (5.0%)	40 (4.8%)	67 (4.9%)
Creatinine Clearance (Group multiple groups)			
N	537 (100.0%)	839 (100.0%)	1376 (100.0%)
missing	3 (0.6%)	5 (0.6%)	8 (0.6%)
< 30 ml/min	0	1 (0.1%)	1 (<0.1%)
30 - < 50 ml/min	49 (9.1%)	70 (8.3%)	119 (8.6%)
50 - < 80 ml/min	157 (29.2%)	209 (24.9%)	366 (26.6%)
>= 80 ml/min	328 (61.1%)	554 (66.0%)	882 (64.1%)

表 2.7.4.7-33　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_PE、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: YES			
	Rivaroxaban	Enoxaparin/VKA	Total
Systolic Blood Pressure (mmHg)			
n	537	839	1376
Nmiss	0	0	0
Mean	130.6	129.8	130.1
SD	18.1	17.5	17.8
Min	88	84	84
Q1	119.0	118.0	118.0
Median	130.0	130.0	130.0
Q3	140.0	140.0	140.0
Max	180	200	200
Diastolic Blood Pressure (mmHg)			
n	537	839	1376
Nmiss	0	0	0
Mean	76.8	76.7	76.7
SD	10.9	10.8	10.8
Min	50	37	37
Q1	70.0	70.0	70.0
Median	79.0	78.0	78.0
Q3	84.0	84.0	84.0
Max	110	108	110

表 2.7.4.7-33 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 11702_PE、安全性解析対象集団：試験 11899 に参加しなかった被験者で、予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study: NO			
	Rivaroxaban	Enoxaparin/VKA	Total
N	1466 (100.0%)	1158 (100.0%)	2624 (100.0%)
Any elevated LFT as defined in protocol			
missing	887 (60.5%)	684 (59.1%)	1571 (59.9%)
NO	502 (34.2%)	402 (34.7%)	904 (34.5%)
YES	77 (5.3%)	72 (6.2%)	149 (5.7%)
missing	0	0	0
N.A.	3 (0.2%)	3 (0.3%)	6 (0.2%)
ABSTINENT	38 (2.6%)	36 (3.1%)	74 (2.8%)
LIGHT ALCOHOL CONSUMPTION	24 (1.6%)	26 (2.2%)	50 (1.9%)
MODERATE ALCOHOL CONSUMPTION	8 (0.5%)	5 (0.4%)	13 (0.5%)
HEAVY ALCOHOL CONSUMPTION	4 (0.3%)	2 (0.2%)	6 (0.2%)
Other anticoagulant medication after stopping study: YES			
N	537 (100.0%)	839 (100.0%)	1376 (100.0%)
Any elevated LFT as defined in protocol			
missing	317 (59.0%)	484 (57.7%)	801 (58.2%)
NO	187 (34.8%)	286 (34.1%)	473 (34.4%)
YES	33 (6.1%)	69 (8.2%)	102 (7.4%)
missing	0	0	0
N.A.	0	2 (0.2%)	2 (0.1%)
ABSTINENT	17 (3.2%)	43 (5.1%)	60 (4.4%)
LIGHT ALCOHOL CONSUMPTION	10 (1.9%)	14 (1.7%)	24 (1.7%)
MODERATE ALCOHOL CONSUMPTION	4 (0.7%)	9 (1.1%)	13 (0.9%)
HEAVY ALCOHOL CONSUMPTION	2 (0.4%)	1 (0.1%)	3 (0.2%)

Note: Creatinine clearance levels were calculated using the equation of Cockroft and Gault, using the last value up to the day of randomization.
Note: Percentages are calculated including missing values.
Note: N.A. in race is not answered due to legal reasons.
Note: Q1 = 25th percentile, Q3 = 75th percentile.
Note: Treatment groups for the safety population are displayed as study treatment administered (not as randomized).
Note: Anticoagulant drugs are selected by ATC codes (see additional SAP). If the above drugs meet the following condition, these drugs are treated as taken after study medication. End date of study treatment < end date of the above concomitant medication drugs or end date of study treatment < start date of the above concomitant medication drugs. Ongoing status at subject's last visit will be also considered.
The patients who completed' means the patients completed intended treatment duration without primary efficacy outcome, death (scope: intended treatment duration) and/or termination by sponsor.
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表 2.7.4.7-34　ベースライン時の CL_{CR} 別の AE の要約（試験 11702-DVT と試験 11702-PE の統合解析、安全性解析対象集団）

Creatinine Clearance: Missing		
Adverse event summary	Rivaroxaban N=38 (100%)	Enoxaparin/VKA N=27 (100%)
Any adverse event	28 (73.7%)	18 (66.7%)
Any adverse event starting >2 days after stop of study drug	4 (10.5%)	2 (7.4%)
Any drug-related adverse event	9 (23.7%)	3 (11.1%)
Any drug-related adverse event starting >2 days after stop of study drug	0	0
Any serious adverse event	4 (10.5%)	1 (3.7%)
Any serious adverse event starting >2 days after stop of study drug	0	1 (3.7%)
Any drug-related serious adverse event	0	0
Any drug-related serious adverse event starting >2 days after stop of study drug	0	0
Any bleeding adverse event (investigator reported)*	12 (31.6%)	5 (18.5%)
Any death	0	0
Any treatment-emergent adverse event (time window: 2 days)	26 (68.4%)	18 (66.7%)
Any treatment-emergent adverse event (time window: 7 days)	26 (68.4%)	18 (66.7%)
Any treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	25 (65.8%)	18 (66.7%)
Any treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	25 (65.8%)	18 (66.7%)
Any treatment-emergent bleeding adverse event (investigator reported, time window: 2 days) *	11 (28.9%)	5 (18.5%)
Any drug-related treatment-emergent adverse event (time windows: 2 days)	9 (23.7%)	3 (11.1%)
Any drug-related treatment-emergent adverse event (time windows: 7 days)	9 (23.7%)	3 (11.1%)
Any drug-related treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	3 (7.9%)	1 (3.7%)
Any drug-related treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	3 (7.9%)	1 (3.7%)
Any drug-related treatment-emergent bleeding adverse event (windows: 2 days) *	7 (18.4%)	2 (7.4%)
Any treatment-emergent serious adverse event (windows: 2 days)	4 (10.5%)	1 (3.7%)
Any treatment-emergent serious adverse event (windows: 7 days)	4 (10.5%)	1 (3.7%)
Any treatment-emergent serious adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	4 (10.5%)	1 (3.7%)
Any treatment-emergent serious adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	4 (10.5%)	1 (3.7%)
Any treatment-emergent bleeding serious adverse event (time windows: 2 days) *	0	0
Any drug-related treatment-emergent serious adverse event (time windows: 2 days)	0	0
Any drug-related treatment-emergent serious adverse event (time windows: 7 days)	0	0
Any adverse event resulting in permanent discontinuation of study drug	2 (5.3%)	1 (3.7%)
Any bleeding adverse event resulting in permanent discontinuation of study drug	1 (2.6%)	1 (3.7%)
Any adverse event leading to (prolonged) hospitalization	4 (10.5%)	1 (3.7%)

表 2.7.4.7-34　ベースライン時の CLCR 別の AE の要約（試験 11702-DVT と試験 11702-PE の統合解析、安全性解析対象集団）（続き）

Creatinine Clearance: <50 ml/min		
Adverse event summary	Rivaroxaban N=329 (100%)	Enoxaparin/VKA N=320 (100%)
Any adverse event	260 (79.0%)	238 (74.4%)
Any adverse event starting >2 days after stop of study drug	43 (13.1%)	41 (12.8%)
Any drug-related adverse event	94 (28.6%)	92 (28.8%)
Any drug-related adverse event starting >2 days after stop of study drug	5 (1.5%)	10 (3.1%)
Any serious adverse event	99 (30.1%)	105 (32.8%)
Any serious adverse event starting >2 days after stop of study drug	19 (5.8%)	18 (5.6%)
Any drug-related serious adverse event	22 (6.7%)	30 (9.4%)
Any drug-related serious adverse event starting >2 days after stop of study drug	0	4 (1.3%)
Any bleeding adverse event (investigator reported)*	113 (34.3%)	96 (30.0%)
Any death	24 (7.3%)	28 (8.8%)
Any treatment-emergent adverse event (time window: 2 days)	257 (78.1%)	234 (73.1%)
Any treatment-emergent adverse event (time window: 7 days)	257 (78.1%)	234 (73.1%)
Any treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	242 (73.6%)	226 (70.6%)
Any treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	243 (73.9%)	227 (70.9%)
Any treatment-emergent bleeding adverse event (investigator reported, time window: 2 days) *	109 (33.1%)	90 (28.1%)
Any drug-related treatment-emergent adverse event (time windows: 2 days)	94 (28.6%)	88 (27.5%)
Any drug-related treatment-emergent adverse event (time windows: 7 days)	94 (28.6%)	88 (27.5%)
Any drug-related treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	39 (11.9%)	37 (11.6%)
Any drug-related treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	39 (11.9%)	37 (11.6%)
Any drug-related treatment-emergent bleeding adverse event (windows: 2 days) *	67 (20.4%)	62 (19.4%)
Any treatment-emergent serious adverse event (windows: 2 days)	91 (27.7%)	98 (30.6%)
Any treatment-emergent serious adverse event (windows: 7 days)	92 (28.0%)	100 (31.3%)
Any treatment-emergent serious adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	82 (24.9%)	83 (25.9%)
Any treatment-emergent serious adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	83 (25.2%)	85 (26.6%)
Any treatment-emergent bleeding serious adverse event (time windows: 2 days) *	18 (5.5%)	27 (8.4%)
Any drug-related treatment-emergent serious adverse event (time windows: 2 days)	22 (6.7%)	26 (8.1%)
Any drug-related treatment-emergent serious adverse event (time windows: 7 days)	22 (6.7%)	27 (8.4%)
Any adverse event resulting in permanent discontinuation of study drug	32 (9.7%)	36 (11.3%)
Any bleeding adverse event resulting in permanent discontinuation of study drug	5 (1.5%)	14 (4.4%)
Any adverse event leading to (prolonged) hospitalization	79 (24.0%)	89 (27.8%)

表 2.7.4.7-34　ベースライン時の CLCR 別の AE の要約（試験 11702-DVT と試験 11702-PE の統合解析、安全性解析対象集団）（続き）

Creatinine Clearance: >50 ml/min		
Adverse event summary	Rivaroxaban N=3763 (100%)	Enoxaparin/VKA N=3769 (100%)
Any adverse event	2774 (73.7%)	2779 (73.7%)
Any adverse event starting >2 days after stop of study drug	437 (11.6%)	448 (11.9%)
Any drug-related adverse event	1081 (28.7%)	1113 (29.5%)
Any drug-related adverse event starting >2 days after stop of study drug	39 (1.0%)	46 (1.2%)
Any serious adverse event	623 (16.6%)	645 (17.1%)
Any serious adverse event starting >2 days after stop of study drug	79 (2.1%)	101 (2.7%)
Any drug-related serious adverse event	135 (3.6%)	145 (3.8%)
Any drug-related serious adverse event starting >2 days after stop of study drug	2 (<0.1%)	5 (0.1%)
Any bleeding adverse event (investigator reported)*	1149 (30.5%)	1166 (30.9%)
Any death	80 (2.1%)	75 (2.0%)
Any treatment-emergent adverse event (time window: 2 days)	2732 (72.6%)	2729 (72.4%)
Any treatment-emergent adverse event (time window: 7 days)	2739 (72.8%)	2737 (72.6%)
Any treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	2574 (68.4%)	2575 (68.3%)
Any treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	2584 (68.7%)	2585 (68.6%)
Any treatment-emergent bleeding adverse event (investigator reported, time window: 2 days) *	1115 (29.6%)	1111 (29.5%)
Any drug-related treatment-emergent adverse event (time windows: 2 days)	1074 (28.5%)	1087 (28.8%)
Any drug-related treatment-emergent adverse event (time windows: 7 days)	1075 (28.6%)	1094 (29.0%)
Any drug-related treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	445 (11.8%)	443 (11.8%)
Any drug-related treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	446 (11.9%)	445 (11.8%)
Any drug-related treatment-emergent bleeding adverse event (windows: 2 days) *	808 (21.5%)	811 (21.5%)
Any treatment-emergent serious adverse event (windows: 2 days)	583 (15.5%)	597 (15.8%)
Any treatment-emergent serious adverse event (windows: 7 days)	588 (15.6%)	609 (16.2%)
Any treatment-emergent serious adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	506 (13.4%)	529 (14.0%)
Any treatment-emergent serious adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	514 (13.7%)	541 (14.4%)
Any treatment-emergent bleeding serious adverse event (time windows: 2 days) *	123 (3.3%)	131 (3.5%)
Any drug-related treatment-emergent serious adverse event (time windows: 2 days)	132 (3.5%)	143 (3.8%)
Any drug-related treatment-emergent serious adverse event (time windows: 7 days)	132 (3.5%)	143 (3.8%)
Any adverse event resulting in permanent discontinuation of study drug	174 (4.6%)	143 (3.8%)
Any bleeding adverse event resulting in permanent discontinuation of study drug	65 (1.7%)	46 (1.2%)

表 2.7.4.7-34　ベースライン時の CLCR 別の AE の要約（試験 11702-DVT と試験 11702-PE の統合解析、安全性解析対象集団）（続き）

Creatinine Clearance: >50 ml/min		
Adverse event summary	Rivaroxaban N=3763 (100%)	Enoxaparin/VKA N=3769 (100%)
Any adverse event leading to (prolonged) hospitalization	535 (14.2%)	551 (14.6%)

Note: Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more clinical AEs, the subject is counted only once in a category. The same subject may appear in different categories.
Note: *Bleeding events reported on the specific adverse event CRF section.
Note: Treatment-emergent AE is defined as the AE occurred after randomization and up to the respective time window after the last dose of study drug.
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表 2.7.4.7-35　ベースライン時の ALT 別の AE の要約（試験 11702-DVT と試験 11702-PE の統合解析、安全性解析対象集団）

Baseline ALT: Missing

Adverse event summary	Rivaroxaban N=7 (100%)	Enoxaparin/VKA N=16 (100%)
Any adverse event	7 (100.0%)	11 (68.8%)
Any adverse event starting >2 days after stop of study drug	3 (42.9%)	0
Any drug-related adverse event	3 (42.9%)	3 (18.8%)
Any drug-related adverse event starting >2 days after stop of study drug	1 (14.3%)	0
Any serious adverse event	3 (42.9%)	2 (12.5%)
Any serious adverse event starting >2 days after stop of study drug	1 (14.3%)	0
Any drug-related serious adverse event	0	0
Any drug-related serious adverse event starting >2 days after stop of study drug	0	0
Any bleeding adverse event (investigator reported)*	3 (42.9%)	3 (18.8%)
Any death	1 (14.3%)	0
Any treatment-emergent adverse event (time window: 2 days)	6 (85.7%)	11 (68.8%)
Any treatment-emergent adverse event (time window: 7 days)	6 (85.7%)	11 (68.8%)
Any treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	6 (85.7%)	10 (62.5%)
Any treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	6 (85.7%)	10 (62.5%)
Any treatment-emergent bleeding adverse event (investigator reported, time window: 2 days) *	1 (14.3%)	3 (18.8%)
Any drug-related treatment-emergent adverse event (time windows: 2 days)	2 (28.6%)	3 (18.8%)
Any drug-related treatment-emergent adverse event (time windows: 7 days)	2 (28.6%)	3 (18.8%)
Any drug-related treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	1 (14.3%)	1 (6.3%)
Any drug-related treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	1 (14.3%)	1 (6.3%)
Any drug-related treatment-emergent bleeding adverse event (windows: 2 days) *	1 (14.3%)	2 (12.5%)
Any treatment-emergent serious adverse event (windows: 2 days)	2 (28.6%)	2 (12.5%)
Any treatment-emergent serious adverse event (windows: 7 days)	2 (28.6%)	2 (12.5%)
Any treatment-emergent serious adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	2 (28.6%)	2 (12.5%)
Any treatment-emergent serious adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	2 (28.6%)	2 (12.5%)
Any treatment-emergent bleeding serious adverse event (time windows: 2 days) *	0	0
Any drug-related treatment-emergent serious adverse event (time windows: 2 days)	0	0
Any drug-related treatment-emergent serious adverse event (time windows: 7 days)	0	0
Any adverse event resulting in permanent discontinuation of study drug	1 (14.3%)	0
Any bleeding adverse event resulting in permanent discontinuation of study drug	0	0
Any adverse event leading to (prolonged) hospitalization	2 (28.6%)	2 (12.5%)

表 2.7.4.7-35　ベースライン時の ALT 別の AE の要約（試験 11702-DVT と試験 11702-PE の統合解析、安全性解析対象集団）（続き）

Baseline ALT: Baseline ALT <= upper limit of normal range

Adverse event summary	Rivaroxaban N=3687 (100%)	Enoxaparin/VKA N=3673 (100%)
Any adverse event	2717 (73.7%)	2699 (73.5%)
Any adverse event starting >2 days after stop of study drug	439 (11.9%)	438 (11.9%)
Any drug-related adverse event	1056 (28.6%)	1073 (29.2%)
Any drug-related adverse event starting >2 days after stop of study drug	41 (1.1%)	50 (1.4%)
Any serious adverse event	634 (17.2%)	671 (18.3%)
Any serious adverse event starting >2 days after stop of study drug	90 (2.4%)	105 (2.9%)
Any drug-related serious adverse event	141 (3.8%)	153 (4.2%)
Any drug-related serious adverse event starting >2 days after stop of study drug	2 (<0.1%)	8 (0.2%)
Any bleeding adverse event (investigator reported)*	1137 (30.8%)	1122 (30.5%)
Any death	91 (2.5%)	86 (2.3%)
Any treatment-emergent adverse event (time window: 2 days)	2677 (72.6%)	2651 (72.2%)
Any treatment-emergent adverse event (time window: 7 days)	2684 (72.8%)	2658 (72.4%)
Any treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	2518 (68.3%)	2510 (68.3%)
Any treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	2529 (68.6%)	2520 (68.6%)
Any treatment-emergent bleeding adverse event (investigator reported, time window: 2 days) *	1103 (29.9%)	1067 (29.0%)
Any drug-related treatment-emergent adverse event (time windows: 2 days)	1050 (28.5%)	1046 (28.5%)
Any drug-related treatment-emergent adverse event (time windows: 7 days)	1051 (28.5%)	1053 (28.7%)
Any drug-related treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	430 (11.7%)	424 (11.5%)
Any drug-related treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	431 (11.7%)	426 (11.6%)
Any drug-related treatment-emergent bleeding adverse event (windows: 2 days) *	789 (21.4%)	779 (21.2%)
Any treatment-emergent serious adverse event (windows: 2 days)	592 (16.1%)	626 (17.0%)
Any treatment-emergent serious adverse event (windows: 7 days)	598 (16.2%)	637 (17.3%)
Any treatment-emergent serious adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	514 (13.9%)	550 (15.0%)
Any treatment-emergent serious adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	523 (14.2%)	561 (15.3%)
Any treatment-emergent bleeding serious adverse event (time windows: 2 days) *	128 (3.5%)	146 (4.0%)
Any drug-related treatment-emergent serious adverse event (time windows: 2 days)	138 (3.7%)	147 (4.0%)
Any drug-related treatment-emergent serious adverse event (time windows: 7 days)	138 (3.7%)	148 (4.0%)
Any adverse event resulting in permanent discontinuation of study drug	187 (5.1%)	164 (4.5%)
Any bleeding adverse event resulting in permanent discontinuation of study drug	67 (1.8%)	55 (1.5%)
Any adverse event leading to (prolonged) hospitalization	543 (14.7%)	575 (15.7%)

表 2.7.4.7-35　ベースライン時の ALT 別の AE の要約（試験 11702-DVT と試験 11702-PE の統合解析、安全性解析対象集団）（続き）

Baseline ALT: Baseline ALT > upper limit of normal range		
Adverse event summary	Rivaroxaban N=436 (100%)	Enoxaparin/VKA N=427 (100%)
Any adverse event	338 (77.5%)	325 (76.1%)
Any adverse event starting >2 days after stop of study drug	42 (9.6%)	53 (12.4%)
Any drug-related adverse event	125 (28.7%)	132 (30.9%)
Any drug-related adverse event starting >2 days after stop of study drug	2 (0.5%)	6 (1.4%)
Any serious adverse event	89 (20.4%)	78 (18.3%)
Any serious adverse event starting >2 days after stop of study drug	7 (1.6%)	15 (3.5%)
Any drug-related serious adverse event	16 (3.7%)	22 (5.2%)
Any drug-related serious adverse event starting >2 days after stop of study drug	0	1 (0.2%)
Any bleeding adverse event (investigator reported)*	134 (30.7%)	142 (33.3%)
Any death	12 (2.8%)	17 (4.0%)
Any treatment-emergent adverse event (time window: 2 days)	332 (76.1%)	319 (74.7%)
Any treatment-emergent adverse event (time window: 7 days)	332 (76.1%)	320 (74.9%)
Any treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	317 (72.7%)	299 (70.0%)
Any treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	317 (72.7%)	300 (70.3%)
Any treatment-emergent bleeding adverse event (investigator reported, time window: 2 days) *	131 (30.0%)	136 (31.9%)
Any drug-related treatment-emergent adverse event (time windows: 2 days)	125 (28.7%)	129 (30.2%)
Any drug-related treatment-emergent adverse event (time windows: 7 days)	125 (28.7%)	129 (30.2%)
Any drug-related treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	56 (12.8%)	56 (13.1%)
Any drug-related treatment-emergent adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	56 (12.8%)	56 (13.1%)
Any drug-related treatment-emergent bleeding adverse event (windows: 2 days) *	92 (21.1%)	94 (22.0%)
Any treatment-emergent serious adverse event (windows: 2 days)	84 (19.3%)	68 (15.9%)
Any treatment-emergent serious adverse event (windows: 7 days)	84 (19.3%)	71 (16.6%)
Any treatment-emergent serious adverse event, excluding bleeding adverse events (investigator reported, time windows: 2 days) *	76 (17.4%)	61 (14.3%)
Any treatment-emergent serious adverse event, excluding bleeding adverse events (investigator reported, time windows: 7 days) *	76 (17.4%)	64 (15.0%)
Any treatment-emergent bleeding serious adverse event (time windows: 2 days) *	13 (3.0%)	12 (2.8%)
Any drug-related treatment-emergent serious adverse event (time windows: 2 days)	16 (3.7%)	22 (5.2%)
Any drug-related treatment-emergent serious adverse event (time windows: 7 days)	16 (3.7%)	22 (5.2%)
Any adverse event resulting in permanent discontinuation of study drug	20 (4.6%)	16 (3.7%)
Any bleeding adverse event resulting in permanent discontinuation of study drug	4 (0.9%)	6 (1.4%)

表 2.7.4.7-35　ベースライン時の ALT 別の AE の要約（試験 11702-DVT と試験 11702-PE の統合解析、安全性解析対象集団）（続き）

Baseline ALT: Baseline ALT > upper limit of normal range

Adverse event summary	Rivaroxaban N=436 (100%)	Enoxaparin/VKA N=427 (100%)
Any adverse event leading to (prolonged) hospitalization	73 (16.7%)	64 (15.0%)

Note: Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more clinical AEs, the subject is counted only once in a category. The same subject may appear in different categories.
Note: *Bleeding events reported on the specific adverse event CRF section.
Note: Treatment-emergent AE is defined as the AE occurred after randomization and up to the respective time window after the last dose of study drug.
GB: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query41/pgms/t-pmda-ae-summary-alt.sas erjli 06MAR2014 17:22
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引用元：5.3.5.1.43 Additional_22/Table/114

表 2.7.4.7-36 治験薬投与期間における併用薬別の治験薬投与下で発現した安全性主要評価項目（「重大な出血事象」又は「重大ではないが臨床的に問題となる出血事象」：CIAC 判定）（試験 11702-DVT と試験 11702-PE の統合解析、安全性解析対象集団）

Covariate	Category	Rivaroxaban n/N(%)	Enoxaparin/VKA n/N(%)
ASA (incl. Acetylsalicylates)	NO	358/3801 (9.4%)	374/3809 (9.8%)
	YES	30/329 (9.1%)	38/307 (12.4%)
CYP3A4 Inhibitors	NO	368/3880 (9.5%)	380/3850 (9.9%)
	YES	20/250 (8.0%)	32/266 (12.0%)
Clopidogrel or Ticlopidine	NO	380/4070 (9.3%)	408/4078 (10.0%)
	YES	8/60 (13.3%)	4/38 (10.5%)
NSAID (ATC code M01A)	NO	327/3447 (9.5%)	344/3497 (9.8%)
	YES	61/683 (8.9%)	68/619 (11.0%)
NSAID (excl. M01AH and M01AX)	NO	336/3547 (9.5%)	354/3574 (9.9%)
	YES	52/583 (8.9%)	58/542 (10.7%)
NSAID and PAI/ASA	NO	382/4052 (9.4%)	406/4048 (10.0%)
	YES	6/78 (7.7%)	6/68 (8.8%)
NSAID or PAI/ASA	NO	292/3134 (9.3%)	307/3220 (9.5%)
	YES	96/996 (9.6%)	105/896 (11.7%)
P-GP Inhibitors	NO	381/4047 (9.4%)	404/4046 (10.0%)
	YES	7/83 (8.4%)	8/70 (11.4%)
P-GP or Strong CYP3A4 Inhibitors	NO	373/3970 (9.4%)	395/3951 (10.0%)
	YES	15/160 (9.4%)	17/165 (10.3%)
PAI or ASA	NO	347/3739 (9.3%)	369/3771 (9.8%)
	YES	41/391 (10.5%)	43/345 (12.5%)
Statin	NO	368/3890 (9.5%)	392/3871 (10.1%)
	YES	20/240 (8.3%)	20/245 (8.2%)
Steroids	NO	346/3687 (9.4%)	381/3747 (10.2%)
	YES	42/443 (9.5%)	31/369 (8.4%)
Steroids (systemic use)	NO	355/3786 (9.4%)	387/3814 (10.1%)
	YES	33/344 (9.6%)	25/302 (8.3%)
Strong CYP3A4 Inhibitors	NO	378/4039 (9.4%)	402/4012 (10.0%)
	YES	10/91 (11.0%)	10/104 (9.6%)

Judgment yes/no of co-medications by the following conditions.
Start date of study medication <= start or end date of the concomitant medication <= first onset or censoring date of treatment emergent principal bleeding event.
If there are concomitant medications with missing start or end date of concomitant medication, any imputation isn't applied in this analysis.
GB: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query41/pgms/t-pmda-posthoc-co-medication.sas erjli 06MAR2014 17:29
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引用元：5.3.5.1.43 Additional_22/Table/43

表 2.7.4.7-37　性別の治験薬投与下の初発発現の安全性主要評価項目（「重大な出血事象」又は「重大ではないが臨床的に問題となる出血事象」：CIAC 判定）（試験 11702-DVT と試験 11702-PE の統合解析、安全性解析対象集団）

Sex: MALE

Bleeding events	Rivaroxaban N=2294 (100%)	Enoxaparin/VKA N=2206 (100%)
Any major or clinically relevant non-major bleeding	192 (8.4%)	203 (9.2%)
MAJOR BLEEDING	16 (0.7%)	32 (1.5%)
RECTAL	0	1 (<0.1%)
Fatal bleeding	2 (<0.1%)	5 (0.2%)
INTRACRANIAL	1 (<0.1%)	4 (0.2%)
GASTROINTESTINAL	1 (<0.1%)	0
THORAX	0	1 (<0.1%)
Non-fatal critical organ bleed	6 (0.3%)	14 (0.6%)
INTRACRANIAL	2 (<0.1%)	4 (0.2%)
RETROPERITONEAL	1 (<0.1%)	4 (0.2%)
INTRAOCULAR	3 (0.1%)	1 (<0.1%)
PERICARDIAL	0	1 (<0.1%)
INTRA-ARTICULAR	0	3 (0.1%)
VITREOUS BODY	0	1 (<0.1%)
Non-fatal non-critical organ bleeding (Fall in Hb >= 2 g/dl and/or transfusions >= 2 units)	8 (0.3%)	12 (0.5%)
SURGICAL SITE	0	2 (<0.1%)
SKIN (OTHER THAN INJECTION SITE)	1 (<0.1%)	1 (<0.1%)
UROGENITAL	1 (<0.1%)	1 (<0.1%)
GASTROINTESTINAL	3 (0.1%)	8 (0.4%)
NASAL	1 (<0.1%)	0
RECTAL	0	1 (<0.1%)
PULMONARY	1 (<0.1%)	0
INTRAMUSCULAR	1 (<0.1%)	0

表 2.7.4.7-37　性別の治験薬投与下の初発発現の安全性主要評価項目（「重大な出血事象」又は「重大ではないが臨床的に問題となる出血事象」：CIAC 判定）（試験 11702-DVT と試験 11702-PE の統合解析、安全性解析対象集団）（続き）

Sex: MALE		
Bleeding events	Rivaroxaban N=2294 (100%)	Enoxaparin/VKA N=2206 (100%)
CLINICALLY RELEVANT NON-MAJOR BLEEDING	176 (7.7%)	171 (7.8%)
SURGICAL SITE	3 (0.1%)	5 (0.2%)
SKIN (OTHER THAN INJECTION SITE)	16 (0.7%)	28 (1.3%)
UROGENITAL	50 (2.2%)	52 (2.4%)
GASTROINTESTINAL	26 (1.1%)	14 (0.6%)
GINGIVAL	1 (<0.1%)	1 (<0.1%)
NASAL	30 (1.3%)	31 (1.4%)
RECTAL	30 (1.3%)	16 (0.7%)
INDETERMINATE	1 (<0.1%)	0
INJECTION / BLOOD SAMPLING SITE	1 (<0.1%)	6 (0.3%)
INTRA-ARTICULAR	2 (<0.1%)	0
TRACHEAL	9 (0.4%)	5 (0.2%)
CONJUNCTIVAL	1 (<0.1%)	4 (0.2%)
EAR	1 (<0.1%)	0
PHARYNX	1 (<0.1%)	0
PULMONARY	2 (<0.1%)	2 (<0.1%)
ANAL	1 (<0.1%)	0
INTRAMUSCULAR	2 (<0.1%)	6 (0.3%)
LEG	0	1 (<0.1%)
PLEURAL	1 (<0.1%)	0
THORAX	0	1 (<0.1%)
THYROID GLAND	0	1 (<0.1%)

表 2.7.4.7-37　性別の治験薬投与下の初発発現の安全性主要評価項目（「重大な出血事象」又は「重大ではないが臨床的に問題となる出血事象」：CIAC 判定）（試験 11702-DVT と試験 11702-PE の統合解析、安全性解析対象集団）（続き）

Sex: FEMALE Bleeding events	Rivaroxaban N=1836 (100%)	Enoxaparin/VKA N=1910 (100%)
Any major or clinically relevant non-major bleeding	196 (10.7%)	209 (10.9%)
MAJOR BLEEDING	18 (1.0%)	34 (1.8%)
PULMONARY	1 (<0.1%)	0
Fatal bleeding	1 (<0.1%)	3 (0.2%)
INTRACRANIAL	1 (<0.1%)	0
RETROPERITONEAL	0	1 (<0.1%)
GASTROINTESTINAL	0	2 (0.1%)
Non-fatal critical organ bleed	1 (<0.1%)	10 (0.5%)
INTRACRANIAL	1 (<0.1%)	5 (0.3%)
RETROPERITONEAL	0	2 (0.1%)
INTRAOCULAR	0	1 (<0.1%)
PERICARDIAL	0	1 (<0.1%)
INTRA-ARTICULAR	0	1 (<0.1%)
Non-fatal non-critical organ bleeding (Fall in Hb >= 2 g/dl and/or transfusions >= 2 units)	15 (0.8%)	21 (1.1%)
SURGICAL SITE	0	1 (<0.1%)
SKIN (OTHER THAN INJECTION SITE)	0	3 (0.2%)
UROGENITAL	1 (<0.1%)	3 (0.2%)
GASTROINTESTINAL	5 (0.3%)	9 (0.5%)
RECTAL	1 (<0.1%)	1 (<0.1%)
INJECTION / BLOOD SAMPLING SITE	0	1 (<0.1%)
UTERUS	7 (0.4%)	0
INTRAMUSCULAR	0	1 (<0.1%)
ABDOMINAL	1 (<0.1%)	2 (0.1%)

表 2.7.4.7-37 性別の治験薬投与下の初発発現の安全性主要評価項目（「重大な出血事象」又は「重大ではないが臨床的に問題となる出血事象」：CIAC 判定）（試験 11702-DVT と試験 11702-PE の統合解析、安全性解析対象集団）（続き）

Sex: FEMALE

Bleeding events	Rivaroxaban N=1836 (100%)	Enoxaparin/VKA N=1910 (100%)
CLINICALLY RELEVANT NON-MAJOR BLEEDING	178 (9.7%)	175 (9.2%)
SURGICAL SITE	2 (0.1%)	6 (0.3%)
INTRAOCULAR	1 (<0.1%)	0
SKIN (OTHER THAN INJECTION SITE)	15 (0.8%)	31 (1.6%)
UROGENITAL	31 (1.7%)	32 (1.7%)
GASTROINTESTINAL	20 (1.1%)	11 (0.6%)
GINGIVAL	1 (<0.1%)	1 (<0.1%)
NASAL	27 (1.5%)	21 (1.1%)
RECTAL	14 (0.8%)	15 (0.8%)
INJECTION / BLOOD SAMPLING SITE	0	4 (0.2%)
INTRA-ARTICULAR	1 (<0.1%)	1 (<0.1%)
TRACHEAL	2 (0.1%)	1 (<0.1%)
CONJUNCTIVAL	0	3 (0.2%)
EAR	0	4 (0.2%)
UTERUS	64 (3.5%)	40 (2.1%)
PHARYNX	0	1 (<0.1%)
INTRAMUSCULAR	0	4 (0.2%)
LEG	0	1 (<0.1%)
PLEURAL	0	1 (<0.1%)

Note: Incidence = # of events / # at risk, where: # of events = # of first treatment-emergent bleedings per subject after randomization. # at risk = # of subjects in reference population.
Note: Treatment-emergent is defined as the event occurred after randomization and up to 2 days after the last dose of study drug.
Note: If a subject's first bleeding had more than one bleeding site, all his sites will be counted.
Note: Treatment groups for the safety population are displayed as study treatment administered (not as randomized).
GB: /by-sasp/patdb/projects/597939/11702_meta/stat/prod_query41/pgms/t-pmda-bleed-1-components-sex.sas erjli 06MAR2014 17:19
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引用元：5.3.5.1.43 Additional_22/Table/102

表 2.7.4.7-38 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 14568、安全性解析対象集団）

	All treatment-emergent adverse events				All treatment-emergent drug-related adverse events			
Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID /15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID /OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)	Rivaroxaban 10 mg BID /15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID /OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)
Number (%) of subjects with at least one adverse event	18 (81.8%)	21 (84.0%)	39 (83.0%)	10 (83.3%)	8 (36.4%)	7 (28.0%)	15 (31.9%)	4 (33.3%)
Blood and lymphatic system disorders（血液およびリンパ系障害）	1 (4.5%)	2 (8.0%)	3 (6.4%)	1 (8.3%)	0	0	0	0
Anaemia（貧血）	1 (4.5%)	2 (8.0%)	3 (6.4%)	1 (8.3%)	0	0	0	0
Cardiac disorders（心臓障害）	2 (9.1%)	0	2 (4.3%)	0	0	0	0	0
Palpitations（動悸）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Tachycardia（頻脈）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Ear and labyrinth disorders（耳および迷路障害）	1 (4.5%)	1 (4.0%)	2 (4.3%)	0	0	0	0	0
Vertigo（回転性めまい）	1 (4.5%)	1 (4.0%)	2 (4.3%)	0	0	0	0	0
Endocrine disorders（内分泌障害）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Cushingoid（クッシング様）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Eye disorders（眼障害）	1 (4.5%)	2 (8.0%)	3 (6.4%)	1 (8.3%)	1 (4.5%)	0	1 (2.1%)	0
Conjunctival haemorrhage（結膜出血）	1 (4.5%)	0	1 (2.1%)	0	1 (4.5%)	0	1 (2.1%)	0
Conjunctivitis（結膜炎）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Diabetic retinopathy（糖尿病網膜症）	0	0	0	1 (8.3%)	0	0	0	0
Glaucoma（緑内障）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0

表 2.7.4.7-38 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 14568、安全性解析対象集団）（続き）

	All treatment-emergent adverse events				All treatment-emergent drug-related adverse events			
Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID /15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID /OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)	Rivaroxaban 10 mg BID /15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID /OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)
Gastrointestinal disorders（胃腸障害）	6 (27.3%)	8 (32.0%)	14 (29.8%)	4 (33.3%)	1 (4.5%)	2 (8.0%)	3 (6.4%)	0
Abdominal discomfort（腹部不快感）	2 (9.1%)	1 (4.0%)	3 (6.4%)	0	0	0	0	0
Abdominal pain（腹痛）	1 (4.5%)	0	1 (2.1%)	0	1 (4.5%)	0	1 (2.1%)	0
Abdominal pain upper（上腹部痛）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Constipation（便秘）	1 (4.5%)	1 (4.0%)	2 (4.3%)	2 (16.7%)	0	0	0	0
Dental caries（齲歯）	0	0	0	1 (8.3%)	0	0	0	0
Diarrhoea（下痢）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Dyspepsia（消化不良）	0	1 (4.0%)	1 (2.1%)	1 (8.3%)	0	0	0	0
Gingival bleeding（歯肉出血）	2 (9.1%)	1 (4.0%)	3 (6.4%)	0	1 (4.5%)	0	1 (2.1%)	0
Haematochezia（血便排泄）	1 (4.5%)	2 (8.0%)	3 (6.4%)	0	1 (4.5%)	2 (8.0%)	3 (6.4%)	0
Haemorrhoids（痔核）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Large intestine polyp（大腸ポリープ）	0	1 (4.0%)	1 (2.1%)	1 (8.3%)	0	0	0	0
Nausea（悪心）	2 (9.1%)	0	2 (4.3%)	0	0	0	0	0
Stomatitis（口内炎）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Subileus（亜イレウス）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Vomiting（嘔吐）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
General disorders and administration site conditions（一般・全身障害および投与部位の状態）	2 (9.1%)	4 (16.0%)	6 (12.8%)	1 (8.3%)	0	3 (12.0%)	3 (6.4%)	0
Fatigue（疲労）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Injection site swelling（注射部位腫脹）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Malaise（倦怠感）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Oedema peripheral（末梢性浮腫）	1 (4.5%)	0	1 (2.1%)	1 (8.3%)	0	0	0	0
Puncture site haemorrhage（穿刺部位出血）	0	1 (4.0%)	1 (2.1%)	0	0	1 (4.0%)	1 (2.1%)	0
Pyrexia（発熱）	0	1 (4.0%)	1 (2.1%)	0	0	1 (4.0%)	1 (2.1%)	0
Thirst（口渇）	0	1 (4.0%)	1 (2.1%)	0	0	1 (4.0%)	1 (2.1%)	0
Hepatobiliary disorders（肝胆道系障害）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Hepatic function abnormal（肝機能異常）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0

表 2.7.4.7-38 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 14568、安全性解析対象集団）（続き）

	All treatment-emergent adverse events				All treatment-emergent drug-related adverse events			
Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID /15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID /OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)	Rivaroxaban 10 mg BID /15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID /OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)
Immune system disorders (免疫系障害)	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Drug hypersensitivity (薬物過敏症)	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Infections and infestations (感染症および寄生虫症)	5 (22.7%)	9 (36.0%)	14 (29.8%)	4 (33.3%)	0	0	0	0
Arthritis bacterial (細菌性関節炎)	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Fungal skin infection (皮膚真菌感染)	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Gastroenteritis (胃腸炎)	0	0	0	1 (8.3%)	0	0	0	0
Gingivitis (歯肉炎)	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Herpes zoster (帯状疱疹)	0	0	0	1 (8.3%)	0	0	0	0
Hordeolum (麦粒腫)	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Infected dermal cyst (感染性皮膚嚢腫)	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Influenza (インフルエンザ)	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Lymphangitis (リンパ管炎)	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Nasopharyngitis (鼻咽頭炎)	2 (9.1%)	6 (24.0%)	8 (17.0%)	1 (8.3%)	0	0	0	0
Otitis externa (外耳炎)	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Periodontitis (歯周炎)	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Tinea manuum (手白癬)	0	0	0	1 (8.3%)	0	0	0	0
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	2 (9.1%)	4 (16.0%)	6 (12.8%)	1 (8.3%)	0	0	0	0
Contusion (挫傷)	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Excoriation (擦過傷)	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Head injury (頭部損傷)	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Ligament sprain (靱帯捻挫)	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Lumbar vertebral fracture (腰椎骨折)	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Wound haemorrhage (創傷出血)	1 (4.5%)	1 (4.0%)	2 (4.3%)	1 (8.3%)	0	0	0	0

表 2.7.4.7-38 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 14568、安全性解析対象集団）（続き）

	All treatment-emergent adverse events				All treatment-emergent drug-related adverse events			
Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID /15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID /OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)	Rivaroxaban 10 mg BID /15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID /OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)
Investigations（臨床検査）	4 (18.2%)	1 (4.0%)	5 (10.6%)	1 (8.3%)	2 (9.1%)	0	2 (4.3%)	1 (8.3%)
Activated partial thromboplastin time prolonged（活性化部分トロンボプラスチン時間延長）	0	0	0	1 (8.3%)	0	0	0	1 (8.3%)
Blood alkaline phosphatase increased（血中アルカリホスファターゼ増加）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Blood creatine phosphokinase increased（血中クレアチンホスホキナーゼ増加）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Blood creatinine increased（血中クレアチニン増加）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Blood urine present（尿中血陽性）	1 (4.5%)	0	1 (2.1%)	0	1 (4.5%)	0	1 (2.1%)	0
Liver function test abnormal（肝機能検査異常）	1 (4.5%)	0	1 (2.1%)	0	1 (4.5%)	0	1 (2.1%)	0
Neutrophil count decreased（好中球数減少）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Platelet count decreased（血小板数減少）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Metabolism and nutrition disorders（代謝および栄養障害）	3 (13.6%)	4 (16.0%)	7 (14.9%)	0	0	0	0	0
Decreased appetite（食欲減退）	1 (4.5%)	1 (4.0%)	2 (4.3%)	0	0	0	0	0
Gout（痛風）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Hyperkalaemia（高カリウム血症）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Hyperlipidaemia（高脂血症）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Hyperuricaemia（高尿酸血症）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Hypoalbuminaemia（低アルブミン血症）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Hypovolaemia（血液量減少症）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0

表 2.7.4.7-38 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 14568、安全性解析対象集団）（続き）

	All treatment-emergent adverse events				All treatment-emergent drug-related adverse events			
Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID /15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID /OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)	Rivaroxaban 10 mg BID /15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID /OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)
Musculoskeletal and connective tissue disorders（筋骨格系および結合組織障害）	3 (13.6%)	8 (32.0%)	11 (23.4%)	4 (33.3%)	0	0	0	0
Arthralgia（関節痛）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Back pain（背部痛）	1 (4.5%)	2 (8.0%)	3 (6.4%)	1 (8.3%)	0	0	0	0
Joint swelling（関節腫脹）	0	2 (8.0%)	2 (4.3%)	0	0	0	0	0
Musculoskeletal discomfort（筋骨格不快感）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Musculoskeletal stiffness（筋骨格硬直）	0	0	0	1 (8.3%)	0	0	0	0
Myalgia（筋肉痛）	0	1 (4.0%)	1 (2.1%)	1 (8.3%)	0	0	0	0
Myositis（筋炎）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Osteoarthritis（変形性関節症）	0	1 (4.0%)	1 (2.1%)	1 (8.3%)	0	0	0	0
Tendonitis（腱炎）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
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））	3 (13.6%)	0	3 (6.4%)	1 (8.3%)	0	0	0	0
Gastrointestinal stromal tumour（消化管間質性腫瘍）	0	0	0	1 (8.3%)	0	0	0	0
Metastases to lymph nodes（リンパ節転移）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Renal cancer（腎癌）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Tumour haemorrhage（腫瘍出血）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Nervous system disorders（神経系障害）	2 (9.1%)	4 (16.0%)	6 (12.8%)	2 (16.7%)	0	0	0	0
Cerebral infarction（脳梗塞）	0	0	0	1 (8.3%)	0	0	0	0
Diabetic neuropathy（糖尿病性ニューロパチー）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Dizziness（浮動性めまい）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Headache（頭痛）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Hypoaesthesia（感覚鈍麻）	0	0	0	1 (8.3%)	0	0	0	0
Hypoglycaemic unconsciousness（低血糖性意識消失）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Presyncope（失神寸前の状態）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Sciatica（坐骨神経痛）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Tension headache（緊張性頭痛）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0

表 2.7.4.7-38 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 14568、安全性解析対象集団）（続き）

	All treatment-emergent adverse events				All treatment-emergent drug-related adverse events			
Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID /15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID /OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)	Rivaroxaban 10 mg BID /15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID /OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)
Psychiatric disorders (精神障害)	0	0	0	3 (25.0%)	0	0	0	0
Anxiety (不安)	0	0	0	1 (8.3%)	0	0	0	0
Insomnia (不眠症)	0	0	0	3 (25.0%)	0	0	0	0
Renal and urinary disorders (腎および尿路障害)	1 (4.5%)	1 (4.0%)	2 (4.3%)	2 (16.7%)	1 (4.5%)	0	1 (2.1%)	1 (8.3%)
Cystitis haemorrhagic (出血性膀胱炎)	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Diabetic nephropathy (糖尿病性腎症)	0	0	0	1 (8.3%)	0	0	0	0
Haematuria (血尿)	0	0	0	1 (8.3%)	0	0	0	1 (8.3%)
Renal failure chronic (慢性腎不全)	1 (4.5%)	0	1 (2.1%)	0	1 (4.5%)	0	1 (2.1%)	0
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	4 (18.2%)	1 (4.0%)	5 (10.6%)	2 (16.7%)	4 (18.2%)	1 (4.0%)	5 (10.6%)	1 (8.3%)
Aspiration (誤嚥)	0	0	0	1 (8.3%)	0	0	0	0
Cough (咳嗽)	1 (4.5%)	0	1 (2.1%)	0	1 (4.5%)	0	1 (2.1%)	0
Epistaxis (鼻出血)	3 (13.6%)	1 (4.0%)	4 (8.5%)	1 (8.3%)	3 (13.6%)	1 (4.0%)	4 (8.5%)	1 (8.3%)
Hiccups (しゃっくり)	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Interstitial lung disease (間質性肺疾患)	1 (4.5%)	0	1 (2.1%)	0	1 (4.5%)	0	1 (2.1%)	0

表 2.7.4.7-38　TEAE 及び治験薬との因果関係が否定できない TEAE（試験 14568、安全性解析対象集団）（続き）

	All treatment-emergent adverse events				All treatment-emergent drug-related adverse events			
Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID /15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID /OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)	Rivaroxaban 10 mg BID /15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID /OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)
Skin and subcutaneous tissue disorders（皮膚および皮下組織障害）	7 (31.8%)	7 (28.0%)	14 (29.8%)	5 (41.7%)	1 (4.5%)	3 (12.0%)	4 (8.5%)	1 (8.3%)
Decubitus ulcer（褥瘡性潰瘍）	2 (9.1%)	0	2 (4.3%)	0	0	0	0	0
Dermatitis（皮膚炎）	0	0	0	1 (8.3%)	0	0	0	0
Dermatitis allergic（アレルギー性皮膚炎）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Dermatitis contact（接触性皮膚炎）	2 (9.1%)	1 (4.0%)	3 (6.4%)	2 (16.7%)	0	0	0	0
Eczema asteatotic（皮脂欠乏性湿疹）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Erythema（紅斑）	0	1 (4.0%)	1 (2.1%)	1 (8.3%)	0	0	0	0
Haemorrhage subcutaneous（皮下出血）	3 (13.6%)	4 (16.0%)	7 (14.9%)	1 (8.3%)	1 (4.5%)	3 (12.0%)	4 (8.5%)	1 (8.3%)
Ingrowing nail（嵌入爪）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Petechiae（点状出血）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Pruritus（そう痒症）	0	2 (8.0%)	2 (4.3%)	1 (8.3%)	0	0	0	0
Skin haemorrhage（皮膚出血）	1 (4.5%)	0	1 (2.1%)	0	0	0	0	0
Urticaria（蕁麻疹）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Vascular disorders（血管障害）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0
Lymphoedema（リンパ浮腫）	0	1 (4.0%)	1 (2.1%)	0	0	0	0	0

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/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j1-table.sas erjli 07MAR2014 15:00
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/96

表 2.7.4.7-39 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 15960、安全性解析対象集団）

	All treatment-emergent adverse events				All treatment-emergent drug-related adverse events			
Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID /15 mg OD N=0 (100%)	Rivaroxaban 15 mg BID /OD N=30 (100%)	Rivaroxaban Total N=30 (100%)	UFH / Warfarin N=7 (100%)	Rivaroxaban 10 mg BID /15 mg OD N=0 (100%)	Rivaroxaban 15 mg BID /OD N=30 (100%)	Rivaroxaban Total N=30 (100%)	UFH / Warfarin N=7 (100%)
Number (%) of subjects with at least one adverse event	0	27 (90.0%)	27 (90.0%)	7 (100.0%)	0	15 (50.0%)	15 (50.0%)	4 (57.1%)
Cardiac disorders（心臓障害）	0	2 (6.7%)	2 (6.7%)	0	0	0	0	0
Atrial fibrillation（心房細動）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Cardiac failure（心不全）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Eye disorders（眼障害）	0	3 (10.0%)	3 (10.0%)	1 (14.3%)	0	1 (3.3%)	1 (3.3%)	0
Cataract（白内障）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Conjunctival haemorrhage（結膜出血）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Conjunctivitis（結膜炎）	0	2 (6.7%)	2 (6.7%)	1 (14.3%)	0	1 (3.3%)	1 (3.3%)	0
Gastrointestinal disorders（胃腸障害）	0	9 (30.0%)	9 (30.0%)	4 (57.1%)	0	4 (13.3%)	4 (13.3%)	2 (28.6%)
Abdominal discomfort（腹部不快感）	0	0	0	1 (14.3%)	0	0	0	0
Abdominal pain（腹痛）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Constipation（便秘）	0	1 (3.3%)	1 (3.3%)	0	0	1 (3.3%)	1 (3.3%)	0
Diarrhoea（下痢）	0	3 (10.0%)	3 (10.0%)	2 (28.6%)	0	0	0	1 (14.3%)
Gastrooesophageal reflux disease（胃食道逆流性疾患）	0	2 (6.7%)	2 (6.7%)	0	0	0	0	0
Gingival bleeding（歯肉出血）	0	1 (3.3%)	1 (3.3%)	1 (14.3%)	0	0	0	1 (14.3%)
Haematochezia（血便排泄）	0	1 (3.3%)	1 (3.3%)	0	0	1 (3.3%)	1 (3.3%)	0
Haemorrhoidal haemorrhage（痔出血）	0	1 (3.3%)	1 (3.3%)	0	0	1 (3.3%)	1 (3.3%)	0
Hypoaesthesia oral（口の感覚鈍麻）	0	1 (3.3%)	1 (3.3%)	0	0	1 (3.3%)	1 (3.3%)	0
Nausea（悪心）	0	2 (6.7%)	2 (6.7%)	1 (14.3%)	0	0	0	0
Stomatitis（口内炎）	0	0	0	1 (14.3%)	0	0	0	0
Vomiting（嘔吐）	0	3 (10.0%)	3 (10.0%)	0	0	0	0	0

表 2.7.4.7-39 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 15960、安全性解析対象集団）（続き）

	All treatment-emergent adverse events				All treatment-emergent drug-related adverse events			
Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID /15 mg OD N=0 (100%)	Rivaroxaban 15 mg BID /OD N=30 (100%)	Rivaroxaban Total N=30 (100%)	UFH / Warfarin N=7 (100%)	Rivaroxaban 10 mg BID /15 mg OD N=0 (100%)	Rivaroxaban 15 mg BID /OD N=30 (100%)	Rivaroxaban Total N=30 (100%)	UFH / Warfarin N=7 (100%)
General disorders and administration site conditions（一般・全身障害および投与部位の状態）	0	3 (10.0%)	3 (10.0%)	2 (28.6%)	0	1 (3.3%)	1 (3.3%)	0
Chest discomfort（胸部不快感）	0	0	0	1 (14.3%)	0	0	0	0
Face oedema（顔面浮腫）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Local swelling（局所腫脹）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Malaise（倦怠感）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Oedema peripheral（末梢性浮腫）	0	1 (3.3%)	1 (3.3%)	1 (14.3%)	0	1 (3.3%)	1 (3.3%)	0
Pyrexia（発熱）	0	0	0	1 (14.3%)	0	0	0	0
Hepatobiliary disorders（肝胆道系障害）	0	2 (6.7%)	2 (6.7%)	0	0	2 (6.7%)	2 (6.7%)	0
Hepatic function abnormal（肝機能異常）	0	2 (6.7%)	2 (6.7%)	0	0	2 (6.7%)	2 (6.7%)	0
Immune system disorders（免疫系障害）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Seasonal allergy（季節性アレルギー）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Infections and infestations（感染症および寄生虫症）	0	14 (46.7%)	14 (46.7%)	5 (71.4%)	0	0	0	0
Abscess neck（頚部膿瘍）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Cellulitis（蜂巣炎）	0	2 (6.7%)	2 (6.7%)	0	0	0	0	0
Cystitis（膀胱炎）	0	2 (6.7%)	2 (6.7%)	0	0	0	0	0
Gastroenteritis（胃腸炎）	0	0	0	2 (28.6%)	0	0	0	0
Herpes zoster（帯状疱疹）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Nasopharyngitis（鼻咽頭炎）	0	8 (26.7%)	8 (26.7%)	2 (28.6%)	0	0	0	0
Oral herpes（口腔ヘルペス）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Otitis externa（外耳炎）	0	0	0	1 (14.3%)	0	0	0	0
Pharyngitis（咽頭炎）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Pneumonia（肺炎）	0	2 (6.7%)	2 (6.7%)	0	0	0	0	0
Tinea pedis（足部白癬）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Urinary tract infection（尿路感染）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0

表 2.7.4.7-39 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 15960、安全性解析対象集団）（続き）

	All treatment-emergent adverse events				All treatment-emergent drug-related adverse events			
Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID /15 mg OD N=0 (100%)	Rivaroxaban 15 mg BID /OD N=30 (100%)	Rivaroxaban Total N=30 (100%)	UFH / Warfarin N=7 (100%)	Rivaroxaban 10 mg BID /15 mg OD N=0 (100%)	Rivaroxaban 15 mg BID /OD N=30 (100%)	Rivaroxaban Total N=30 (100%)	UFH / Warfarin N=7 (100%)
Injury, poisoning and procedural complications（傷害、中毒および処置合併症）	0	4 (13.3%)	4 (13.3%)	1 (14.3%)	0	1 (3.3%)	1 (3.3%)	0
Chemical burns of eye（眼部化学熱傷）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Radiation skin injury（放射線皮膚損傷）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Spinal compression fracture（脊椎圧迫骨折）	0	0	0	1 (14.3%)	0	0	0	0
Subcutaneous haematoma（皮下血腫）	0	2 (6.7%)	2 (6.7%)	0	0	1 (3.3%)	1 (3.3%)	0
Wound haemorrhage（創傷出血）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Investigations（臨床検査）	0	5 (16.7%)	5 (16.7%)	4 (57.1%)	0	3 (10.0%)	3 (10.0%)	2 (28.6%)
Alanine aminotransferase increased（アラニンアミノトランスフェラーゼ増加）	0	0	0	3 (42.9%)	0	0	0	2 (28.6%)
Aspartate aminotransferase increased（アスパラギン酸アミノトランスフェラーゼ増加）	0	0	0	2 (28.6%)	0	0	0	2 (28.6%)
Blood bilirubin increased（血中ビリルビン増加）	0	1 (3.3%)	1 (3.3%)	0	0	1 (3.3%)	1 (3.3%)	0
Blood calcium decreased（血中カルシウム減少）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Blood cholesterol increased（血中コレステロール増加）	0	0	0	1 (14.3%)	0	0	0	0
Blood urine present（尿中血陽性）	0	1 (3.3%)	1 (3.3%)	0	0	1 (3.3%)	1 (3.3%)	0
Liver function test abnormal（肝機能検査異常）	0	2 (6.7%)	2 (6.7%)	0	0	1 (3.3%)	1 (3.3%)	0
Occult blood positive（便潜血陽性）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Metabolism and nutrition disorders（代謝および栄養障害）	0	3 (10.0%)	3 (10.0%)	0	0	0	0	0
Decreased appetite（食欲減退）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Dehydration（脱水）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Gout（痛風）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0

表 2.7.4.7-39 TEAE 及び治験薬との因果関係が否定できない TEAE（試験 15960、安全性解析対象集団）（続き）

	All treatment-emergent adverse events				All treatment-emergent drug-related adverse events			
Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID /15 mg OD N=0 (100%)	Rivaroxaban 15 mg BID /OD N=30 (100%)	Rivaroxaban Total N=30 (100%)	UFH / Warfarin N=7 (100%)	Rivaroxaban 10 mg BID /15 mg OD N=0 (100%)	Rivaroxaban 15 mg BID /OD N=30 (100%)	Rivaroxaban Total N=30 (100%)	UFH / Warfarin N=7 (100%)
Musculoskeletal and connective tissue disorders（筋骨格系および結合組織障害）	0	2 (6.7%)	2 (6.7%)	3 (42.9%)	0	0	0	0
Arthralgia（関節痛）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Muscle spasms（筋痙縮）	0	0	0	1 (14.3%)	0	0	0	0
Musculoskeletal stiffness（筋骨格硬直）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Osteoporosis（骨粗鬆症）	0	1 (3.3%)	1 (3.3%)	1 (14.3%)	0	0	0	0
Sacroiliitis（仙腸骨炎）	0	0	0	1 (14.3%)	0	0	0	0
Synovial cyst（滑液嚢腫）	0	0	0	1 (14.3%)	0	0	0	0
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））	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Hypopharyngeal cancer（下咽頭癌）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Nervous system disorders（神経系障害）	0	4 (13.3%)	4 (13.3%)	1 (14.3%)	0	0	0	0
Dizziness（浮動性めまい）	0	2 (6.7%)	2 (6.7%)	1 (14.3%)	0	0	0	0
Headache（頭痛）	0	2 (6.7%)	2 (6.7%)	0	0	0	0	0
Hypoaesthesia（感覚鈍麻）	0	0	0	1 (14.3%)	0	0	0	0
Sciatica（坐骨神経痛）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Sensory disturbance（感覚障害）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Somnolence（傾眠）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Psychiatric disorders（精神障害）	0	2 (6.7%)	2 (6.7%)	0	0	0	0	0
Delirium（譫妄）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Insomnia（不眠症）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0

表 2.7.4.7-39　TEAE 及び治験薬との因果関係が否定できない TEAE（試験 15960、安全性解析対象集団）（続き）

	All treatment-emergent adverse events				All treatment-emergent drug-related adverse events			
Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID /15 mg OD N=0 (100%)	Rivaroxaban 15 mg BID /OD N=30 (100%)	Rivaroxaban Total N=30 (100%)	UFH / Warfarin N=7 (100%)	Rivaroxaban 10 mg BID /15 mg OD N=0 (100%)	Rivaroxaban 15 mg BID /OD N=30 (100%)	Rivaroxaban Total N=30 (100%)	UFH / Warfarin N=7 (100%)
Respiratory, thoracic and mediastinal disorders（呼吸器、胸郭および縦隔障害）	0	7 (23.3%)	7 (23.3%)	2 (28.6%)	0	3 (10.0%)	3 (10.0%)	0
Cough（咳嗽）	0	0	0	1 (14.3%)	0	0	0	0
Epistaxis（鼻出血）	0	3 (10.0%)	3 (10.0%)	0	0	2 (6.7%)	2 (6.7%)	0
Haemoptysis（喀血）	0	1 (3.3%)	1 (3.3%)	0	0	1 (3.3%)	1 (3.3%)	0
Hiccups（しゃっくり）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Laryngeal pain（喉頭痛）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Nasal congestion（鼻閉）	0	0	0	1 (14.3%)	0	0	0	0
Upper respiratory tract inflammation（上気道の炎症）	0	2 (6.7%)	2 (6.7%)	0	0	0	0	0
Skin and subcutaneous tissue disorders（皮膚および皮下組織障害）	0	12 (40.0%)	12 (40.0%)	5 (71.4%)	0	6 (20.0%)	6 (20.0%)	2 (28.6%)
Dermatitis（皮膚炎）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Dermatitis contact（接触性皮膚炎）	0	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Drug eruption（薬疹）	0	1 (3.3%)	1 (3.3%)	0	0	1 (3.3%)	1 (3.3%)	0
Eczema（湿疹）	0	3 (10.0%)	3 (10.0%)	1 (14.3%)	0	0	0	0
Haemorrhage subcutaneous（皮下出血）	0	4 (13.3%)	4 (13.3%)	4 (57.1%)	0	4 (13.3%)	4 (13.3%)	2 (28.6%)
Petechiae（点状出血）	0	1 (3.3%)	1 (3.3%)	0	0	1 (3.3%)	1 (3.3%)	0
Pruritus（そう痒症）	0	2 (6.7%)	2 (6.7%)	0	0	0	0	0
Pruritus generalised（全身性そう痒症）	0	0	0	1 (14.3%)	0	0	0	0
Rash（発疹）	0	2 (6.7%)	2 (6.7%)	0	0	0	0	0

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/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j1-table.sas erjli 07MAR2014 15:00
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/96

表 2.7.4.7-40 重症度別の TEAE（試験 14568、安全性解析対象集団）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID/15 mg OD				Rivaroxaban 15 mg BID/OD			
	Mild N=22 (100%)	Moderate N=22 (100%)	Severe N=22 (100%)	Missing N=22 (100%)	Mild N=25 (100%)	Moderate N=25 (100%)	Severe N=25 (100%)	Missing N=25 (100%)
Number (%) of subjects with at least one adverse event	18 (81.8%)	6 (27.3%)	0	0	21 (84.0%)	2 (8.0%)	0	0
Blood and lymphatic system disorders (血液およびリンパ系障害)	1 (4.5%)	0	0	0	1 (4.0%)	1 (4.0%)	0	0
Anaemia (貧血)	1 (4.5%)	0	0	0	1 (4.0%)	1 (4.0%)	0	0
Cardiac disorders (心臓障害)	2 (9.1%)	0	0	0	0	0	0	0
Palpitations (動悸)	1 (4.5%)	0	0	0	0	0	0	0
Tachycardia (頻脈)	1 (4.5%)	0	0	0	0	0	0	0
Ear and labyrinth disorders (耳および迷路障害)	1 (4.5%)	0	0	0	1 (4.0%)	0	0	0
Vertigo (回転性めまい)	1 (4.5%)	0	0	0	1 (4.0%)	0	0	0
Endocrine disorders (内分泌障害)	1 (4.5%)	0	0	0	0	0	0	0
Cushingoid (クッシング様)	1 (4.5%)	0	0	0	0	0	0	0
Eye disorders (眼障害)	1 (4.5%)	0	0	0	2 (8.0%)	0	0	0
Conjunctival haemorrhage (結膜出血)	1 (4.5%)	0	0	0	0	0	0	0
Conjunctivitis (結膜炎)	0	0	0	0	1 (4.0%)	0	0	0
Diabetic retinopathy (糖尿病網膜症)	0	0	0	0	0	0	0	0
Glaucoma (緑内障)	0	0	0	0	1 (4.0%)	0	0	0

表 2.7.4.7-40 重症度別の TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID/15 mg OD				Rivaroxaban 15 mg BID/OD			
	Mild N=22 (100%)	Moderate N=22 (100%)	Severe N=22 (100%)	Missing N=22 (100%)	Mild N=25 (100%)	Moderate N=25 (100%)	Severe N=25 (100%)	Missing N=25 (100%)
Gastrointestinal disorders（胃腸障害）	6 (27.3%)	0	0	0	8 (32.0%)	1 (4.0%)	0	0
Abdominal discomfort（腹部不快感）	2 (9.1%)	0	0	0	1 (4.0%)	0	0	0
Abdominal pain（腹痛）	1 (4.5%)	0	0	0	0	0	0	0
Abdominal pain upper（上腹部痛）	1 (4.5%)	0	0	0	0	0	0	0
Constipation（便秘）	1 (4.5%)	0	0	0	1 (4.0%)	0	0	0
Dental caries（齲歯）	0	0	0	0	0	0	0	0
Diarrhoea（下痢）	1 (4.5%)	0	0	0	0	0	0	0
Dyspepsia（消化不良）	0	0	0	0	1 (4.0%)	0	0	0
Gingival bleeding（歯肉出血）	2 (9.1%)	0	0	0	1 (4.0%)	0	0	0
Haematochezia（血便排泄）	1 (4.5%)	0	0	0	2 (8.0%)	0	0	0
Haemorrhoids（痔核）	0	0	0	0	1 (4.0%)	0	0	0
Large intestine polyp（大腸ポリープ）	0	0	0	0	1 (4.0%)	0	0	0
Nausea（悪心）	2 (9.1%)	0	0	0	0	0	0	0
Stomatitis（口内炎）	0	0	0	0	1 (4.0%)	0	0	0
Subileus（亜イレウス）	0	0	0	0	1 (4.0%)	1 (4.0%)	0	0
Vomiting（嘔吐）	1 (4.5%)	0	0	0	0	0	0	0
General disorders and administration site conditions（一般・全身障害および投与部位の状態）	2 (9.1%)	0	0	0	4 (16.0%)	0	0	0
Fatigue（疲労）	0	0	0	0	1 (4.0%)	0	0	0
Injection site swelling（注射部位腫脹）	1 (4.5%)	0	0	0	0	0	0	0
Malaise（倦怠感）	1 (4.5%)	0	0	0	0	0	0	0
Oedema peripheral（末梢性浮腫）	1 (4.5%)	0	0	0	0	0	0	0
Puncture site haemorrhage（穿刺部位出血）	0	0	0	0	1 (4.0%)	0	0	0
Pyrexia（発熱）	0	0	0	0	1 (4.0%)	0	0	0
Thirst（口渇）	0	0	0	0	1 (4.0%)	0	0	0
Hepatobiliary disorders（肝胆道系障害）	1 (4.5%)	0	0	0	0	0	0	0
Hepatic function abnormal（肝機能異常）	1 (4.5%)	0	0	0	0	0	0	0
Immune system disorders（免疫系障害）	1 (4.5%)	0	0	0	0	0	0	0
Drug hypersensitivity（薬物過敏症）	1 (4.5%)	0	0	0	0	0	0	0

表 2.7.4.7-40 重症度別の TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID/15 mg OD				Rivaroxaban 15 mg BID/OD			
	Mild N=22 (100%)	Moderate N=22 (100%)	Severe N=22 (100%)	Missing N=22 (100%)	Mild N=25 (100%)	Moderate N=25 (100%)	Severe N=25 (100%)	Missing N=25 (100%)
Infections and infestations (感染症および寄生虫症)	5 (22.7%)	0	0	0	9 (36.0%)	0	0	0
Arthritis bacterial (細菌性関節炎)	1 (4.5%)	0	0	0	0	0	0	0
Fungal skin infection (皮膚真菌感染)	1 (4.5%)	0	0	0	0	0	0	0
Gastroenteritis (胃腸炎)	0	0	0	0	0	0	0	0
Gingivitis (歯肉炎)	0	0	0	0	1 (4.0%)	0	0	0
Herpes zoster (帯状疱疹)	0	0	0	0	0	0	0	0
Hordeolum (麦粒腫)	0	0	0	0	1 (4.0%)	0	0	0
Infected dermal cyst (感染性皮膚嚢腫)	1 (4.5%)	0	0	0	0	0	0	0
Influenza (インフルエンザ)	0	0	0	0	1 (4.0%)	0	0	0
Lymphangitis (リンパ管炎)	1 (4.5%)	0	0	0	0	0	0	0
Nasopharyngitis (鼻咽頭炎)	2 (9.1%)	0	0	0	6 (24.0%)	0	0	0
Otitis externa (外耳炎)	0	0	0	0	1 (4.0%)	0	0	0
Periodontitis (歯周炎)	0	0	0	0	1 (4.0%)	0	0	0
Tinea manuum (手白癬)	0	0	0	0	0	0	0	0
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	2 (9.1%)	0	0	0	4 (16.0%)	0	0	0
Contusion (挫傷)	0	0	0	0	1 (4.0%)	0	0	0
Excoriation (擦過傷)	0	0	0	0	1 (4.0%)	0	0	0
Head injury (頭部損傷)	0	0	0	0	1 (4.0%)	0	0	0
Ligament sprain (靭帯捻挫)	0	0	0	0	1 (4.0%)	0	0	0
Lumbar vertebral fracture (腰椎骨折)	1 (4.5%)	0	0	0	0	0	0	0
Wound haemorrhage (創傷出血)	1 (4.5%)	0	0	0	1 (4.0%)	0	0	0

表 2.7.4.7-40 重症度別の TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID/15 mg OD				Rivaroxaban 15 mg BID/OD			
	Mild N=22 (100%)	Moderate N=22 (100%)	Severe N=22 (100%)	Missing N=22 (100%)	Mild N=25 (100%)	Moderate N=25 (100%)	Severe N=25 (100%)	Missing N=25 (100%)
Investigations（臨床検査）	4 (18.2%)	2 (9.1%)	0	0	1 (4.0%)	0	0	0
Activated partial thromboplastin time prolonged（活性化部分トロンボプラスチン時間延長）	0	0	0	0	0	0	0	0
Blood alkaline phosphatase increased（血中アルカリホスファターゼ増加）	0	0	0	0	1 (4.0%)	0	0	0
Blood creatine phosphokinase increased（血中クレアチンホスホキナーゼ増加）	1 (4.5%)	0	0	0	0	0	0	0
Blood creatinine increased（血中クレアチニン増加）	1 (4.5%)	0	0	0	0	0	0	0
Blood urine present（尿中血陽性）	1 (4.5%)	0	0	0	0	0	0	0
Liver function test abnormal（肝機能検査異常）	0	1 (4.5%)	0	0	0	0	0	0
Neutrophil count decreased（好中球数減少）	1 (4.5%)	1 (4.5%)	0	0	0	0	0	0
Platelet count decreased（血小板数減少）	1 (4.5%)	0	0	0	0	0	0	0
Metabolism and nutrition disorders（代謝および栄養障害）	3 (13.6%)	0	0	0	3 (12.0%)	1 (4.0%)	0	0
Decreased appetite（食欲減退）	1 (4.5%)	0	0	0	0	1 (4.0%)	0	0
Gout（痛風）	1 (4.5%)	0	0	0	0	0	0	0
Hyperkalaemia（高カリウム血症）	0	0	0	0	1 (4.0%)	0	0	0
Hyperlipidaemia（高脂血症）	0	0	0	0	1 (4.0%)	0	0	0
Hyperuricaemia（高尿酸血症）	0	0	0	0	1 (4.0%)	0	0	0
Hypoalbuminaemia（低アルブミン血症）	0	0	0	0	0	1 (4.0%)	0	0
Hypovolaemia（血液量減少症）	1 (4.5%)	0	0	0	0	0	0	0

表 2.7.4.7-40 重症度別の TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID/15 mg OD				Rivaroxaban 15 mg BID/OD			
	Mild N=22 (100%)	Moderate N=22 (100%)	Severe N=22 (100%)	Missing N=22 (100%)	Mild N=25 (100%)	Moderate N=25 (100%)	Severe N=25 (100%)	Missing N=25 (100%)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	3 (13.6%)	0	0	0	8 (32.0%)	0	0	0
Arthralgia (関節痛)	0	0	0	0	1 (4.0%)	0	0	0
Back pain (背部痛)	1 (4.5%)	0	0	0	2 (8.0%)	0	0	0
Joint swelling (関節腫脹)	0	0	0	0	2 (8.0%)	0	0	0
Musculoskeletal discomfort (筋骨格不快感)	0	0	0	0	1 (4.0%)	0	0	0
Musculoskeletal stiffness (筋骨格硬直)	0	0	0	0	0	0	0	0
Myalgia (筋肉痛)	0	0	0	0	1 (4.0%)	0	0	0
Myositis (筋炎)	1 (4.5%)	0	0	0	0	0	0	0
Osteoarthritis (変形性関節症)	0	0	0	0	1 (4.0%)	0	0	0
Tendonitis (腱炎)	1 (4.5%)	0	0	0	0	0	0	0
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))	0	3 (13.6%)	0	0	0	0	0	0
Gastrointestinal stromal tumour (消化管間質性腫瘍)	0	0	0	0	0	0	0	0
Metastases to lymph nodes (リンパ節転移)	0	1 (4.5%)	0	0	0	0	0	0
Renal cancer (腎癌)	0	1 (4.5%)	0	0	0	0	0	0
Tumour haemorrhage (腫瘍出血)	0	1 (4.5%)	0	0	0	0	0	0
Nervous system disorders (神経系障害)	2 (9.1%)	0	0	0	4 (16.0%)	0	0	0
Cerebral infarction (脳梗塞)	0	0	0	0	0	0	0	0
Diabetic neuropathy (糖尿病性ニューロパチー)	0	0	0	0	1 (4.0%)	0	0	0
Dizziness (浮動性めまい)	0	0	0	0	1 (4.0%)	0	0	0
Headache (頭痛)	0	0	0	0	1 (4.0%)	0	0	0
Hypoaesthesia (感覚鈍麻)	0	0	0	0	0	0	0	0
Hypoglycaemic unconsciousness (低血糖性意識消失)	1 (4.5%)	0	0	0	0	0	0	0
Presyncope (失神寸前の状態)	1 (4.5%)	0	0	0	0	0	0	0
Sciatica (坐骨神経痛)	0	0	0	0	1 (4.0%)	0	0	0
Tension headache (緊張性頭痛)	0	0	0	0	1 (4.0%)	0	0	0

表 2.7.4.7-40 重症度別の TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID/15 mg OD				Rivaroxaban 15 mg BID/OD			
	Mild N=22 (100%)	Moderate N=22 (100%)	Severe N=22 (100%)	Missing N=22 (100%)	Mild N=25 (100%)	Moderate N=25 (100%)	Severe N=25 (100%)	Missing N=25 (100%)
Psychiatric disorders（精神障害）	0	0	0	0	0	0	0	0
Anxiety（不安）	0	0	0	0	0	0	0	0
Insomnia（不眠症）	0	0	0	0	0	0	0	0
Renal and urinary disorders（腎および尿路障害）	0	1 (4.5%)	0	0	1 (4.0%)	0	0	0
Cystitis haemorrhagic（出血性膀胱炎）	0	0	0	0	1 (4.0%)	0	0	0
Diabetic nephropathy（糖尿病性腎症）	0	0	0	0	0	0	0	0
Haematuria（血尿）	0	0	0	0	0	0	0	0
Renal failure chronic（慢性腎不全）	0	1 (4.5%)	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders（呼吸器、胸郭および縦隔障害）	4 (18.2%)	1 (4.5%)	0	0	1 (4.0%)	0	0	0
Aspiration（誤嚥）	0	0	0	0	0	0	0	0
Cough（咳嗽）	1 (4.5%)	0	0	0	0	0	0	0
Epistaxis（鼻出血）	3 (13.6%)	0	0	0	1 (4.0%)	0	0	0
Hiccups（しゃっくり）	1 (4.5%)	0	0	0	0	0	0	0
Interstitial lung disease（間質性肺疾患）	0	1 (4.5%)	0	0	0	0	0	0
Skin and subcutaneous tissue disorders（皮膚および皮下組織障害）	7 (31.8%)	0	0	0	7 (28.0%)	0	0	0
Decubitus ulcer（褥瘡性潰瘍）	2 (9.1%)	0	0	0	0	0	0	0
Dermatitis（皮膚炎）	0	0	0	0	0	0	0	0
Dermatitis allergic（アレルギー性皮膚炎）	1 (4.5%)	0	0	0	0	0	0	0
Dermatitis contact（接触性皮膚炎）	2 (9.1%)	0	0	0	1 (4.0%)	0	0	0
Eczema asteatotic（皮脂欠乏性湿疹）	1 (4.5%)	0	0	0	0	0	0	0
Erythema（紅斑）	0	0	0	0	1 (4.0%)	0	0	0
Haemorrhage subcutaneous（皮下出血）	3 (13.6%)	0	0	0	4 (16.0%)	0	0	0
Ingrowing nail（嵌入爪）	1 (4.5%)	0	0	0	0	0	0	0
Petechiae（点状出血）	0	0	0	0	1 (4.0%)	0	0	0
Pruritus（そう痒症）	0	0	0	0	2 (8.0%)	0	0	0
Skin haemorrhage（皮膚出血）	1 (4.5%)	0	0	0	0	0	0	0
Urticaria（蕁麻疹）	0	0	0	0	1 (4.0%)	0	0	0

表 2.7.4.7-40 重症度別の TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID/15 mg OD				Rivaroxaban 15 mg BID/OD			
	Mild N=22 (100%)	Moderate N=22 (100%)	Severe N=22 (100%)	Missing N=22 (100%)	Mild N=25 (100%)	Moderate N=25 (100%)	Severe N=25 (100%)	Missing N=25 (100%)
Vascular disorders (血管障害)	0	0	0	0	1 (4.0%)	0	0	0
Lymphoedema (リンパ浮腫)	0	0	0	0	1 (4.0%)	0	0	0

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Only the most severe intensity is counted for multiple occurrences of the same AE in each subject.
Global Biostatistics: /by-sasp/patdb/projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j2-table.sas erjli 07MAR2014 15:03
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/98

表 2.7.4.7-40 重症度別の TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total				UFH / Warfarin			
	Mild N=47 (100%)	Moderate N=47 (100%)	Severe N=47 (100%)	Missing N=47 (100%)	Mild N=12 (100%)	Moderate N=12 (100%)	Severe N=12 (100%)	Missing N=12 (100%)
Number (%) of subjects with at least one adverse event	39 (83.0%)	8 (17.0%)	0	0	10 (83.3%)	2 (16.7%)	1 (8.3%)	0
Blood and lymphatic system disorders (血液およびリンパ系障害)	2 (4.3%)	1 (2.1%)	0	0	1 (8.3%)	0	0	0
Anaemia (貧血)	2 (4.3%)	1 (2.1%)	0	0	1 (8.3%)	0	0	0
Cardiac disorders (心臓障害)	2 (4.3%)	0	0	0	0	0	0	0
Palpitations (動悸)	1 (2.1%)	0	0	0	0	0	0	0
Tachycardia (頻脈)	1 (2.1%)	0	0	0	0	0	0	0
Ear and labyrinth disorders (耳および迷路障害)	2 (4.3%)	0	0	0	0	0	0	0
Vertigo (回転性めまい)	2 (4.3%)	0	0	0	0	0	0	0
Endocrine disorders (内分泌障害)	1 (2.1%)	0	0	0	0	0	0	0
Cushingoid (クッシング様)	1 (2.1%)	0	0	0	0	0	0	0
Eye disorders (眼障害)	3 (6.4%)	0	0	0	1 (8.3%)	0	0	0
Conjunctival haemorrhage (結膜出血)	1 (2.1%)	0	0	0	0	0	0	0
Conjunctivitis (結膜炎)	1 (2.1%)	0	0	0	0	0	0	0
Diabetic retinopathy (糖尿病網膜症)	0	0	0	0	1 (8.3%)	0	0	0
Glaucoma (緑内障)	1 (2.1%)	0	0	0	0	0	0	0

表 2.7.4.7-40 重症度別の TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total				UFH / Warfarin			
	Mild N=47 (100%)	Moderate N=47 (100%)	Severe N=47 (100%)	Missing N=47 (100%)	Mild N=12 (100%)	Moderate N=12 (100%)	Severe N=12 (100%)	Missing N=12 (100%)
Gastrointestinal disorders（胃腸障害）	14 (29.8%)	1 (2.1%)	0	0	4 (33.3%)	0	0	0
Abdominal discomfort（腹部不快感）	3 (6.4%)	0	0	0	0	0	0	0
Abdominal pain（腹痛）	1 (2.1%)	0	0	0	0	0	0	0
Abdominal pain upper（上腹部痛）	1 (2.1%)	0	0	0	0	0	0	0
Constipation（便秘）	2 (4.3%)	0	0	0	2 (16.7%)	0	0	0
Dental caries（齲歯）	0	0	0	0	1 (8.3%)	0	0	0
Diarrhoea（下痢）	1 (2.1%)	0	0	0	0	0	0	0
Dyspepsia（消化不良）	1 (2.1%)	0	0	0	1 (8.3%)	0	0	0
Gingival bleeding（歯肉出血）	3 (6.4%)	0	0	0	0	0	0	0
Haematochezia（血便排泄）	3 (6.4%)	0	0	0	0	0	0	0
Haemorrhoids（痔核）	1 (2.1%)	0	0	0	0	0	0	0
Large intestine polyp（大腸ポリープ）	1 (2.1%)	0	0	0	1 (8.3%)	0	0	0
Nausea（悪心）	2 (4.3%)	0	0	0	0	0	0	0
Stomatitis（口内炎）	1 (2.1%)	0	0	0	0	0	0	0
Subileus（亜イレウス）	1 (2.1%)	1 (2.1%)	0	0	0	0	0	0
Vomiting（嘔吐）	1 (2.1%)	0	0	0	0	0	0	0
General disorders and administration site conditions（一般・全身障害および投与部位の状態）	6 (12.8%)	0	0	0	1 (8.3%)	0	0	0
Fatigue（疲労）	1 (2.1%)	0	0	0	0	0	0	0
Injection site swelling（注射部位腫脹）	1 (2.1%)	0	0	0	0	0	0	0
Malaise（倦怠感）	1 (2.1%)	0	0	0	0	0	0	0
Oedema peripheral（末梢性浮腫）	1 (2.1%)	0	0	0	1 (8.3%)	0	0	0
Puncture site haemorrhage（穿刺部位出血）	1 (2.1%)	0	0	0	0	0	0	0
Pyrexia（発熱）	1 (2.1%)	0	0	0	0	0	0	0
Thirst（口渇）	1 (2.1%)	0	0	0	0	0	0	0
Hepatobiliary disorders（肝胆道系障害）	1 (2.1%)	0	0	0	0	0	0	0
Hepatic function abnormal（肝機能異常）	1 (2.1%)	0	0	0	0	0	0	0
Immune system disorders（免疫系障害）	1 (2.1%)	0	0	0	0	0	0	0
Drug hypersensitivity（薬物過敏症）	1 (2.1%)	0	0	0	0	0	0	0

表 2.7.4.7-40 重症度別の TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total				UFH / Warfarin			
	Mild N=47 (100%)	Moderate N=47 (100%)	Severe N=47 (100%)	Missing N=47 (100%)	Mild N=12 (100%)	Moderate N=12 (100%)	Severe N=12 (100%)	Missing N=12 (100%)
Infections and infestations（感染症および寄生虫症）	14 (29.8%)	0	0	0	3 (25.0%)	1 (8.3%)	0	0
Arthritis bacterial（細菌性関節炎）	1 (2.1%)	0	0	0	0	0	0	0
Fungal skin infection（皮膚真菌感染）	1 (2.1%)	0	0	0	0	0	0	0
Gastroenteritis（胃腸炎）	0	0	0	0	0	1 (8.3%)	0	0
Gingivitis（歯肉炎）	1 (2.1%)	0	0	0	0	0	0	0
Herpes zoster（帯状疱疹）	0	0	0	0	1 (8.3%)	0	0	0
Hordeolum（麦粒腫）	1 (2.1%)	0	0	0	0	0	0	0
Infected dermal cyst（感染性皮膚嚢腫）	1 (2.1%)	0	0	0	0	0	0	0
Influenza（インフルエンザ）	1 (2.1%)	0	0	0	0	0	0	0
Lymphangitis（リンパ管炎）	1 (2.1%)	0	0	0	0	0	0	0
Nasopharyngitis（鼻咽頭炎）	8 (17.0%)	0	0	0	1 (8.3%)	0	0	0
Otitis externa（外耳炎）	1 (2.1%)	0	0	0	0	0	0	0
Periodontitis（歯周炎）	1 (2.1%)	0	0	0	0	0	0	0
Tinea manuum（手白癬）	0	0	0	0	1 (8.3%)	0	0	0
Injury, poisoning and procedural complications（傷害、中毒および処置合併症）	6 (12.8%)	0	0	0	1 (8.3%)	0	0	0
Contusion（挫傷）	1 (2.1%)	0	0	0	0	0	0	0
Excoriation（擦過傷）	1 (2.1%)	0	0	0	0	0	0	0
Head injury（頭部損傷）	1 (2.1%)	0	0	0	0	0	0	0
Ligament sprain（靭帯捻挫）	1 (2.1%)	0	0	0	0	0	0	0
Lumbar vertebral fracture（腰椎骨折）	1 (2.1%)	0	0	0	0	0	0	0
Wound haemorrhage（創傷出血）	2 (4.3%)	0	0	0	1 (8.3%)	0	0	0

表 2.7.4.7-40 重症度別の TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total				UFH / Warfarin			
	Mild N=47 (100%)	Moderate N=47 (100%)	Severe N=47 (100%)	Missing N=47 (100%)	Mild N=12 (100%)	Moderate N=12 (100%)	Severe N=12 (100%)	Missing N=12 (100%)
Investigations（臨床検査）	5 (10.6%)	2 (4.3%)	0	0	1 (8.3%)	0	0	0
Activated partial thromboplastin time prolonged（活性化部分トロンボプラスチン時間延長）	0	0	0	0	1 (8.3%)	0	0	0
Blood alkaline phosphatase increased（血中アルカリホスファターゼ増加）	1 (2.1%)	0	0	0	0	0	0	0
Blood creatine phosphokinase increased（血中クレアチンホスホキナーゼ増加）	1 (2.1%)	0	0	0	0	0	0	0
Blood creatinine increased（血中クレアチニン増加）	1 (2.1%)	0	0	0	0	0	0	0
Blood urine present（尿中血陽性）	1 (2.1%)	0	0	0	0	0	0	0
Liver function test abnormal（肝機能検査異常）	0	1 (2.1%)	0	0	0	0	0	0
Neutrophil count decreased（好中球数減少）	1 (2.1%)	1 (2.1%)	0	0	0	0	0	0
Platelet count decreased（血小板数減少）	1 (2.1%)	0	0	0	0	0	0	0
Metabolism and nutrition disorders（代謝および栄養障害）	6 (12.8%)	1 (2.1%)	0	0	0	0	0	0
Decreased appetite（食欲減退）	1 (2.1%)	1 (2.1%)	0	0	0	0	0	0
Gout（痛風）	1 (2.1%)	0	0	0	0	0	0	0
Hyperkalaemia（高カリウム血症）	1 (2.1%)	0	0	0	0	0	0	0
Hyperlipidaemia（高脂血症）	1 (2.1%)	0	0	0	0	0	0	0
Hyperuricaemia（高尿酸血症）	1 (2.1%)	0	0	0	0	0	0	0
Hypoalbuminaemia（低アルブミン血症）	0	1 (2.1%)	0	0	0	0	0	0
Hypovolaemia（血液量減少症）	1 (2.1%)	0	0	0	0	0	0	0

表 2.7.4.7-40 重症度別の TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total				UFH / Warfarin			
	Mild N=47 (100%)	Moderate N=47 (100%)	Severe N=47 (100%)	Missing N=47 (100%)	Mild N=12 (100%)	Moderate N=12 (100%)	Severe N=12 (100%)	Missing N=12 (100%)
Musculoskeletal and connective tissue disorders（筋骨格系および結合組織障害）	11 (23.4%)	0	0	0	4 (33.3%)	0	0	0
Arthralgia（関節痛）	1 (2.1%)	0	0	0	0	0	0	0
Back pain（背部痛）	3 (6.4%)	0	0	0	1 (8.3%)	0	0	0
Joint swelling（関節腫脹）	2 (4.3%)	0	0	0	0	0	0	0
Musculoskeletal discomfort（筋骨格不快感）	1 (2.1%)	0	0	0	0	0	0	0
Musculoskeletal stiffness（筋骨格硬直）	0	0	0	0	1 (8.3%)	0	0	0
Myalgia（筋肉痛）	1 (2.1%)	0	0	0	1 (8.3%)	0	0	0
Myositis（筋炎）	1 (2.1%)	0	0	0	0	0	0	0
Osteoarthritis（変形性関節症）	1 (2.1%)	0	0	0	1 (8.3%)	0	0	0
Tendonitis（腱炎）	1 (2.1%)	0	0	0	0	0	0	0
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））	0	3 (6.4%)	0	0	0	0	1 (8.3%)	0
Gastrointestinal stromal tumour（消化管間質性腫瘍）	0	0	0	0	0	0	1 (8.3%)	0
Metastases to lymph nodes（リンパ節転移）	0	1 (2.1%)	0	0	0	0	0	0
Renal cancer（腎癌）	0	1 (2.1%)	0	0	0	0	0	0
Tumour haemorrhage（腫瘍出血）	0	1 (2.1%)	0	0	0	0	0	0
Nervous system disorders（神経系障害）	6 (12.8%)	0	0	0	2 (16.7%)	0	0	0
Cerebral infarction（脳梗塞）	0	0	0	0	1 (8.3%)	0	0	0
Diabetic neuropathy（糖尿病性ニューロパチー）	1 (2.1%)	0	0	0	0	0	0	0
Dizziness（浮動性めまい）	1 (2.1%)	0	0	0	0	0	0	0
Headache（頭痛）	1 (2.1%)	0	0	0	0	0	0	0
Hypoaesthesia（感覚鈍麻）	0	0	0	0	1 (8.3%)	0	0	0
Hypoglycaemic unconsciousness（低血糖性意識消失）	1 (2.1%)	0	0	0	0	0	0	0
Presyncope（失神寸前の状態）	1 (2.1%)	0	0	0	0	0	0	0
Sciatica（坐骨神経痛）	1 (2.1%)	0	0	0	0	0	0	0
Tension headache（緊張性頭痛）	1 (2.1%)	0	0	0	0	0	0	0

表 2.7.4.7-40 重症度別の TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total				UFH / Warfarin			
	Mild N=47 (100%)	Moderate N=47 (100%)	Severe N=47 (100%)	Missing N=47 (100%)	Mild N=12 (100%)	Moderate N=12 (100%)	Severe N=12 (100%)	Missing N=12 (100%)
Psychiatric disorders（精神障害）	0	0	0	0	3 (25.0%)	0	0	0
Anxiety（不安）	0	0	0	0	1 (8.3%)	0	0	0
Insomnia（不眠症）	0	0	0	0	3 (25.0%)	0	0	0
Renal and urinary disorders（腎および尿路障害）	1 (2.1%)	1 (2.1%)	0	0	2 (16.7%)	0	0	0
Cystitis haemorrhagic（出血性膀胱炎）	1 (2.1%)	0	0	0	0	0	0	0
Diabetic nephropathy（糖尿病性腎症）	0	0	0	0	1 (8.3%)	0	0	0
Haematuria（血尿）	0	0	0	0	1 (8.3%)	0	0	0
Renal failure chronic（慢性腎不全）	0	1 (2.1%)	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders（呼吸器、胸郭および縦隔障害）	5 (10.6%)	1 (2.1%)	0	0	2 (16.7%)	0	0	0
Aspiration（誤嚥）	0	0	0	0	1 (8.3%)	0	0	0
Cough（咳嗽）	1 (2.1%)	0	0	0	0	0	0	0
Epistaxis（鼻出血）	4 (8.5%)	0	0	0	1 (8.3%)	0	0	0
Hiccups（しゃっくり）	1 (2.1%)	0	0	0	0	0	0	0
Interstitial lung disease（間質性肺疾患）	0	1 (2.1%)	0	0	0	0	0	0
Skin and subcutaneous tissue disorders（皮膚および皮下組織障害）	14 (29.8%)	0	0	0	4 (33.3%)	2 (16.7%)	0	0
Decubitus ulcer（褥瘡性潰瘍）	2 (4.3%)	0	0	0	0	0	0	0
Dermatitis（皮膚炎）	0	0	0	0	1 (8.3%)	1 (8.3%)	0	0
Dermatitis allergic（アレルギー性皮膚炎）	1 (2.1%)	0	0	0	0	0	0	0
Dermatitis contact（接触性皮膚炎）	3 (6.4%)	0	0	0	1 (8.3%)	1 (8.3%)	0	0
Eczema asteatotic（皮脂欠乏性湿疹）	1 (2.1%)	0	0	0	0	0	0	0
Erythema（紅斑）	1 (2.1%)	0	0	0	1 (8.3%)	0	0	0
Haemorrhage subcutaneous（皮下出血）	7 (14.9%)	0	0	0	1 (8.3%)	0	0	0
Ingrowing nail（嵌入爪）	1 (2.1%)	0	0	0	0	0	0	0
Petechiae（点状出血）	1 (2.1%)	0	0	0	0	0	0	0
Pruritus（そう痒症）	2 (4.3%)	0	0	0	1 (8.3%)	0	0	0
Skin haemorrhage（皮膚出血）	1 (2.1%)	0	0	0	0	0	0	0
Urticaria（蕁麻疹）	1 (2.1%)	0	0	0	0	0	0	0

表 2.7.4.7-40　重症度別の TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class / Preferred term / MedDRA version 16.1	Rivaroxaban Total				UFH / Warfarin			
	Mild	Moderate	Severe	Missing	Mild	Moderate	Severe	Missing
	N=47 (100%)	N=47 (100%)	N=47 (100%)	N=47 (100%)	N=12 (100%)	N=12 (100%)	N=12 (100%)	N=12 (100%)
Vascular disorders（血管障害）	1 (2.1%)	0	0	0	0	0	0	0
Lymphoedema（リンパ浮腫）	1 (2.1%)	0	0	0	0	0	0	0

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Only the most severe intensity is counted for multiple occurrences of the same AE in each subject.
Global Biostatistics: /by-sasp/patdb/projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j2-table.sas erjli 07MAR2014 15:03
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/98

表 2.7.4.7-41 重症度別の TEAE（試験 15960、安全性解析対象集団）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 15 mg BID/OD Mild N=30 (100%)	 Moderate N=30 (100%)	 Severe N=30 (100%)	 Missing N=30 (100%)
Number (%) of subjects with at least one adverse event	24 (80.0%)	7 (23.3%)	1 (3.3%)	0
Cardiac disorders (心臓障害)	1 (3.3%)	1 (3.3%)	0	0
Atrial fibrillation (心房細動)	1 (3.3%)	0	0	0
Cardiac failure (心不全)	0	1 (3.3%)	0	0
Eye disorders (眼障害)	3 (10.0%)	0	0	0
Cataract (白内障)	1 (3.3%)	0	0	0
Conjunctival haemorrhage (結膜出血)	1 (3.3%)	0	0	0
Conjunctivitis (結膜炎)	2 (6.7%)	0	0	0
Gastrointestinal disorders (胃腸障害)	9 (30.0%)	0	0	0
Abdominal discomfort (腹部不快感)	0	0	0	0
Abdominal pain (腹痛)	1 (3.3%)	0	0	0
Constipation (便秘)	1 (3.3%)	0	0	0
Diarrhoea (下痢)	3 (10.0%)	0	0	0
Gastrooesophageal reflux disease (胃食道逆流性疾患)	2 (6.7%)	0	0	0
Gingival bleeding (歯肉出血)	1 (3.3%)	0	0	0
Haematochezia (血便排泄)	1 (3.3%)	0	0	0
Haemorrhoidal haemorrhage (痔出血)	1 (3.3%)	0	0	0
Hypoaesthesia oral (口の感覚鈍麻)	1 (3.3%)	0	0	0
Nausea (悪心)	2 (6.7%)	0	0	0
Stomatitis (口内炎)	0	0	0	0
Vomiting (嘔吐)	3 (10.0%)	0	0	0

表 2.7.4.7-41 重症度別の TEAE（試験 15960、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 15 mg BID/OD Mild N=30 (100%)	 Moderate N=30 (100%)	 Severe N=30 (100%)	 Missing N=30 (100%)
General disorders and administration site conditions（一般・全身障害および投与部位の状態）	3 (10.0%)	0	0	0
Chest discomfort（胸部不快感）	0	0	0	0
Face oedema（顔面浮腫）	1 (3.3%)	0	0	0
Local swelling（局所腫脹）	1 (3.3%)	0	0	0
Malaise（倦怠感）	1 (3.3%)	0	0	0
Oedema peripheral（末梢性浮腫）	1 (3.3%)	0	0	0
Pyrexia（発熱）	0	0	0	0
Hepatobiliary disorders（肝胆道系障害）	1 (3.3%)	1 (3.3%)	0	0
Hepatic function abnormal（肝機能異常）	1 (3.3%)	1 (3.3%)	0	0
Immune system disorders（免疫系障害）	1 (3.3%)	0	0	0
Seasonal allergy（季節性アレルギー）	1 (3.3%)	0	0	0
Infections and infestations（感染症および寄生虫症）	13 (43.3%)	4 (13.3%)	0	0
Abscess neck（頚部膿瘍）	1 (3.3%)	0	0	0
Cellulitis（蜂巣炎）	1 (3.3%)	2 (6.7%)	0	0
Cystitis（膀胱炎）	2 (6.7%)	0	0	0
Gastroenteritis（胃腸炎）	0	0	0	0
Herpes zoster（帯状疱疹）	0	1 (3.3%)	0	0
Nasopharyngitis（鼻咽頭炎）	8 (26.7%)	0	0	0
Oral herpes（口腔ヘルペス）	1 (3.3%)	0	0	0
Otitis externa（外耳炎）	0	0	0	0
Pharyngitis（咽頭炎）	1 (3.3%)	0	0	0
Pneumonia（肺炎）	2 (6.7%)	1 (3.3%)	0	0
Tinea pedis（足部白癬）	1 (3.3%)	0	0	0
Urinary tract infection（尿路感染）	1 (3.3%)	0	0	0

表 2.7.4.7-41 重症度別の TEAE（試験 15960、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 15 mg BID/OD Mild N=30 (100%)	Moderate N=30 (100%)	Severe N=30 (100%)	Missing N=30 (100%)
Injury, poisoning and procedural complications（傷害、中毒および処置合併症）	4 (13.3%)	0	0	0
Chemical burns of eye（眼部化学熱傷）	1 (3.3%)	0	0	0
Radiation skin injury（放射線皮膚損傷）	1 (3.3%)	0	0	0
Spinal compression fracture（脊椎圧迫骨折）	0	0	0	0
Subcutaneous haematoma（皮下血腫）	2 (6.7%)	0	0	0
Wound haemorrhage（創傷出血）	1 (3.3%)	0	0	0
Investigations（臨床検査）	5 (16.7%)	0	0	0
Alanine aminotransferase increased（アラニンアミノトランスフェラーゼ増加）	0	0	0	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）	0	0	0	0
Blood bilirubin increased（血中ビリルビン増加）	1 (3.3%)	0	0	0
Blood calcium decreased（血中カルシウム減少）	1 (3.3%)	0	0	0
Blood cholesterol increased（血中コレステロール増加）	0	0	0	0
Blood urine present（尿中血陽性）	1 (3.3%)	0	0	0
Liver function test abnormal（肝機能検査異常）	2 (6.7%)	0	0	0
Occult blood positive（便潜血陽性）	1 (3.3%)	0	0	0
Metabolism and nutrition disorders（代謝および栄養障害）	3 (10.0%)	0	0	0
Decreased appetite（食欲減退）	1 (3.3%)	0	0	0
Dehydration（脱水）	1 (3.3%)	0	0	0
Gout（痛風）	1 (3.3%)	0	0	0
Musculoskeletal and connective tissue disorders（筋骨格系および結合組織障害）	2 (6.7%)	0	0	0
Arthralgia（関節痛）	1 (3.3%)	0	0	0
Muscle spasms（筋痙縮）	0	0	0	0
Musculoskeletal stiffness（筋骨格硬直）	1 (3.3%)	0	0	0
Osteoporosis（骨粗鬆症）	1 (3.3%)	0	0	0
Sacroiliitis（仙腸骨炎）	0	0	0	0
Synovial cyst（滑液嚢腫）	0	0	0	0

表 2.7.4.7-41 重症度別の TEAE（試験 15960、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 15 mg BID/OD Mild N=30 (100%)	 Moderate N=30 (100%)	 Severe N=30 (100%)	 Missing N=30 (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））	1 (3.3%)	0	1 (3.3%)	0
Hypopharyngeal cancer（下咽頭癌）	1 (3.3%)	0	1 (3.3%)	0
Nervous system disorders（神経系障害）	4 (13.3%)	1 (3.3%)	0	0
Dizziness（浮動性めまい）	2 (6.7%)	0	0	0
Headache（頭痛）	2 (6.7%)	1 (3.3%)	0	0
Hypoaesthesia（感覚鈍麻）	0	0	0	0
Sciatica（坐骨神経痛）	1 (3.3%)	0	0	0
Sensory disturbance（感覚障害）	1 (3.3%)	0	0	0
Somnolence（傾眠）	1 (3.3%)	0	0	0
Psychiatric disorders（精神障害）	2 (6.7%)	0	0	0
Delirium（譫妄）	1 (3.3%)	0	0	0
Insomnia（不眠症）	1 (3.3%)	0	0	0
Respiratory, thoracic and mediastinal disorders（呼吸器、胸郭および縦隔障害）	7 (23.3%)	0	0	0
Cough（咳嗽）	0	0	0	0
Epistaxis（鼻出血）	3 (10.0%)	0	0	0
Haemoptysis（喀血）	1 (3.3%)	0	0	0
Hiccups（しゃっくり）	1 (3.3%)	0	0	0
Laryngeal pain（喉頭痛）	1 (3.3%)	0	0	0
Nasal congestion（鼻閉）	0	0	0	0
Upper respiratory tract inflammation（上気道の炎症）	2 (6.7%)	0	0	0

表 2.7.4.7-41 重症度別の TEAE（試験 15960、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 15 mg BID/OD Mild N=30 (100%)	 Moderate N=30 (100%)	 Severe N=30 (100%)	 Missing N=30 (100%)
Skin and subcutaneous tissue disorders（皮膚および皮下組織障害）	11 (36.7%)	1 (3.3%)	0	0
Dermatitis（皮膚炎）	1 (3.3%)	0	0	0
Dermatitis contact（接触性皮膚炎）	1 (3.3%)	0	0	0
Drug eruption（薬疹）	0	1 (3.3%)	0	0
Eczema（湿疹）	3 (10.0%)	0	0	0
Haemorrhage subcutaneous（皮下出血）	4 (13.3%)	0	0	0
Petechiae（点状出血）	1 (3.3%)	0	0	0
Pruritus（そう痒症）	2 (6.7%)	0	0	0
Pruritus generalised（全身性そう痒症）	0	0	0	0
Rash（発疹）	2 (6.7%)	0	0	0

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Only the most severe intensity is counted for multiple occurrences of the same AE in each subject.
Global Biostatistics: /by-sasp/patdb/projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j2-table.sas erjli 07MAR2014 15:03
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/98

表 2.7.4.7-41 重症度別の TEAE（試験 15960、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total				UFH / Warfarin			
	Mild N=30 (100%)	Moderate N=30 (100%)	Severe N=30 (100%)	Missing N=30 (100%)	Mild N=7 (100%)	Moderate N=7 (100%)	Severe N=7 (100%)	Missing N=7 (100%)
Number (%) of subjects with at least one adverse event	24 (80.0%)	7 (23.3%)	1 (3.3%)	0	7 (100.0%)	0	0	0
Cardiac disorders (心臓障害)	1 (3.3%)	1 (3.3%)	0	0	0	0	0	0
Atrial fibrillation (心房細動)	1 (3.3%)	0	0	0	0	0	0	0
Cardiac failure (心不全)	0	1 (3.3%)	0	0	0	0	0	0
Eye disorders (眼障害)	3 (10.0%)	0	0	0	1 (14.3%)	0	0	0
Cataract (白内障)	1 (3.3%)	0	0	0	0	0	0	0
Conjunctival haemorrhage (結膜出血)	1 (3.3%)	0	0	0	0	0	0	0
Conjunctivitis (結膜炎)	2 (6.7%)	0	0	0	1 (14.3%)	0	0	0
Gastrointestinal disorders (胃腸障害)	9 (30.0%)	0	0	0	4 (57.1%)	0	0	0
Abdominal discomfort (腹部不快感)	0	0	0	0	1 (14.3%)	0	0	0
Abdominal pain (腹痛)	1 (3.3%)	0	0	0	0	0	0	0
Constipation (便秘)	1 (3.3%)	0	0	0	0	0	0	0
Diarrhoea (下痢)	3 (10.0%)	0	0	0	2 (28.6%)	0	0	0
Gastrooesophageal reflux disease (胃食道逆流性疾患)	2 (6.7%)	0	0	0	0	0	0	0
Gingival bleeding (歯肉出血)	1 (3.3%)	0	0	0	1 (14.3%)	0	0	0
Haematochezia (血便排泄)	1 (3.3%)	0	0	0	0	0	0	0
Haemorrhoidal haemorrhage (痔出血)	1 (3.3%)	0	0	0	0	0	0	0
Hypoaesthesia oral (口の感覚鈍麻)	1 (3.3%)	0	0	0	0	0	0	0
Nausea (悪心)	2 (6.7%)	0	0	0	1 (14.3%)	0	0	0
Stomatitis (口内炎)	0	0	0	0	1 (14.3%)	0	0	0
Vomiting (嘔吐)	3 (10.0%)	0	0	0	0	0	0	0

表 2.7.4.7-41 重症度別の TEAE（試験 15960、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total				UFH / Warfarin			
	Mild N=30 (100%)	Moderate N=30 (100%)	Severe N=30 (100%)	Missing N=30 (100%)	Mild N=7 (100%)	Moderate N=7 (100%)	Severe N=7 (100%)	Missing N=7 (100%)
General disorders and administration site conditions（一般・全身障害および投与部位の状態）	3 (10.0%)	0	0	0	2 (28.6%)	0	0	0
Chest discomfort（胸部不快感）	0	0	0	0	1 (14.3%)	0	0	0
Face oedema（顔面浮腫）	1 (3.3%)	0	0	0	0	0	0	0
Local swelling（局所腫脹）	1 (3.3%)	0	0	0	0	0	0	0
Malaise（倦怠感）	1 (3.3%)	0	0	0	0	0	0	0
Oedema peripheral（末梢性浮腫）	1 (3.3%)	0	0	0	1 (14.3%)	0	0	0
Pyrexia（発熱）	0	0	0	0	1 (14.3%)	0	0	0
Hepatobiliary disorders（肝胆道系障害）	1 (3.3%)	1 (3.3%)	0	0	0	0	0	0
Hepatic function abnormal（肝機能異常）	1 (3.3%)	1 (3.3%)	0	0	0	0	0	0
Immune system disorders（免疫系障害）	1 (3.3%)	0	0	0	0	0	0	0
Seasonal allergy（季節性アレルギー）	1 (3.3%)	0	0	0	0	0	0	0
Infections and infestations（感染症および寄生虫症）	13 (43.3%)	4 (13.3%)	0	0	5 (71.4%)	0	0	0
Abscess neck（頚部膿瘍）	1 (3.3%)	0	0	0	0	0	0	0
Cellulitis（蜂巣炎）	1 (3.3%)	2 (6.7%)	0	0	0	0	0	0
Cystitis（膀胱炎）	2 (6.7%)	0	0	0	0	0	0	0
Gastroenteritis（胃腸炎）	0	0	0	0	2 (28.6%)	0	0	0
Herpes zoster（帯状疱疹）	0	1 (3.3%)	0	0	0	0	0	0
Nasopharyngitis（鼻咽頭炎）	8 (26.7%)	0	0	0	2 (28.6%)	0	0	0
Oral herpes（口腔ヘルペス）	1 (3.3%)	0	0	0	0	0	0	0
Otitis externa（外耳炎）	0	0	0	0	1 (14.3%)	0	0	0
Pharyngitis（咽頭炎）	1 (3.3%)	0	0	0	0	0	0	0
Pneumonia（肺炎）	2 (6.7%)	1 (3.3%)	0	0	0	0	0	0
Tinea pedis（足部白癬）	1 (3.3%)	0	0	0	0	0	0	0
Urinary tract infection（尿路感染）	1 (3.3%)	0	0	0	0	0	0	0

表 2.7.4.7-41 重症度別の TEAE（試験 15960、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total				UFH / Warfarin			
	Mild N=30 (100%)	Moderate N=30 (100%)	Severe N=30 (100%)	Missing N=30 (100%)	Mild N=7 (100%)	Moderate N=7 (100%)	Severe N=7 (100%)	Missing N=7 (100%)
Injury, poisoning and procedural complications（傷害、中毒および処置合併症）	4 (13.3%)	0	0	0	1 (14.3%)	0	0	0
Chemical burns of eye（眼部化学熱傷）	1 (3.3%)	0	0	0	0	0	0	0
Radiation skin injury（放射線皮膚損傷）	1 (3.3%)	0	0	0	0	0	0	0
Spinal compression fracture（脊椎圧迫骨折）	0	0	0	0	1 (14.3%)	0	0	0
Subcutaneous haematoma（皮下血腫）	2 (6.7%)	0	0	0	0	0	0	0
Wound haemorrhage（創傷出血）	1 (3.3%)	0	0	0	0	0	0	0
Investigations（臨床検査）	5 (16.7%)	0	0	0	4 (57.1%)	0	0	0
Alanine aminotransferase increased（アラニンアミノトランスフェラーゼ増加）	0	0	0	0	3 (42.9%)	0	0	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）	0	0	0	0	2 (28.6%)	0	0	0
Blood bilirubin increased（血中ビリルビン増加）	1 (3.3%)	0	0	0	0	0	0	0
Blood calcium decreased（血中カルシウム減少）	1 (3.3%)	0	0	0	0	0	0	0
Blood cholesterol increased（血中コレステロール増加）	0	0	0	0	1 (14.3%)	0	0	0
Blood urine present（尿中血陽性）	1 (3.3%)	0	0	0	0	0	0	0
Liver function test abnormal（肝機能検査異常）	2 (6.7%)	0	0	0	0	0	0	0
Occult blood positive（便潜血陽性）	1 (3.3%)	0	0	0	0	0	0	0
Metabolism and nutrition disorders（代謝および栄養障害）	3 (10.0%)	0	0	0	0	0	0	0
Decreased appetite（食欲減退）	1 (3.3%)	0	0	0	0	0	0	0
Dehydration（脱水）	1 (3.3%)	0	0	0	0	0	0	0
Gout（痛風）	1 (3.3%)	0	0	0	0	0	0	0

表 2.7.4.7-41 重症度別の TEAE（試験 15960、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total				UFH / Warfarin			
	Mild N=30 (100%)	Moderate N=30 (100%)	Severe N=30 (100%)	Missing N=30 (100%)	Mild N=7 (100%)	Moderate N=7 (100%)	Severe N=7 (100%)	Missing N=7 (100%)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	2 (6.7%)	0	0	0	3 (42.9%)	0	0	0
Arthralgia (関節痛)	1 (3.3%)	0	0	0	0	0	0	0
Muscle spasms (筋痙縮)	0	0	0	0	1 (14.3%)	0	0	0
Musculoskeletal stiffness (筋骨格硬直)	1 (3.3%)	0	0	0	0	0	0	0
Osteoporosis (骨粗鬆症)	1 (3.3%)	0	0	0	1 (14.3%)	0	0	0
Sacroiliitis (仙腸骨炎)	0	0	0	0	1 (14.3%)	0	0	0
Synovial cyst (滑液嚢腫)	0	0	0	0	1 (14.3%)	0	0	0
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))	1 (3.3%)	0	1 (3.3%)	0	0	0	0	0
Hypopharyngeal cancer (下咽頭癌)	1 (3.3%)	0	1 (3.3%)	0	0	0	0	0
Nervous system disorders (神経系障害)	4 (13.3%)	1 (3.3%)	0	0	1 (14.3%)	0	0	0
Dizziness (浮動性めまい)	2 (6.7%)	0	0	0	1 (14.3%)	0	0	0
Headache (頭痛)	2 (6.7%)	1 (3.3%)	0	0	0	0	0	0
Hypoaesthesia (感覚鈍麻)	0	0	0	0	1 (14.3%)	0	0	0
Sciatica (坐骨神経痛)	1 (3.3%)	0	0	0	0	0	0	0
Sensory disturbance (感覚障害)	1 (3.3%)	0	0	0	0	0	0	0
Somnolence (傾眠)	1 (3.3%)	0	0	0	0	0	0	0
Psychiatric disorders (精神障害)	2 (6.7%)	0	0	0	0	0	0	0
Delirium (譫妄)	1 (3.3%)	0	0	0	0	0	0	0
Insomnia (不眠症)	1 (3.3%)	0	0	0	0	0	0	0

表 2.7.4.7-41 重症度別の TEAE（試験 15960、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total				UFH / Warfarin			
	Mild N=30 (100%)	Moderate N=30 (100%)	Severe N=30 (100%)	Missing N=30 (100%)	Mild N=7 (100%)	Moderate N=7 (100%)	Severe N=7 (100%)	Missing N=7 (100%)
Respiratory, thoracic and mediastinal disorders（呼吸器、胸郭および縦隔障害）	7 (23.3%)	0	0	0	2 (28.6%)	0	0	0
Cough（咳嗽）	0	0	0	0	1 (14.3%)	0	0	0
Epistaxis（鼻出血）	3 (10.0%)	0	0	0	0	0	0	0
Haemoptysis（喀血）	1 (3.3%)	0	0	0	0	0	0	0
Hiccups（しゃっくり）	1 (3.3%)	0	0	0	0	0	0	0
Laryngeal pain（喉頭痛）	1 (3.3%)	0	0	0	0	0	0	0
Nasal congestion（鼻閉）	0	0	0	0	1 (14.3%)	0	0	0
Upper respiratory tract inflammation（上気道の炎症）	2 (6.7%)	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders（皮膚および皮下組織障害）	11 (36.7%)	1 (3.3%)	0	0	5 (71.4%)	0	0	0
Dermatitis（皮膚炎）	1 (3.3%)	0	0	0	0	0	0	0
Dermatitis contact（接触性皮膚炎）	1 (3.3%)	0	0	0	0	0	0	0
Drug eruption（薬疹）	0	1 (3.3%)	0	0	0	0	0	0
Eczema（湿疹）	3 (10.0%)	0	0	0	1 (14.3%)	0	0	0
Haemorrhage subcutaneous（皮下出血）	4 (13.3%)	0	0	0	4 (57.1%)	0	0	0
Petechiae（点状出血）	1 (3.3%)	0	0	0	0	0	0	0
Pruritus（そう痒症）	2 (6.7%)	0	0	0	0	0	0	0
Pruritus generalised（全身性そう痒症）	0	0	0	0	1 (14.3%)	0	0	0
Rash（発疹）	2 (6.7%)	0	0	0	0	0	0	0

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Only the most severe intensity is counted for multiple occurrences of the same AE in each subject.
Global Biostatistics: /by-sasp/patdb/projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j2-table.sas erjli 07MAR2014 15:03
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/98

表 2.7.4.7-42 重症度別の治験薬との因果関係が否定できない TEAE（試験 14568、安全性解析対象集団）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID/15 mg OD				Rivaroxaban 15 mg BID/OD			
	Mild N=22 (100%)	Moderate N=22 (100%)	Severe N=22 (100%)	Missing N=22 (100%)	Mild N=25 (100%)	Moderate N=25 (100%)	Severe N=25 (100%)	Missing N=25 (100%)
Number (%) of subjects with at least one adverse event	7 (31.8%)	3 (13.6%)	0	0	7 (28.0%)	0	0	0
Eye disorders (眼障害)	1 (4.5%)	0	0	0	0	0	0	0
Conjunctival haemorrhage (結膜出血)	1 (4.5%)	0	0	0	0	0	0	0
Gastrointestinal disorders (胃腸障害)	1 (4.5%)	0	0	0	2 (8.0%)	0	0	0
Abdominal pain (腹痛)	1 (4.5%)	0	0	0	0	0	0	0
Gingival bleeding (歯肉出血)	1 (4.5%)	0	0	0	0	0	0	0
Haematochezia (血便排泄)	1 (4.5%)	0	0	0	2 (8.0%)	0	0	0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	0	0	0	0	3 (12.0%)	0	0	0
Puncture site haemorrhage (穿刺部位出血)	0	0	0	0	1 (4.0%)	0	0	0
Pyrexia (発熱)	0	0	0	0	1 (4.0%)	0	0	0
Thirst (口渇)	0	0	0	0	1 (4.0%)	0	0	0
Investigations (臨床検査)	1 (4.5%)	1 (4.5%)	0	0	0	0	0	0
Activated partial thromboplastin time prolonged (活性化部分トロンボプラスチン時間延長)	0	0	0	0	0	0	0	0
Blood urine present (尿中血陽性)	1 (4.5%)	0	0	0	0	0	0	0
Liver function test abnormal (肝機能検査異常)	0	1 (4.5%)	0	0	0	0	0	0
Renal and urinary disorders (腎および尿路障害)	0	1 (4.5%)	0	0	0	0	0	0
Haematuria (血尿)	0	0	0	0	0	0	0	0
Renal failure chronic (慢性腎不全)	0	1 (4.5%)	0	0	0	0	0	0

表 2.7.4.7-42　重症度別の治験薬との因果関係が否定できない TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID/15 mg OD Mild N=22 (100%)	 Moderate N=22 (100%)	 Severe N=22 (100%)	 Missing N=22 (100%)	Rivaroxaban 15 mg BID/OD Mild N=25 (100%)	 Moderate N=25 (100%)	 Severe N=25 (100%)	 Missing N=25 (100%)
Respiratory, thoracic and mediastinal disorders（呼吸器、胸郭および縦隔障害）	4 (18.2%)	1 (4.5%)	0	0	1 (4.0%)	0	0	0
Cough（咳嗽）	1 (4.5%)	0	0	0	0	0	0	0
Epistaxis（鼻出血）	3 (13.6%)	0	0	0	1 (4.0%)	0	0	0
Interstitial lung disease（間質性肺疾患）	0	1 (4.5%)	0	0	0	0	0	0
Skin and subcutaneous tissue disorders（皮膚および皮下組織障害）	1 (4.5%)	0	0	0	3 (12.0%)	0	0	0
Haemorrhage subcutaneous（皮下出血）	1 (4.5%)	0	0	0	3 (12.0%)	0	0	0

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Only the most severe intensity is counted for multiple occurrences of the same AE in each subject.
Global Biostatistics: /by-sasp/patdb/projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j2-table.sas　erjli　07MAR2014 15:03
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/100

表 2.7.4.7-42 重症度別の治験薬との因果関係が否定できない TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total Mild N=47 (100%)	 Moderate N=47 (100%)	 Severe N=47 (100%)	 Missing N=47 (100%)	UFH / Warfarin Mild N=12 (100%)	 Moderate N=12 (100%)	 Severe N=12 (100%)	 Missing N=12 (100%)
Number (%) of subjects with at least one adverse event	14 (29.8%)	3 (6.4%)	0	0	4 (33.3%)	0	0	0
Eye disorders（眼障害）	1 (2.1%)	0	0	0	0	0	0	0
Conjunctival haemorrhage（結膜出血）	1 (2.1%)	0	0	0	0	0	0	0
Gastrointestinal disorders（胃腸障害）	3 (6.4%)	0	0	0	0	0	0	0
Abdominal pain（腹痛）	1 (2.1%)	0	0	0	0	0	0	0
Gingival bleeding（歯肉出血）	1 (2.1%)	0	0	0	0	0	0	0
Haematochezia（血便排泄）	3 (6.4%)	0	0	0	0	0	0	0
General disorders and administration site conditions（一般・全身障害および投与部位の状態）	3 (6.4%)	0	0	0	0	0	0	0
Puncture site haemorrhage（穿刺部位出血）	1 (2.1%)	0	0	0	0	0	0	0
Pyrexia（発熱）	1 (2.1%)	0	0	0	0	0	0	0
Thirst（口渇）	1 (2.1%)	0	0	0	0	0	0	0
Investigations（臨床検査）	1 (2.1%)	1 (2.1%)	0	0	1 (8.3%)	0	0	0
Activated partial thromboplastin time prolonged（活性化部分トロンボプラスチン時間延長）	0	0	0	0	1 (8.3%)	0	0	0
Blood urine present（尿中血陽性）	1 (2.1%)	0	0	0	0	0	0	0
Liver function test abnormal（肝機能検査異常）	0	1 (2.1%)	0	0	0	0	0	0
Renal and urinary disorders（腎および尿路障害）	0	1 (2.1%)	0	0	1 (8.3%)	0	0	0
Haematuria（血尿）	0	0	0	0	1 (8.3%)	0	0	0
Renal failure chronic（慢性腎不全）	0	1 (2.1%)	0	0	0	0	0	0

表 2.7.4.7-42 重症度別の治験薬との因果関係が否定できない TEAE（試験 14568、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total Mild N=47 (100%)	 Moderate N=47 (100%)	 Severe N=47 (100%)	 Missing N=47 (100%)	UFH / Warfarin Mild N=12 (100%)	 Moderate N=12 (100%)	 Severe N=12 (100%)	 Missing N=12 (100%)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	5 (10.6%)	1 (2.1%)	0	0	1 (8.3%)	0	0	0
Cough (咳嗽)	1 (2.1%)	0	0	0	0	0	0	0
Epistaxis (鼻出血)	4 (8.5%)	0	0	0	1 (8.3%)	0	0	0
Interstitial lung disease (間質性肺疾患)	0	1 (2.1%)	0	0	0	0	0	0
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	4 (8.5%)	0	0	0	1 (8.3%)	0	0	0
Haemorrhage subcutaneous (皮下出血)	4 (8.5%)	0	0	0	1 (8.3%)	0	0	0

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Only the most severe intensity is counted for multiple occurrences of the same AE in each subject.
Global Biostatistics: /by-sasp/patdb/projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j2-table.sas erjli 07MAR2014 15:03
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/100

表 2.7.4.7-43 重症度別の治験薬との因果関係が否定できない TEAE（試験 15960、安全性解析対象集団）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID/15 mg OD				Rivaroxaban 15 mg BID/OD			
	Mild N=0 (100%)	Moderate N=0 (100%)	Severe N=0 (100%)	Missing N=0 (100%)	Mild N=30 (100%)	Moderate N=30 (100%)	Severe N=30 (100%)	Missing N=30 (100%)
Number (%) of subjects with at least one adverse event	0	0	0	0	13 (43.3%)	2 (6.7%)	0	0
Eye disorders (眼障害)	0	0	0	0	1 (3.3%)	0	0	0
Conjunctivitis (結膜炎)	0	0	0	0	1 (3.3%)	0	0	0
Gastrointestinal disorders (胃腸障害)	0	0	0	0	4 (13.3%)	0	0	0
Constipation (便秘)	0	0	0	0	1 (3.3%)	0	0	0
Diarrhoea (下痢)	0	0	0	0	0	0	0	0
Gingival bleeding (歯肉出血)	0	0	0	0	0	0	0	0
Haematochezia (血便排泄)	0	0	0	0	1 (3.3%)	0	0	0
Haemorrhoidal haemorrhage (痔出血)	0	0	0	0	1 (3.3%)	0	0	0
Hypoaesthesia oral (口の感覚鈍麻)	0	0	0	0	1 (3.3%)	0	0	0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	0	0	0	0	1 (3.3%)	0	0	0
Oedema peripheral (末梢性浮腫)	0	0	0	0	1 (3.3%)	0	0	0
Hepatobiliary disorders (肝胆道系障害)	0	0	0	0	1 (3.3%)	1 (3.3%)	0	0
Hepatic function abnormal (肝機能異常)	0	0	0	0	1 (3.3%)	1 (3.3%)	0	0
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	0	0	0	0	1 (3.3%)	0	0	0
Subcutaneous haematoma (皮下血腫)	0	0	0	0	1 (3.3%)	0	0	0

表 2.7.4.7-43 重症度別の治験薬との因果関係が否定できない TEAE（試験 15960、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID/15 mg OD Mild N=0 (100%)	 Moderate N=0 (100%)	 Severe N=0 (100%)	 Missing N=0 (100%)	Rivaroxaban 15 mg BID/OD Mild N=30 (100%)	 Moderate N=30 (100%)	 Severe N=30 (100%)	 Missing N=30 (100%)
Investigations（臨床検査）	0	0	0	0	3 (10.0%)	0	0	0
Alanine aminotransferase increased（アラニンアミノトランスフェラーゼ増加）	0	0	0	0	0	0	0	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）	0	0	0	0	0	0	0	0
Blood bilirubin increased（血中ビリルビン増加）	0	0	0	0	1 (3.3%)	0	0	0
Blood urine present（尿中血陽性）	0	0	0	0	1 (3.3%)	0	0	0
Liver function test abnormal（肝機能検査異常）	0	0	0	0	1 (3.3%)	0	0	0
Respiratory, thoracic and mediastinal disorders（呼吸器、胸郭および縦隔障害）	0	0	0	0	3 (10.0%)	0	0	0
Epistaxis（鼻出血）	0	0	0	0	2 (6.7%)	0	0	0
Haemoptysis（喀血）	0	0	0	0	1 (3.3%)	0	0	0
Skin and subcutaneous tissue disorders（皮膚および皮下組織障害）	0	0	0	0	5 (16.7%)	1 (3.3%)	0	0
Drug eruption（薬疹）	0	0	0	0	0	1 (3.3%)	0	0
Haemorrhage subcutaneous（皮下出血）	0	0	0	0	4 (13.3%)	0	0	0
Petechiae（点状出血）	0	0	0	0	1 (3.3%)	0	0	0

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Only the most severe intensity is counted for multiple occurrences of the same AE in each subject.
Global Biostatistics: /by-sasp/patdb/projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j2-table.sas erjli 07MAR2014 15:03
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/100

表 2.7.4.7-43　重症度別の治験薬との因果関係が否定できない TEAE（試験 15960、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total Mild N=30 (100%)	 Moderate N=30 (100%)	 Severe N=30 (100%)	 Missing N=30 (100%)	UFH / Warfarin Mild N=7 (100%)	 Moderate N=7 (100%)	 Severe N=7 (100%)	 Missing N=7 (100%)
Number (%) of subjects with at least one adverse event	13 (43.3%)	2 (6.7%)	0	0	4 (57.1%)	0	0	0
Eye disorders (眼障害)	1 (3.3%)	0	0	0	0	0	0	0
Conjunctivitis (結膜炎)	1 (3.3%)	0	0	0	0	0	0	0
Gastrointestinal disorders (胃腸障害)	4 (13.3%)	0	0	0	2 (28.6%)	0	0	0
Constipation (便秘)	1 (3.3%)	0	0	0	0	0	0	0
Diarrhoea (下痢)	0	0	0	0	1 (14.3%)	0	0	0
Gingival bleeding (歯肉出血)	0	0	0	0	1 (14.3%)	0	0	0
Haematochezia (血便排泄)	1 (3.3%)	0	0	0	0	0	0	0
Haemorrhoidal haemorrhage (痔出血)	1 (3.3%)	0	0	0	0	0	0	0
Hypoaesthesia oral (口の感覚鈍麻)	1 (3.3%)	0	0	0	0	0	0	0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	1 (3.3%)	0	0	0	0	0	0	0
Oedema peripheral (末梢性浮腫)	1 (3.3%)	0	0	0	0	0	0	0
Hepatobiliary disorders (肝胆道系障害)	1 (3.3%)	1 (3.3%)	0	0	0	0	0	0
Hepatic function abnormal (肝機能異常)	1 (3.3%)	1 (3.3%)	0	0	0	0	0	0
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	1 (3.3%)	0	0	0	0	0	0	0
Subcutaneous haematoma (皮下血腫)	1 (3.3%)	0	0	0	0	0	0	0

表 2.7.4.7-43 重症度別の治験薬との因果関係が否定できない TEAE（試験 15960、安全性解析対象集団）（続き）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban Total Mild N=30 (100%)	 Moderate N=30 (100%)	 Severe N=30 (100%)	 Missing N=30 (100%)	UFH / Warfarin Mild N=7 (100%)	 Moderate N=7 (100%)	 Severe N=7 (100%)	 Missing N=7 (100%)
Investigations（臨床検査）	3 (10.0%)	0	0	0	2 (28.6%)	0	0	0
Alanine aminotransferase increased（アラニンアミノトランスフェラーゼ増加）	0	0	0	0	2 (28.6%)	0	0	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）	0	0	0	0	2 (28.6%)	0	0	0
Blood bilirubin increased（血中ビリルビン増加）	1 (3.3%)	0	0	0	0	0	0	0
Blood urine present（尿中血陽性）	1 (3.3%)	0	0	0	0	0	0	0
Liver function test abnormal（肝機能検査異常）	1 (3.3%)	0	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders（呼吸器、胸郭および縦隔障害）	3 (10.0%)	0	0	0	0	0	0	0
Epistaxis（鼻出血）	2 (6.7%)	0	0	0	0	0	0	0
Haemoptysis（喀血）	1 (3.3%)	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders（皮膚および皮下組織障害）	5 (16.7%)	1 (3.3%)	0	0	2 (28.6%)	0	0	0
Drug eruption（薬疹）	0	1 (3.3%)	0	0	0	0	0	0
Haemorrhage subcutaneous（皮下出血）	4 (13.3%)	0	0	0	2 (28.6%)	0	0	0
Petechiae（点状出血）	1 (3.3%)	0	0	0	0	0	0	0

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Only the most severe intensity is counted for multiple occurrences of the same AE in each subject.
Global Biostatistics: /by-sasp/patdb/projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j2-table.sas erjli 07MAR2014 15:03
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/100

表 2.7.4.7-44　全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 10 mg BID/15 mg OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated	22 (100%)	22 (100%)	20 (100%)	20 (100%)	22 (100%)	20 (100%)	9 (100%)	5 (100%)
Blood and lymphatic system disorders (血液およびリンパ系障害)	1 (4.5%)					1 (5.0%)		
Anaemia (貧血)	1 (4.5%)					1 (5.0%)		
Cardiac disorders (心臓障害)	2 (9.1%)	2 (9.1%)			2 (9.1%)			
Palpitations (動悸)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Tachycardia (頻脈)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Ear and labyrinth disorders (耳および迷路障害)	1 (4.5%)					1 (5.0%)		
Vertigo (回転性めまい)	1 (4.5%)					1 (5.0%)		
Endocrine disorders (内分泌障害)	1 (4.5%)			1 (5.0%)	1 (4.5%)			
Cushingoid (クッシング様)	1 (4.5%)			1 (5.0%)	1 (4.5%)			
Eye disorders (眼障害)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Conjunctival haemorrhage (結膜出血)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Gastrointestinal disorders (胃腸障害)	6 (27.3%)	3 (13.6%)	1 (5.0%)	1 (5.0%)	5 (22.7%)	2 (10.0%)		
Abdominal discomfort (腹部不快感)	2 (9.1%)	1 (4.5%)			1 (4.5%)	1 (5.0%)		
Abdominal pain (腹痛)	1 (4.5%)					1 (5.0%)		
Abdominal pain upper (上腹部痛)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Constipation (便秘)	1 (4.5%)					1 (5.0%)		
Diarrhoea (下痢)	1 (4.5%)					1 (5.0%)		
Gingival bleeding (歯肉出血)	2 (9.1%)	1 (4.5%)	1 (5.0%)		2 (9.1%)			
Haematochezia (血便排泄)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Nausea (悪心)	2 (9.1%)			1 (5.0%)	1 (4.5%)	1 (5.0%)		
Vomiting (嘔吐)	1 (4.5%)					1 (5.0%)		
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	2 (9.1%)	1 (4.5%)			1 (4.5%)	1 (5.0%)		
Injection site swelling (注射部位腫脹)	1 (4.5%)					1 (5.0%)		
Malaise (倦怠感)	1 (4.5%)					1 (5.0%)		
Oedema peripheral (末梢性浮腫)	1 (4.5%)	1 (4.5%)			1 (4.5%)			

表 2.7.4.7-44　全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 10 mg BID/15 mg OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Hepatobiliary disorders (肝胆道系障害)	1 (4.5%)			1 (5.0%)	1 (4.5%)			
Hepatic function abnormal (肝機能異常)	1 (4.5%)			1 (5.0%)	1 (4.5%)			
Immune system disorders (免疫系障害)	1 (4.5%)					1 (5.0%)		
Drug hypersensitivity (薬物過敏症)	1 (4.5%)					1 (5.0%)		
Infections and infestations (感染症および寄生虫症)	5 (22.7%)	2 (9.1%)	1 (5.0%)	1 (5.0%)	3 (13.6%)		2 (22.2%)	
Arthritis bacterial (細菌性関節炎)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Fungal skin infection (皮膚真菌感染)	1 (4.5%)		1 (5.0%)		1 (4.5%)			
Infected dermal cyst (感染性皮膚嚢腫)	1 (4.5%)			1 (5.0%)	1 (4.5%)			
Lymphangitis (リンパ管炎)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Nasopharyngitis (鼻咽頭炎)	2 (9.1%)						2 (22.2%)	
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	2 (9.1%)			1 (5.0%)	1 (4.5%)	1 (5.0%)		
Lumbar vertebral fracture (腰椎骨折)	1 (4.5%)			1 (5.0%)	1 (4.5%)			
Wound haemorrhage (創傷出血)	1 (4.5%)					1 (5.0%)		
Investigations (臨床検査)	4 (18.2%)	1 (4.5%)	1 (5.0%)		2 (9.1%)	2 (10.0%)		
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Blood creatinine increased (血中クレアチニン増加)	1 (4.5%)					1 (5.0%)		
Blood urine present (尿中血陽性)	1 (4.5%)		1 (5.0%)		1 (4.5%)			
Liver function test abnormal (肝機能検査異常)	1 (4.5%)					1 (5.0%)		
Neutrophil count decreased (好中球数減少)	1 (4.5%)					1 (5.0%)		
Platelet count decreased (血小板数減少)	1 (4.5%)					1 (5.0%)		
Metabolism and nutrition disorders (代謝および栄養障害)	3 (13.6%)	1 (4.5%)	1 (5.0%)	1 (5.0%)	3 (13.6%)			
Decreased appetite (食欲減退)	1 (4.5%)			1 (5.0%)	1 (4.5%)			
Gout (痛風)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Hypovolaemia (血液量減少症)	1 (4.5%)		1 (5.0%)		1 (4.5%)			

表 2.7.4.7-44 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 10 mg BID/15 mg OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Musculoskeletal and connective tissue disorders（筋骨格系および結合組織障害）	3 (13.6%)	1 (4.5%)		1 (5.0%)	2 (9.1%)	1 (5.0%)		
Back pain（背部痛）	1 (4.5%)			1 (5.0%)	1 (4.5%)			
Myositis（筋炎）	1 (4.5%)					1 (5.0%)		
Tendonitis（腱炎）	1 (4.5%)	1 (4.5%)			1 (4.5%)			
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））	3 (13.6%)	1 (4.5%)		2 (10.0%)	3 (13.6%)			
Metastases to lymph nodes（リンパ節転移）	1 (4.5%)			1 (5.0%)	1 (4.5%)			
Renal cancer（腎癌）	1 (4.5%)			1 (5.0%)	1 (4.5%)			
Tumour haemorrhage（腫瘍出血）	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Nervous system disorders（神経系障害）	2 (9.1%)					1 (5.0%)	1 (11.1%)	
Hypoglycaemic unconsciousness（低血糖性意識消失）	1 (4.5%)						1 (11.1%)	
Presyncope（失神寸前の状態）	1 (4.5%)					1 (5.0%)		
Renal and urinary disorders（腎および尿路障害）	1 (4.5%)							1 (20.0%)
Renal failure chronic（慢性腎不全）	1 (4.5%)							1 (20.0%)
Respiratory, thoracic and mediastinal disorders（呼吸器、胸郭および縦隔障害）	4 (18.2%)	2 (9.1%)		1 (5.0%)	3 (13.6%)	1 (5.0%)		1 (20.0%)
Cough（咳嗽）	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Epistaxis（鼻出血）	3 (13.6%)	1 (4.5%)			1 (4.5%)	1 (5.0%)		1 (20.0%)
Hiccups（しゃっくり）	1 (4.5%)			1 (5.0%)	1 (4.5%)			
Interstitial lung disease（間質性肺疾患）	1 (4.5%)	1 (4.5%)			1 (4.5%)			

表 2.7.4.7-44 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 10 mg BID/15 mg OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	7 (31.8%)	3 (13.6%)		2 (10.0%)	5 (22.7%)	3 (15.0%)		
Decubitus ulcer (褥瘡性潰瘍)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Dermatitis allergic (アレルギー性皮膚炎)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Dermatitis contact (接触性皮膚炎)	2 (9.1%)	1 (4.5%)		1 (5.0%)	2 (9.1%)			
Eczema asteatotic (皮脂欠乏性湿疹)	1 (4.5%)					1 (5.0%)		
Haemorrhage subcutaneous (皮下出血)	3 (13.6%)					3 (15.0%)		
Ingrowing nail (嵌入爪)	1 (4.5%)			1 (5.0%)	1 (4.5%)			
Skin haemorrhage (皮膚出血)	1 (4.5%)					1 (5.0%)		

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
GB: .../projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j3-period-summary-common-2percent-ae.sas erjli 07MAR2014 15:07
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/103

表 2.7.4.7-44 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 15 mg BID/OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated	25 (100%)	25 (100%)	23 (100%)	23 (100%)	25 (100%)	20 (100%)	8 (100%)	6 (100%)
Blood and lymphatic system disorders (血液およびリンパ系障害)	2 (8.0%)	1 (4.0%)		1 (4.3%)	2 (8.0%)			
Anaemia (貧血)	2 (8.0%)	1 (4.0%)		1 (4.3%)	2 (8.0%)			
Ear and labyrinth disorders (耳および迷路障害)	1 (4.0%)						1 (12.5%)	
Vertigo (回転性めまい)	1 (4.0%)						1 (12.5%)	
Eye disorders (眼障害)	2 (8.0%)		1 (4.3%)		1 (4.0%)	1 (5.0%)		
Conjunctivitis (結膜炎)	1 (4.0%)					1 (5.0%)		
Glaucoma (緑内障)	1 (4.0%)		1 (4.3%)		1 (4.0%)			
Gastrointestinal disorders (胃腸障害)	8 (32.0%)	3 (12.0%)	1 (4.3%)	1 (4.3%)	5 (20.0%)			2 (33.3%)
Abdominal discomfort (腹部不快感)	1 (4.0%)							1 (16.7%)
Constipation (便秘)	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Dyspepsia (消化不良)	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Gingival bleeding (歯肉出血)	1 (4.0%)							1 (16.7%)
Haematochezia (血便排泄)	2 (8.0%)	1 (4.0%)		1 (4.3%)	2 (8.0%)			
Haemorrhoids (痔核)	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Large intestine polyp (大腸ポリープ)	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Stomatitis (口内炎)	1 (4.0%)							
Subileus (亜イレウス)	1 (4.0%)		1 (4.3%)		1 (4.0%)			
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	4 (16.0%)	2 (8.0%)	1 (4.3%)		3 (12.0%)		1 (12.5%)	
Fatigue (疲労)	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Puncture site haemorrhage (穿刺部位出血)	1 (4.0%)		1 (4.3%)		1 (4.0%)			
Pyrexia (発熱)	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Thirst (口渇)	1 (4.0%)						1 (12.5%)	

表 2.7.4.7-44 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 15 mg BID/OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Infections and infestations (感染症および寄生虫症)	9 (36.0%)	3 (12.0%)	1 (4.3%)		4 (16.0%)	4 (20.0%)	1 (12.5%)	
Gingivitis (歯肉炎)	1 (4.0%)						1 (12.5%)	
Hordeolum (麦粒腫)	1 (4.0%)					1 (5.0%)		
Influenza (インフルエンザ)	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Nasopharyngitis (鼻咽頭炎)	6 (24.0%)	2 (8.0%)	1 (4.3%)		3 (12.0%)	2 (10.0%)		
Otitis externa (外耳炎)	1 (4.0%)					1 (5.0%)		
Periodontitis (歯周炎)	1 (4.0%)					1 (5.0%)		
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	4 (16.0%)	1 (4.0%)	1 (4.3%)		2 (8.0%)	1 (5.0%)		2 (33.3%)
Contusion (挫傷)	1 (4.0%)							1 (16.7%)
Excoriation (擦過傷)	1 (4.0%)		1 (4.3%)		1 (4.0%)			
Head injury (頭部損傷)	1 (4.0%)							1 (16.7%)
Ligament sprain (靱帯捻挫)	1 (4.0%)					1 (5.0%)		
Wound haemorrhage (創傷出血)	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Investigations (臨床検査)	1 (4.0%)		1 (4.3%)		1 (4.0%)			
Blood alkaline phosphatase increased (血中アルカリホスファターゼ増加)	1 (4.0%)		1 (4.3%)		1 (4.0%)			
Metabolism and nutrition disorders (代謝および栄養障害)	4 (16.0%)	1 (4.0%)		2 (8.7%)	3 (12.0%)	1 (5.0%)		1 (16.7%)
Decreased appetite (食欲減退)	1 (4.0%)			1 (4.3%)	1 (4.0%)			
Hyperkalaemia (高カリウム血症)	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Hyperlipidaemia (高脂血症)	1 (4.0%)			1 (4.3%)	1 (4.0%)			
Hyperuricaemia (高尿酸血症)	1 (4.0%)							1 (16.7%)
Hypoalbuminaemia (低アルブミン血症)	1 (4.0%)					1 (5.0%)		

表 2.7.4.7-44　全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 15 mg BID/OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Musculoskeletal and connective tissue disorders（筋骨格系および結合組織障害）	8 (32.0%)	3 (12.0%)		1 (4.3%)	4 (16.0%)	3 (15.0%)	1 (12.5%)	
Arthralgia（関節痛）	1 (4.0%)						1 (12.5%)	
Back pain（背部痛）	2 (8.0%)	1 (4.0%)		1 (4.3%)	2 (8.0%)			
Joint swelling（関節腫脹）	2 (8.0%)					2 (10.0%)		
Musculoskeletal discomfort（筋骨格不快感）	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Myalgia（筋肉痛）	1 (4.0%)					1 (5.0%)		
Osteoarthritis（変形性関節症）	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Nervous system disorders（神経系障害）	4 (16.0%)	1 (4.0%)	1 (4.3%)		2 (8.0%)	2 (10.0%)	1 (12.5%)	
Diabetic neuropathy（糖尿病性ニューロパチー）	1 (4.0%)					1 (5.0%)		
Dizziness（浮動性めまい）	1 (4.0%)					1 (5.0%)		
Headache（頭痛）	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Sciatica（坐骨神経痛）	1 (4.0%)		1 (4.3%)		1 (4.0%)			
Tension headache（緊張性頭痛）	1 (4.0%)						1 (12.5%)	
Renal and urinary disorders（腎および尿路障害）	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Cystitis haemorrhagic（出血性膀胱炎）	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Respiratory, thoracic and mediastinal disorders（呼吸器、胸郭および縦隔障害）	1 (4.0%)						1 (12.5%)	
Epistaxis（鼻出血）	1 (4.0%)						1 (12.5%)	
Skin and subcutaneous tissue disorders（皮膚および皮下組織障害）	7 (28.0%)	4 (16.0%)	1 (4.3%)	3 (13.0%)	7 (28.0%)		1 (12.5%)	1 (16.7%)
Dermatitis contact（接触性皮膚炎）	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Erythema（紅斑）	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Haemorrhage subcutaneous（皮下出血）	4 (16.0%)	1 (4.0%)		3 (13.0%)	4 (16.0%)			
Petechiae（点状出血）	1 (4.0%)						1 (12.5%)	
Pruritus（そう痒症）	2 (8.0%)	1 (4.0%)			1 (4.0%)			1 (16.7%)
Urticaria（蕁麻疹）	1 (4.0%)		1 (4.3%)		1 (4.0%)			

表 2.7.4.7-44 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 15 mg BID/OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Vascular disorders (血管障害)	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Lymphoedema (リンパ浮腫)	1 (4.0%)	1 (4.0%)			1 (4.0%)			

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
GB: .../projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j3-period-summary-common-2percent-ae.sas erjli 07MAR2014 15:07
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/103

表 2.7.4.7-44 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban Total

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated	47 (100%)	47 (100%)	43 (100%)	43 (100%)	47 (100%)	40 (100%)	17 (100%)	11 (100%)
Blood and lymphatic system disorders (血液およびリンパ系障害)	3 (6.4%)	1 (2.1%)		1 (2.3%)	2 (4.3%)	1 (2.5%)		
Anaemia (貧血)	3 (6.4%)	1 (2.1%)		1 (2.3%)	2 (4.3%)	1 (2.5%)		
Cardiac disorders (心臓障害)	2 (4.3%)	2 (4.3%)			2 (4.3%)			
Palpitations (動悸)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Tachycardia (頻脈)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Ear and labyrinth disorders (耳および迷路障害)	2 (4.3%)					1 (2.5%)	1 (5.9%)	
Vertigo (回転性めまい)	2 (4.3%)					1 (2.5%)	1 (5.9%)	
Endocrine disorders (内分泌障害)	1 (2.1%)			1 (2.3%)	1 (2.1%)			
Cushingoid (クッシング様)	1 (2.1%)			1 (2.3%)	1 (2.1%)			
Eye disorders (眼障害)	3 (6.4%)	1 (2.1%)	1 (2.3%)		2 (4.3%)	1 (2.5%)		
Conjunctival haemorrhage (結膜出血)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Conjunctivitis (結膜炎)	1 (2.1%)					1 (2.5%)		
Glaucoma (緑内障)	1 (2.1%)		1 (2.3%)		1 (2.1%)			

表 2.7.4.7-44 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban Total

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Gastrointestinal disorders（胃腸障害）	14 (29.8%)	6 (12.8%)	2 (4.7%)	2 (4.7%)	10 (21.3%)	2 (5.0%)		2 (18.2%)
Abdominal discomfort（腹部不快感）	3 (6.4%)	1 (2.1%)			1 (2.1%)	1 (2.5%)		1 (9.1%)
Abdominal pain（腹痛）	1 (2.1%)					1 (2.5%)		
Abdominal pain upper（上腹部痛）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Constipation（便秘）	2 (4.3%)	1 (2.1%)			1 (2.1%)	1 (2.5%)		
Diarrhoea（下痢）	1 (2.1%)					1 (2.5%)		
Dyspepsia（消化不良）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Gingival bleeding（歯肉出血）	3 (6.4%)	1 (2.1%)	1 (2.3%)		2 (4.3%)			1 (9.1%)
Haematochezia（血便排泄）	3 (6.4%)	2 (4.3%)		1 (2.3%)	3 (6.4%)			
Haemorrhoids（痔核）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Large intestine polyp（大腸ポリープ）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Nausea（悪心）	2 (4.3%)			1 (2.3%)	1 (2.1%)	1 (2.5%)		
Stomatitis（口内炎）	1 (2.1%)							
Subileus（亜イレウス）	1 (2.1%)		1 (2.3%)		1 (2.1%)			
Vomiting（嘔吐）	1 (2.1%)					1 (2.5%)		
General disorders and administration site conditions（一般・全身障害および投与部位の状態）	6 (12.8%)	3 (6.4%)	1 (2.3%)		4 (8.5%)	1 (2.5%)	1 (5.9%)	
Fatigue（疲労）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Injection site swelling（注射部位腫脹）	1 (2.1%)					1 (2.5%)		
Malaise（倦怠感）	1 (2.1%)					1 (2.5%)		
Oedema peripheral（末梢性浮腫）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Puncture site haemorrhage（穿刺部位出血）	1 (2.1%)		1 (2.3%)		1 (2.1%)			
Pyrexia（発熱）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Thirst（口渇）	1 (2.1%)						1 (5.9%)	
Hepatobiliary disorders（肝胆道系障害）	1 (2.1%)			1 (2.3%)	1 (2.1%)			
Hepatic function abnormal（肝機能異常）	1 (2.1%)			1 (2.3%)	1 (2.1%)			
Immune system disorders（免疫系障害）	1 (2.1%)					1 (2.5%)		
Drug hypersensitivity（薬物過敏症）	1 (2.1%)					1 (2.5%)		

表 2.7.4.7-44 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban Total

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Infections and infestations (感染症および寄生虫症)	14 (29.8%)	5 (10.6%)	2 (4.7%)	1 (2.3%)	7 (14.9%)	4 (10.0%)	3 (17.6%)	
Arthritis bacterial (細菌性関節炎)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Fungal skin infection (皮膚真菌感染)	1 (2.1%)		1 (2.3%)		1 (2.1%)			
Gingivitis (歯肉炎)	1 (2.1%)						1 (5.9%)	
Hordeolum (麦粒腫)	1 (2.1%)					1 (2.5%)		
Infected dermal cyst (感染性皮膚嚢腫)	1 (2.1%)			1 (2.3%)	1 (2.1%)			
Influenza (インフルエンザ)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Lymphangitis (リンパ管炎)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Nasopharyngitis (鼻咽頭炎)	8 (17.0%)	2 (4.3%)	1 (2.3%)		3 (6.4%)	2 (5.0%)	2 (11.8%)	
Otitis externa (外耳炎)	1 (2.1%)					1 (2.5%)		
Periodontitis (歯周炎)	1 (2.1%)					1 (2.5%)		
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	6 (12.8%)	1 (2.1%)	1 (2.3%)	1 (2.3%)	3 (6.4%)	2 (5.0%)		2 (18.2%)
Contusion (挫傷)	1 (2.1%)							1 (9.1%)
Excoriation (擦過傷)	1 (2.1%)		1 (2.3%)		1 (2.1%)			
Head injury (頭部損傷)	1 (2.1%)							1 (9.1%)
Ligament sprain (靭帯捻挫)	1 (2.1%)					1 (2.5%)		
Lumbar vertebral fracture (腰椎骨折)	1 (2.1%)			1 (2.3%)	1 (2.1%)			
Wound haemorrhage (創傷出血)	2 (4.3%)	1 (2.1%)			1 (2.1%)	1 (2.5%)		

表 2.7.4.7-44 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban Total

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Investigations（臨床検査）	5 (10.6%)	1 (2.1%)	2 (4.7%)		3 (6.4%)	2 (5.0%)		
Blood alkaline phosphatase increased（血中アルカリホスファターゼ増加）	1 (2.1%)		1 (2.3%)		1 (2.1%)			
Blood creatine phosphokinase increased（血中クレアチンホスホキナーゼ増加）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Blood creatinine increased（血中クレアチニン増加）	1 (2.1%)					1 (2.5%)		
Blood urine present（尿中血陽性）	1 (2.1%)		1 (2.3%)		1 (2.1%)			
Liver function test abnormal（肝機能検査異常）	1 (2.1%)					1 (2.5%)		
Neutrophil count decreased（好中球数減少）	1 (2.1%)					1 (2.5%)		
Platelet count decreased（血小板数減少）	1 (2.1%)					1 (2.5%)		
Metabolism and nutrition disorders（代謝および栄養障害）	7 (14.9%)	2 (4.3%)	1 (2.3%)	3 (7.0%)	6 (12.8%)	1 (2.5%)		1 (9.1%)
Decreased appetite（食欲減退）	2 (4.3%)			2 (4.7%)	2 (4.3%)			
Gout（痛風）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Hyperkalaemia（高カリウム血症）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Hyperlipidaemia（高脂血症）	1 (2.1%)			1 (2.3%)	1 (2.1%)			
Hyperuricaemia（高尿酸血症）	1 (2.1%)							1 (9.1%)
Hypoalbuminaemia（低アルブミン血症）	1 (2.1%)					1 (2.5%)		
Hypovolaemia（血液量減少症）	1 (2.1%)		1 (2.3%)		1 (2.1%)			
Musculoskeletal and connective tissue disorders（筋骨格系および結合組織障害）	11 (23.4%)	4 (8.5%)		2 (4.7%)	6 (12.8%)	4 (10.0%)	1 (5.9%)	
Arthralgia（関節痛）	1 (2.1%)						1 (5.9%)	
Back pain（背部痛）	3 (6.4%)	1 (2.1%)		2 (4.7%)	3 (6.4%)			
Joint swelling（関節腫脹）	2 (4.3%)					2 (5.0%)		
Musculoskeletal discomfort（筋骨格不快感）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Myalgia（筋肉痛）	1 (2.1%)					1 (2.5%)		
Myositis（筋炎）	1 (2.1%)					1 (2.5%)		
Osteoarthritis（変形性関節症）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Tendonitis（腱炎）	1 (2.1%)	1 (2.1%)			1 (2.1%)			

表 2.7.4.7-44　全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban Total

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
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））	3 (6.4%)	1 (2.1%)		2 (4.7%)	3 (6.4%)			
Metastases to lymph nodes（リンパ節転移）	1 (2.1%)			1 (2.3%)	1 (2.1%)			
Renal cancer（腎癌）	1 (2.1%)			1 (2.3%)	1 (2.1%)			
Tumour haemorrhage（腫瘍出血）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Nervous system disorders（神経系障害）	6 (12.8%)	1 (2.1%)	1 (2.3%)		2 (4.3%)	3 (7.5%)	2 (11.8%)	
Diabetic neuropathy（糖尿病性ニューロパチー）	1 (2.1%)					1 (2.5%)		
Dizziness（浮動性めまい）	1 (2.1%)					1 (2.5%)		
Headache（頭痛）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Hypoglycaemic unconsciousness（低血糖性意識消失）	1 (2.1%)						1 (5.9%)	
Presyncope（失神寸前の状態）	1 (2.1%)					1 (2.5%)		
Sciatica（坐骨神経痛）	1 (2.1%)		1 (2.3%)		1 (2.1%)			
Tension headache（緊張性頭痛）	1 (2.1%)						1 (5.9%)	
Renal and urinary disorders（腎および尿路障害）	2 (4.3%)	1 (2.1%)			1 (2.1%)			1 (9.1%)
Cystitis haemorrhagic（出血性膀胱炎）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Renal failure chronic（慢性腎不全）	1 (2.1%)							1 (9.1%)
Respiratory, thoracic and mediastinal disorders（呼吸器、胸郭および縦隔障害）	5 (10.6%)	2 (4.3%)		1 (2.3%)	3 (6.4%)	1 (2.5%)	1 (5.9%)	1 (9.1%)
Cough（咳嗽）	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Epistaxis（鼻出血）	4 (8.5%)	1 (2.1%)			1 (2.1%)	1 (2.5%)	1 (5.9%)	1 (9.1%)
Hiccups（しゃっくり）	1 (2.1%)			1 (2.3%)	1 (2.1%)			
Interstitial lung disease（間質性肺疾患）	1 (2.1%)	1 (2.1%)			1 (2.1%)			

表 2.7.4.7-44 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban Total

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	14 (29.8%)	7 (14.9%)	1 (2.3%)	5 (11.6%)	12 (25.5%)	3 (7.5%)	1 (5.9%)	1 (9.1%)
Decubitus ulcer (褥瘡性潰瘍)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Dermatitis allergic (アレルギー性皮膚炎)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Dermatitis contact (接触性皮膚炎)	3 (6.4%)	2 (4.3%)		1 (2.3%)	3 (6.4%)			
Eczema asteatotic (皮脂欠乏性湿疹)	1 (2.1%)					1 (2.5%)		
Erythema (紅斑)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Haemorrhage subcutaneous (皮下出血)	7 (14.9%)	1 (2.1%)		3 (7.0%)	4 (8.5%)	3 (7.5%)		
Ingrowing nail (嵌入爪)	1 (2.1%)			1 (2.3%)	1 (2.1%)			
Petechiae (点状出血)	1 (2.1%)						1 (5.9%)	
Pruritus (そう痒症)	2 (4.3%)	1 (2.1%)			1 (2.1%)			1 (9.1%)
Skin haemorrhage (皮膚出血)	1 (2.1%)					1 (2.5%)		
Urticaria (蕁麻疹)	1 (2.1%)		1 (2.3%)		1 (2.1%)			
Vascular disorders (血管障害)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Lymphoedema (リンパ浮腫)	1 (2.1%)	1 (2.1%)			1 (2.1%)			

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
GB: .../projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j3-period-summary-common-2percent-ae.sas erjli 07MAR2014 15:07
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/103

表 2.7.4.7-44　全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: UFH / Warfarin

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated	12 (100%)	12 (100%)	12 (100%)	12 (100%)	12 (100%)	10 (100%)	3 (100%)	3 (100%)
Blood and lymphatic system disorders (血液およびリンパ系障害)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Anaemia (貧血)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Eye disorders (眼障害)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Diabetic retinopathy (糖尿病網膜症)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Gastrointestinal disorders (胃腸障害)	4 (33.3%)	3 (25.0%)			3 (25.0%)	1 (10.0%)	1 (33.3%)	
Constipation (便秘)	2 (16.7%)	2 (16.7%)			2 (16.7%)			
Dental caries (齲歯)	1 (8.3%)					1 (10.0%)		
Dyspepsia (消化不良)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Large intestine polyp (大腸ポリープ)	1 (8.3%)						1 (33.3%)	
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	1 (8.3%)						1 (33.3%)	
Oedema peripheral (末梢性浮腫)	1 (8.3%)						1 (33.3%)	
Infections and infestations (感染症および寄生虫症)	4 (33.3%)	1 (8.3%)	1 (8.3%)		2 (16.7%)	1 (10.0%)		1 (33.3%)
Gastroenteritis (胃腸炎)	1 (8.3%)							1 (33.3%)
Herpes zoster (帯状疱疹)	1 (8.3%)					1 (10.0%)		
Nasopharyngitis (鼻咽頭炎)	1 (8.3%)		1 (8.3%)		1 (8.3%)			
Tinea manuum (手白癬)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Wound haemorrhage (創傷出血)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Investigations (臨床検査)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Activated partial thromboplastin time prolonged (活性化部分トロンボプラスチン時間延長)	1 (8.3%)	1 (8.3%)			1 (8.3%)			

表 2.7.4.7-44　全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: UFH / Warfarin

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	4 (33.3%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	3 (25.0%)	1 (10.0%)		
Back pain (背部痛)	1 (8.3%)			1 (8.3%)	1 (8.3%)			
Musculoskeletal stiffness (筋骨格硬直)	1 (8.3%)					1 (10.0%)		
Myalgia (筋肉痛)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Osteoarthritis (変形性関節症)	1 (8.3%)		1 (8.3%)		1 (8.3%)			
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))	1 (8.3%)							1 (33.3%)
Gastrointestinal stromal tumour (消化管間質性腫瘍)	1 (8.3%)							1 (33.3%)
Nervous system disorders (神経系障害)	2 (16.7%)		1 (8.3%)		1 (8.3%)			1 (33.3%)
Cerebral infarction (脳梗塞)	1 (8.3%)							1 (33.3%)
Hypoaesthesia (感覚鈍麻)	1 (8.3%)		1 (8.3%)		1 (8.3%)			
Psychiatric disorders (精神障害)	3 (25.0%)	2 (16.7%)			2 (16.7%)			1 (33.3%)
Anxiety (不安)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Insomnia (不眠症)	3 (25.0%)	2 (16.7%)			2 (16.7%)			1 (33.3%)
Renal and urinary disorders (腎および尿路障害)	2 (16.7%)	1 (8.3%)			1 (8.3%)	1 (10.0%)		
Diabetic nephropathy (糖尿病性腎症)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Haematuria (血尿)	1 (8.3%)					1 (10.0%)		
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	2 (16.7%)	1 (8.3%)	1 (8.3%)		2 (16.7%)			
Aspiration (誤嚥)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Epistaxis (鼻出血)	1 (8.3%)		1 (8.3%)		1 (8.3%)			

表 2.7.4.7-44　全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: UFH / Warfarin

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	5 (41.7%)	2 (16.7%)	1 (8.3%)		3 (25.0%)	2 (20.0%)	1 (33.3%)	
Dermatitis (皮膚炎)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Dermatitis contact (接触性皮膚炎)	2 (16.7%)	1 (8.3%)			1 (8.3%)		1 (33.3%)	
Erythema (紅斑)	1 (8.3%)					1 (10.0%)		
Haemorrhage subcutaneous (皮下出血)	1 (8.3%)		1 (8.3%)		1 (8.3%)			
Pruritus (そう痒症)	1 (8.3%)					1 (10.0%)		

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
GB: .../projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j3-period-summary-common-2percent-ae.sas erjli 07MAR2014 15:07
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引用元：5.3.5.3.12 Integrated-J Table 14.3.1/103

表 2.7.4.7-45　全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 15 mg BID/OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated	30 (100%)	30 (100%)	26 (100%)	26 (100%)	30 (100%)	25 (100%)	10 (100%)	10 (100%)
Cardiac disorders (心臓障害)	2 (6.7%)					1 (4.0%)		1 (10.0%)
Atrial fibrillation (心房細動)	1 (3.3%)							1 (10.0%)
Cardiac failure (心不全)	1 (3.3%)					1 (4.0%)		
Eye disorders (眼障害)	3 (10.0%)		1 (3.8%)	1 (3.8%)	2 (6.7%)	1 (4.0%)		
Cataract (白内障)	1 (3.3%)					1 (4.0%)		
Conjunctival haemorrhage (結膜出血)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Conjunctivitis (結膜炎)	2 (6.7%)		1 (3.8%)	1 (3.8%)	2 (6.7%)			
Gastrointestinal disorders (胃腸障害)	9 (30.0%)	1 (3.3%)	6 (23.1%)	2 (7.7%)	7 (23.3%)	1 (4.0%)		2 (20.0%)
Abdominal pain (腹痛)	1 (3.3%)							1 (10.0%)
Constipation (便秘)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Diarrhoea (下痢)	3 (10.0%)		1 (3.8%)	1 (3.8%)	2 (6.7%)	1 (4.0%)		
Gastrooesophageal reflux disease (胃食道逆流性疾患)	2 (6.7%)		1 (3.8%)		1 (3.3%)			1 (10.0%)
Gingival bleeding (歯肉出血)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Haematochezia (血便排泄)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Haemorrhoidal haemorrhage (痔出血)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Hypoaesthesia oral (口の感覚鈍麻)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Nausea (悪心)	2 (6.7%)		1 (3.8%)	1 (3.8%)	2 (6.7%)			
Vomiting (嘔吐)	3 (10.0%)		1 (3.8%)	1 (3.8%)	2 (6.7%)	1 (4.0%)		
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	3 (10.0%)			2 (7.7%)	2 (6.7%)	2 (8.0%)		
Face oedema (顔面浮腫)	1 (3.3%)					1 (4.0%)		
Local swelling (局所腫脹)	1 (3.3%)					1 (4.0%)		
Malaise (倦怠感)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Oedema peripheral (末梢性浮腫)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Hepatobiliary disorders (肝胆道系障害)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		
Hepatic function abnormal (肝機能異常)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		

表 2.7.4.7-45 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 15 mg BID/OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Immune system disorders (免疫系障害)	1 (3.3%)					1 (4.0%)		
Seasonal allergy (季節性アレルギー)	1 (3.3%)					1 (4.0%)		
Infections and infestations (感染症および寄生虫症)	14 (46.7%)	8 (26.7%)	4 (15.4%)	1 (3.8%)	12 (40.0%)	4 (16.0%)	1 (10.0%)	1 (10.0%)
Abscess neck (頚部膿瘍)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Cellulitis (蜂巣炎)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		
Cystitis (膀胱炎)	2 (6.7%)	2 (6.7%)			2 (6.7%)			
Herpes zoster (帯状疱疹)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Nasopharyngitis (鼻咽頭炎)	8 (26.7%)	1 (3.3%)	2 (7.7%)		3 (10.0%)	3 (12.0%)	1 (10.0%)	1 (10.0%)
Oral herpes (口腔ヘルペス)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Pharyngitis (咽頭炎)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Pneumonia (肺炎)	2 (6.7%)	1 (3.3%)		1 (3.8%)	2 (6.7%)			
Tinea pedis (足部白癬)	1 (3.3%)					1 (4.0%)		
Urinary tract infection (尿路感染)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	4 (13.3%)	2 (6.7%)		1 (3.8%)	3 (10.0%)	1 (4.0%)		
Chemical burns of eye (眼部化学熱傷)	1 (3.3%)					1 (4.0%)		
Radiation skin injury (放射線皮膚損傷)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Subcutaneous haematoma (皮下血腫)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		
Wound haemorrhage (創傷出血)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Investigations (臨床検査)	5 (16.7%)	2 (6.7%)	1 (3.8%)	1 (3.8%)	3 (10.0%)	2 (8.0%)		
Blood bilirubin increased (血中ビリルビン増加)	1 (3.3%)					1 (4.0%)		
Blood calcium decreased (血中カルシウム減少)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Blood urine present (尿中血陽性)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Liver function test abnormal (肝機能検査異常)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		
Occult blood positive (便潜血陽性)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Metabolism and nutrition disorders (代謝および栄養障害)	3 (10.0%)	1 (3.3%)		1 (3.8%)	2 (6.7%)			1 (10.0%)
Decreased appetite (食欲減退)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Dehydration (脱水)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Gout (痛風)	1 (3.3%)							1 (10.0%)

表 2.7.4.7-45 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 15 mg BID/OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	2 (6.7%)	1 (3.3%)		1 (3.8%)	2 (6.7%)	1 (4.0%)		
Arthralgia (関節痛)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Musculoskeletal stiffness (筋骨格硬直)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Osteoporosis (骨粗鬆症)	1 (3.3%)					1 (4.0%)		
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))	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Hypopharyngeal cancer (下咽頭癌)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Nervous system disorders (神経系障害)	4 (13.3%)	3 (10.0%)	1 (3.8%)		4 (13.3%)			1 (10.0%)
Dizziness (浮動性めまい)	2 (6.7%)		1 (3.8%)		1 (3.3%)			1 (10.0%)
Headache (頭痛)	2 (6.7%)	2 (6.7%)			2 (6.7%)			
Sciatica (坐骨神経痛)	1 (3.3%)							1 (10.0%)
Sensory disturbance (感覚障害)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Somnolence (傾眠)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Psychiatric disorders (精神障害)	2 (6.7%)	1 (3.3%)	1 (3.8%)		2 (6.7%)			
Delirium (譫妄)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Insomnia (不眠症)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	7 (23.3%)	2 (6.7%)	1 (3.8%)	1 (3.8%)	4 (13.3%)	3 (12.0%)	1 (10.0%)	
Epistaxis (鼻出血)	3 (10.0%)		1 (3.8%)		1 (3.3%)	1 (4.0%)	1 (10.0%)	
Haemoptysis (喀血)	1 (3.3%)					1 (4.0%)		
Hiccups (しゃっくり)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Laryngeal pain (喉頭痛)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Upper respiratory tract inflammation (上気道の炎症)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		

表 2.7.4.7-45　全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 15 mg BID/OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Skin and subcutaneous tissue disorders（皮膚および皮下組織障害）	12 (40.0%)	9 (30.0%)		1 (3.8%)	10 (33.3%)	1 (4.0%)	1 (10.0%)	1 (10.0%)
Dermatitis（皮膚炎）	1 (3.3%)					1 (4.0%)		
Dermatitis contact（接触性皮膚炎）	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Drug eruption（薬疹）	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Eczema（湿疹）	3 (10.0%)	2 (6.7%)		1 (3.8%)	3 (10.0%)			
Haemorrhage subcutaneous（皮下出血）	4 (13.3%)	4 (13.3%)			4 (13.3%)			
Petechiae（点状出血）	1 (3.3%)						1 (10.0%)	
Pruritus（そう痒症）	2 (6.7%)			1 (3.8%)	1 (3.3%)			1 (10.0%)
Rash（発疹）	2 (6.7%)	2 (6.7%)			2 (6.7%)			

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
GB: .../projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j3-period-summary-common-2percent-ae.sas erjli 07MAR2014 15:07
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/105

表 2.7.4.7-45 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban Total

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated	30 (100%)	30 (100%)	26 (100%)	26 (100%)	30 (100%)	25 (100%)	10 (100%)	10 (100%)
Cardiac disorders (心臓障害)	2 (6.7%)					1 (4.0%)		1 (10.0%)
Atrial fibrillation (心房細動)	1 (3.3%)							1 (10.0%)
Cardiac failure (心不全)	1 (3.3%)					1 (4.0%)		
Eye disorders (眼障害)	3 (10.0%)		1 (3.8%)	1 (3.8%)	2 (6.7%)	1 (4.0%)		
Cataract (白内障)	1 (3.3%)					1 (4.0%)		
Conjunctival haemorrhage (結膜出血)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Conjunctivitis (結膜炎)	2 (6.7%)		1 (3.8%)	1 (3.8%)	2 (6.7%)			
Gastrointestinal disorders (胃腸障害)	9 (30.0%)	1 (3.3%)	6 (23.1%)	2 (7.7%)	7 (23.3%)	1 (4.0%)		2 (20.0%)
Abdominal pain (腹痛)	1 (3.3%)							1 (10.0%)
Constipation (便秘)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Diarrhoea (下痢)	3 (10.0%)		1 (3.8%)	1 (3.8%)	2 (6.7%)	1 (4.0%)		
Gastrooesophageal reflux disease (胃食道逆流性疾患)	2 (6.7%)		1 (3.8%)		1 (3.3%)			1 (10.0%)
Gingival bleeding (歯肉出血)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Haematochezia (血便排泄)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Haemorrhoidal haemorrhage (痔出血)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Hypoaesthesia oral (口の感覚鈍麻)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Nausea (悪心)	2 (6.7%)		1 (3.8%)	1 (3.8%)	2 (6.7%)			
Vomiting (嘔吐)	3 (10.0%)		1 (3.8%)	1 (3.8%)	2 (6.7%)	1 (4.0%)		
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	3 (10.0%)			2 (7.7%)	2 (6.7%)	2 (8.0%)		
Face oedema (顔面浮腫)	1 (3.3%)					1 (4.0%)		
Local swelling (局所腫脹)	1 (3.3%)					1 (4.0%)		
Malaise (倦怠感)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Oedema peripheral (末梢性浮腫)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Hepatobiliary disorders (肝胆道系障害)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		
Hepatic function abnormal (肝機能異常)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		
Immune system disorders (免疫系障害)	1 (3.3%)					1 (4.0%)		
Seasonal allergy (季節性アレルギー)	1 (3.3%)					1 (4.0%)		

表 2.7.4.7-45 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban Total

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Infections and infestations (感染症および寄生虫症)	14 (46.7%)	8 (26.7%)	4 (15.4%)	1 (3.8%)	12 (40.0%)	4 (16.0%)	1 (10.0%)	1 (10.0%)
Abscess neck (頚部膿瘍)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Cellulitis (蜂巣炎)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		
Cystitis (膀胱炎)	2 (6.7%)	2 (6.7%)			2 (6.7%)			
Herpes zoster (帯状疱疹)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Nasopharyngitis (鼻咽頭炎)	8 (26.7%)	1 (3.3%)	2 (7.7%)		3 (10.0%)	3 (12.0%)	1 (10.0%)	1 (10.0%)
Oral herpes (口腔ヘルペス)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Pharyngitis (咽頭炎)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Pneumonia (肺炎)	2 (6.7%)	1 (3.3%)		1 (3.8%)	2 (6.7%)			
Tinea pedis (足部白癬)	1 (3.3%)					1 (4.0%)		
Urinary tract infection (尿路感染)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	4 (13.3%)	2 (6.7%)		1 (3.8%)	3 (10.0%)	1 (4.0%)		
Chemical burns of eye (眼部化学熱傷)	1 (3.3%)					1 (4.0%)		
Radiation skin injury (放射線皮膚損傷)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Subcutaneous haematoma (皮下血腫)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		
Wound haemorrhage (創傷出血)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Investigations (臨床検査)	5 (16.7%)	2 (6.7%)	1 (3.8%)	1 (3.8%)	3 (10.0%)	2 (8.0%)		
Blood bilirubin increased (血中ビリルビン増加)	1 (3.3%)					1 (4.0%)		
Blood calcium decreased (血中カルシウム減少)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Blood urine present (尿中血陽性)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Liver function test abnormal (肝機能検査異常)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		
Occult blood positive (便潜血陽性)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Metabolism and nutrition disorders (代謝および栄養障害)	3 (10.0%)	1 (3.3%)		1 (3.8%)	2 (6.7%)			1 (10.0%)
Decreased appetite (食欲減退)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Dehydration (脱水)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Gout (痛風)	1 (3.3%)							1 (10.0%)

表 2.7.4.7-45　全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban Total

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Musculoskeletal and connective tissue disorders（筋骨格系および結合組織障害）	2 (6.7%)	1 (3.3%)		1 (3.8%)	2 (6.7%)	1 (4.0%)		
Arthralgia（関節痛）	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Musculoskeletal stiffness（筋骨格硬直）	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Osteoporosis（骨粗鬆症）	1 (3.3%)					1 (4.0%)		
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））	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Hypopharyngeal cancer（下咽頭癌）	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Nervous system disorders（神経系障害）	4 (13.3%)	3 (10.0%)	1 (3.8%)		4 (13.3%)			1 (10.0%)
Dizziness（浮動性めまい）	2 (6.7%)		1 (3.8%)		1 (3.3%)			1 (10.0%)
Headache（頭痛）	2 (6.7%)	2 (6.7%)			2 (6.7%)			
Sciatica（坐骨神経痛）	1 (3.3%)							1 (10.0%)
Sensory disturbance（感覚障害）	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Somnolence（傾眠）	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Psychiatric disorders（精神障害）	2 (6.7%)	1 (3.3%)	1 (3.8%)		2 (6.7%)			
Delirium（譫妄）	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Insomnia（不眠症）	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Respiratory, thoracic and mediastinal disorders（呼吸器、胸郭および縦隔障害）	7 (23.3%)	2 (6.7%)	1 (3.8%)	1 (3.8%)	4 (13.3%)	3 (12.0%)	1 (10.0%)	
Epistaxis（鼻出血）	3 (10.0%)		1 (3.8%)		1 (3.3%)	1 (4.0%)	1 (10.0%)	
Haemoptysis（喀血）	1 (3.3%)					1 (4.0%)		
Hiccups（しゃっくり）	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Laryngeal pain（喉頭痛）	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Upper respiratory tract inflammation（上気道の炎症）	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		

表 2.7.4.7-45　全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban Total

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Skin and subcutaneous tissue disorders（皮膚および皮下組織障害）	12 (40.0%)	9 (30.0%)		1 (3.8%)	10 (33.3%)	1 (4.0%)	1 (10.0%)	1 (10.0%)
Dermatitis（皮膚炎）	1 (3.3%)					1 (4.0%)		
Dermatitis contact（接触性皮膚炎）	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Drug eruption（薬疹）	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Eczema（湿疹）	3 (10.0%)	2 (6.7%)		1 (3.8%)	3 (10.0%)			
Haemorrhage subcutaneous（皮下出血）	4 (13.3%)	4 (13.3%)			4 (13.3%)			
Petechiae（点状出血）	1 (3.3%)						1 (10.0%)	
Pruritus（そう痒症）	2 (6.7%)			1 (3.8%)	1 (3.3%)			1 (10.0%)
Rash（発疹）	2 (6.7%)	2 (6.7%)			2 (6.7%)			

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
GB: .../projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j3-period-summary-common-2percent-ae.sas erjli 07MAR2014 15:07
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/105

表 2.7.4.7-45 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: UFH / Warfarin

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated	7 (100%)	7 (100%)	7 (100%)	7 (100%)	7 (100%)	7 (100%)	2 (100%)	2 (100%)
Eye disorders (眼障害)	1 (14.3%)			1 (14.3%)	1 (14.3%)			
Conjunctivitis (結膜炎)	1 (14.3%)			1 (14.3%)	1 (14.3%)			
Gastrointestinal disorders (胃腸障害)	4 (57.1%)	3 (42.9%)			3 (42.9%)	1 (14.3%)		
Abdominal discomfort (腹部不快感)	1 (14.3%)	1 (14.3%)			1 (14.3%)			
Diarrhoea (下痢)	2 (28.6%)	2 (28.6%)			2 (28.6%)			
Gingival bleeding (歯肉出血)	1 (14.3%)					1 (14.3%)		
Nausea (悪心)	1 (14.3%)	1 (14.3%)			1 (14.3%)			
Stomatitis (口内炎)	1 (14.3%)	1 (14.3%)			1 (14.3%)			
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	2 (28.6%)	1 (14.3%)			1 (14.3%)		1 (50.0%)	
Chest discomfort (胸部不快感)	1 (14.3%)	1 (14.3%)			1 (14.3%)			
Oedema peripheral (末梢性浮腫)	1 (14.3%)						1 (50.0%)	
Pyrexia (発熱)	1 (14.3%)							
Infections and infestations (感染症および寄生虫症)	5 (71.4%)		3 (42.9%)		3 (42.9%)	2 (28.6%)		
Gastroenteritis (胃腸炎)	2 (28.6%)		1 (14.3%)		1 (14.3%)	1 (14.3%)		
Nasopharyngitis (鼻咽頭炎)	2 (28.6%)		1 (14.3%)		1 (14.3%)	1 (14.3%)		
Otitis externa (外耳炎)	1 (14.3%)		1 (14.3%)		1 (14.3%)			
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	1 (14.3%)							1 (50.0%)
Spinal compression fracture (脊椎圧迫骨折)	1 (14.3%)							1 (50.0%)
Investigations (臨床検査)	4 (57.1%)	2 (28.6%)			2 (28.6%)	1 (14.3%)	1 (50.0%)	
Alanine aminotransferase increased (アラニンアミノトランスフェラーゼ増加)	3 (42.9%)	2 (28.6%)			2 (28.6%)	1 (14.3%)		
Aspartate aminotransferase increased (アスパラギン酸アミノトランスフェラーゼ増加)	2 (28.6%)	2 (28.6%)			2 (28.6%)			
Blood cholesterol increased (血中コレステロール増加)	1 (14.3%)						1 (50.0%)	

表 2.7.4.7-45 全期間で合計 2%以上に認められた治験薬投与下で発現した有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: UFH / Warfarin

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	3 (42.9%)			1 (14.3%)	1 (14.3%)	1 (14.3%)		1 (50.0%)
Muscle spasms (筋痙縮)	1 (14.3%)							
Osteoporosis (骨粗鬆症)	1 (14.3%)							1 (50.0%)
Sacroiliitis (仙腸骨炎)	1 (14.3%)			1 (14.3%)	1 (14.3%)			
Synovial cyst (滑液嚢腫)	1 (14.3%)					1 (14.3%)		
Nervous system disorders (神経系障害)	1 (14.3%)						1 (50.0%)	
Dizziness (浮動性めまい)	1 (14.3%)							
Hypoaesthesia (感覚鈍麻)	1 (14.3%)						1 (50.0%)	
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	2 (28.6%)		1 (14.3%)		1 (14.3%)	1 (14.3%)		
Cough (咳嗽)	1 (14.3%)		1 (14.3%)		1 (14.3%)			
Nasal congestion (鼻閉)	1 (14.3%)					1 (14.3%)		
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	5 (71.4%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	3 (42.9%)	1 (14.3%)	2 (100.0%)	
Eczema (湿疹)	1 (14.3%)						1 (50.0%)	
Haemorrhage subcutaneous (皮下出血)	4 (57.1%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	3 (42.9%)	1 (14.3%)		
Pruritus generalised (全身性そう痒症)	1 (14.3%)						1 (50.0%)	

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
GB: .../projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j3-period-summary-common-2percent-ae.sas erjli 07MAR2014 15:07
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引用元：5.3.5.3.12 Integrated-J Table 14.3.1/105

表 2.7.4.7-46 全期間で合計 2%以上に認められた治験薬投与下で発現した治験薬との因果関係が否定できない有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 10 mg BID/15 mg OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated	22 (100%)	22 (100%)	20 (100%)		22 (100%)	20 (100%)		5 (100%)
Eye disorders (眼障害)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Conjunctival haemorrhage (結膜出血)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Gastrointestinal disorders (胃腸障害)	1 (4.5%)	1 (4.5%)			1 (4.5%)	1 (5.0%)		
Abdominal pain (腹痛)	1 (4.5%)					1 (5.0%)		
Gingival bleeding (歯肉出血)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Haematochezia (血便排泄)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Investigations (臨床検査)	2 (9.1%)		1 (5.0%)		1 (4.5%)	1 (5.0%)		
Blood urine present (尿中血陽性)	1 (4.5%)		1 (5.0%)		1 (4.5%)			
Liver function test abnormal (肝機能検査異常)	1 (4.5%)					1 (5.0%)		
Renal and urinary disorders (腎および尿路障害)	1 (4.5%)							1 (20.0%)
Renal failure chronic (慢性腎不全)	1 (4.5%)							1 (20.0%)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	4 (18.2%)	2 (9.1%)			2 (9.1%)	1 (5.0%)		1 (20.0%)
Cough (咳嗽)	1 (4.5%)	1 (4.5%)			1 (4.5%)			
Epistaxis (鼻出血)	3 (13.6%)	1 (4.5%)			1 (4.5%)	1 (5.0%)		1 (20.0%)
Interstitial lung disease (間質性肺疾患)	1 (4.5%)	1 (4.5%)			1 (4.5%)			

表 2.7.4.7-46　全期間で合計 2%以上に認められた治験薬投与下で発現した治験薬との因果関係が否定できない有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 10 mg BID/15 mg OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	1 (4.5%)					1 (5.0%)		
Haemorrhage subcutaneous (皮下出血)	1 (4.5%)					1 (5.0%)		

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
GB: .../projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j3-period-summary-common-2percent-ae.sas erjli 07MAR2014 15:07
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/109

表 2.7.4.7-46　全期間で合計 2%以上に認められた治験薬投与下で発現した治験薬との因果関係が否定できない有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 15 mg BID/OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated	25 (100%)	25 (100%)	23 (100%)	23 (100%)	25 (100%)		8 (100%)	
Gastrointestinal disorders (胃腸障害)	2 (8.0%)	1 (4.0%)		1 (4.3%)	2 (8.0%)			
Haematochezia (血便排泄)	2 (8.0%)	1 (4.0%)		1 (4.3%)	2 (8.0%)			
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	3 (12.0%)	1 (4.0%)	1 (4.3%)		2 (8.0%)		1 (12.5%)	
Puncture site haemorrhage (穿刺部位出血)	1 (4.0%)		1 (4.3%)		1 (4.0%)			
Pyrexia (発熱)	1 (4.0%)	1 (4.0%)			1 (4.0%)			
Thirst (口渇)	1 (4.0%)						1 (12.5%)	
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	1 (4.0%)						1 (12.5%)	
Epistaxis (鼻出血)	1 (4.0%)						1 (12.5%)	
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	3 (12.0%)	1 (4.0%)		2 (8.7%)	3 (12.0%)			
Haemorrhage subcutaneous (皮下出血)	3 (12.0%)	1 (4.0%)		2 (8.7%)	3 (12.0%)			

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
GB:.../projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j3-period-summary-common-2percent-ae.sas erjli 07MAR2014 15:07
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/109

表 2.7.4.7-46　全期間で合計 2%以上に認められた治験薬投与下で発現した治験薬との因果関係が否定できない有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban Total

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated	47 (100%)	47 (100%)	43 (100%)	43 (100%)	47 (100%)	40 (100%)	17 (100%)	11 (100%)
Eye disorders (眼障害)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Conjunctival haemorrhage (結膜出血)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Gastrointestinal disorders (胃腸障害)	3 (6.4%)	2 (4.3%)		1 (2.3%)	3 (6.4%)	1 (2.5%)		
Abdominal pain (腹痛)	1 (2.1%)					1 (2.5%)		
Gingival bleeding (歯肉出血)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Haematochezia (血便排泄)	3 (6.4%)	2 (4.3%)		1 (2.3%)	3 (6.4%)			
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	3 (6.4%)	1 (2.1%)	1 (2.3%)		2 (4.3%)		1 (5.9%)	
Puncture site haemorrhage (穿刺部位出血)	1 (2.1%)		1 (2.3%)		1 (2.1%)			
Pyrexia (発熱)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Thirst (口渇)	1 (2.1%)						1 (5.9%)	
Investigations (臨床検査)	2 (4.3%)		1 (2.3%)		1 (2.1%)	1 (2.5%)		
Blood urine present (尿中血陽性)	1 (2.1%)		1 (2.3%)		1 (2.1%)			
Liver function test abnormal (肝機能検査異常)	1 (2.1%)					1 (2.5%)		
Renal and urinary disorders (腎および尿路障害)	1 (2.1%)							1 (9.1%)
Renal failure chronic (慢性腎不全)	1 (2.1%)							1 (9.1%)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	5 (10.6%)	2 (4.3%)			2 (4.3%)	1 (2.5%)	1 (5.9%)	1 (9.1%)
Cough (咳嗽)	1 (2.1%)	1 (2.1%)			1 (2.1%)			
Epistaxis (鼻出血)	4 (8.5%)	1 (2.1%)			1 (2.1%)	1 (2.5%)	1 (5.9%)	1 (9.1%)
Interstitial lung disease (間質性肺疾患)	1 (2.1%)	1 (2.1%)			1 (2.1%)			

表 2.7.4.7-46 全期間で合計 2%以上に認められた治験薬投与下で発現した治験薬との因果関係が否定できない有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban Total

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	4 (8.5%)	1 (2.1%)		2 (4.7%)	3 (6.4%)	1 (2.5%)		
Haemorrhage subcutaneous (皮下出血)	4 (8.5%)	1 (2.1%)		2 (4.7%)	3 (6.4%)	1 (2.5%)		

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
GB: .../projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j3-period-summary-common-2percent-ae.sas erjli 07MAR2014 15:07
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/109

表 2.7.4.7-46　全期間で合計 2%以上に認められた治験薬投与下で発現した治験薬との因果関係が否定できない有害事象の時期別発現頻度（30 日ごと）（試験 14568、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: UFH / Warfarin

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated	12 (100%)	12 (100%)	12 (100%)		12 (100%)	10 (100%)		
Investigations (臨床検査)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Activated partial thromboplastin time prolonged (活性化部分トロンボプラスチン時間延長)	1 (8.3%)	1 (8.3%)			1 (8.3%)			
Renal and urinary disorders (腎および尿路障害)	1 (8.3%)					1 (10.0%)		
Haematuria (血尿)	1 (8.3%)					1 (10.0%)		
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	1 (8.3%)		1 (8.3%)		1 (8.3%)			
Epistaxis (鼻出血)	1 (8.3%)		1 (8.3%)		1 (8.3%)			
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	1 (8.3%)		1 (8.3%)		1 (8.3%)			
Haemorrhage subcutaneous (皮下出血)	1 (8.3%)		1 (8.3%)		1 (8.3%)			

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
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End of table
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/109

表 2.7.4.7-47　全期間で合計 2%以上に認められた治験薬投与下で発現した治験薬との因果関係が否定できない有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 15 mg BID/OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated	30 (100%)	30 (100%)	26 (100%)	26 (100%)	30 (100%)	25 (100%)	10 (100%)	
Eye disorders (眼障害)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Conjunctivitis (結膜炎)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Gastrointestinal disorders (胃腸障害)	4 (13.3%)	1 (3.3%)	2 (7.7%)	1 (3.8%)	4 (13.3%)			
Constipation (便秘)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Haematochezia (血便排泄)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Haemorrhoidal haemorrhage (痔出血)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Hypoaesthesia oral (口の感覚鈍麻)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Oedema peripheral (末梢性浮腫)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Hepatobiliary disorders (肝胆道系障害)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		
Hepatic function abnormal (肝機能異常)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Subcutaneous haematoma (皮下血腫)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Investigations (臨床検査)	3 (10.0%)	2 (6.7%)			2 (6.7%)	1 (4.0%)		
Blood bilirubin increased (血中ビリルビン増加)	1 (3.3%)					1 (4.0%)		
Blood urine present (尿中血陽性)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Liver function test abnormal (肝機能検査異常)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	3 (10.0%)					2 (8.0%)	1 (10.0%)	
Epistaxis (鼻出血)	2 (6.7%)					1 (4.0%)	1 (10.0%)	
Haemoptysis (喀血)	1 (3.3%)					1 (4.0%)		

表 2.7.4.7-47　全期間で合計 2%以上に認められた治験薬投与下で発現した治験薬との因果関係が否定できない有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban 15 mg BID/OD

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Skin and subcutaneous tissue disorders（皮膚および皮下組織障害）	6 (20.0%)	5 (16.7%)			5 (16.7%)		1 (10.0%)	
Drug eruption（薬疹）	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Haemorrhage subcutaneous（皮下出血）	4 (13.3%)	4 (13.3%)			4 (13.3%)			
Petechiae（点状出血）	1 (3.3%)						1 (10.0%)	

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
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引用元：5.3.5.3.12 Integrated-J Table 14.3.1/111

表 2.7.4.7-47 全期間で合計 2%以上に認められた治験薬投与下で発現した治験薬との因果関係が否定できない有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban Total

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated	30 (100%)	30 (100%)	26 (100%)	26 (100%)	30 (100%)	25 (100%)	10 (100%)	
Eye disorders (眼障害)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Conjunctivitis (結膜炎)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Gastrointestinal disorders (胃腸障害)	4 (13.3%)	1 (3.3%)	2 (7.7%)	1 (3.8%)	4 (13.3%)			
Constipation (便秘)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Haematochezia (血便排泄)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Haemorrhoidal haemorrhage (痔出血)	1 (3.3%)		1 (3.8%)		1 (3.3%)			
Hypoaesthesia oral (口の感覚鈍麻)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Oedema peripheral (末梢性浮腫)	1 (3.3%)			1 (3.8%)	1 (3.3%)			
Hepatobiliary disorders (肝胆道系障害)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		
Hepatic function abnormal (肝機能異常)	2 (6.7%)	1 (3.3%)			1 (3.3%)	1 (4.0%)		
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Subcutaneous haematoma (皮下血腫)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Investigations (臨床検査)	3 (10.0%)	2 (6.7%)			2 (6.7%)	1 (4.0%)		
Blood bilirubin increased (血中ビリルビン増加)	1 (3.3%)					1 (4.0%)		
Blood urine present (尿中血陽性)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Liver function test abnormal (肝機能検査異常)	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	3 (10.0%)					2 (8.0%)	1 (10.0%)	
Epistaxis (鼻出血)	2 (6.7%)					1 (4.0%)	1 (10.0%)	
Haemoptysis (喀血)	1 (3.3%)					1 (4.0%)		

表 2.7.4.7-47　全期間で合計 2%以上に認められた治験薬投与下で発現した治験薬との因果関係が否定できない有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: Rivaroxaban Total

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Skin and subcutaneous tissue disorders（皮膚および皮下組織障害）	6 (20.0%)	5 (16.7%)			5 (16.7%)		1 (10.0%)	
Drug eruption（薬疹）	1 (3.3%)	1 (3.3%)			1 (3.3%)			
Haemorrhage subcutaneous（皮下出血）	4 (13.3%)	4 (13.3%)			4 (13.3%)			
Petechiae（点状出血）	1 (3.3%)						1 (10.0%)	

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
GB: .../projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j3-period-summary-common-2percent-ae.sas erjli 07MAR2014 15:07
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/111

表 2.7.4.7-47　全期間で合計 2%以上に認められた治験薬投与下で発現した治験薬との因果関係が否定できない有害事象の時期別発現頻度（30 日ごと）（試験 15960、安全性解析対象集団）（続き）

Intended treatment duration: ALL DURATION
Treatment Group: UFH / Warfarin

Primary System Organ Class Preferred Term MedDRA version{16.1}	Total n(%)	Month 1 (Day 1 - 30) n(%)	Month 2 (Day 31 - 60) n(%)	Month 3 (Day 61 - 90) n(%)	Month 1 to 3 (Day 1 - 90) n(%)	Month 4 to 6 (Day 91 - 180) n(%)	Month 7 to 9 (Day 181 - 270) n(%)	Month 10 to 12 (Day 271 - 360) n(%)
Number of subjects evaluated	7 (100%)	7 (100%)	7 (100%)	7 (100%)	7 (100%)	7 (100%)		
Gastrointestinal disorders (胃腸障害)	2 (28.6%)	1 (14.3%)			1 (14.3%)	1 (14.3%)		
Diarrhoea (下痢)	1 (14.3%)	1 (14.3%)			1 (14.3%)			
Gingival bleeding (歯肉出血)	1 (14.3%)					1 (14.3%)		
Investigations (臨床検査)	2 (28.6%)	2 (28.6%)			2 (28.6%)			
Alanine aminotransferase increased (アラニンアミノトランスフェラーゼ増加)	2 (28.6%)	2 (28.6%)			2 (28.6%)			
Aspartate aminotransferase increased (アスパラギン酸アミノトランスフェラーゼ増加)	2 (28.6%)	2 (28.6%)			2 (28.6%)			
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	2 (28.6%)		1 (14.3%)	1 (14.3%)	2 (28.6%)			
Haemorrhage subcutaneous (皮下出血)	2 (28.6%)		1 (14.3%)	1 (14.3%)	2 (28.6%)			

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
Number of subjects evaluated is the number of subject who was in the study at the first day of each period.
Only the first target event (per subject per preferred term) should be counted, and hence, double counts should be avoided.
Only the target AEs with incidence of 2 % or higher (per preferred term) during the corresponding entire study period per treatment group and the corresponding primary SOCs are presented.
Day 1 is the first day of study drug administration.
Adverse events with missing onset date are excluded.
GB:.../projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adae-j3-period-summary-common-2percent-ae.sas erjli 07MAR2014 15:07
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引用元：5.3.5.3.12 Integrated-J Table 14.3.1/111

表 2.7.4.7-48 死亡例一覧（試験 14568、安全性解析対象集団）

Actual Treatment for Period 01	Subject identifier/ age/sex/race	Study drug start date/stop date	Last dose [mg]	Date of death	Relative to start day/relative to stop day	MedDRA preferred term with fatal outcome	Relation ship to study drug	Cause of death
Rivaroxaban 15 mg BID/OD	200110054/70/M/A	06JUN2012 / 05NOV2012	15.0	08DEC2012	186 / 34	Pulmonary oedema (肺水腫)	N	OTHER CAUSE: OTHER RESPIRATORY FAILURE

Race: A=Asian B=Black W=White AI=American Indian or Alaska Native NH=Native Hawaiian or Other Pacific Islander NR=Not Reported MUL=Multiple
Sex: F=female M=male
Relative to start day = date of death minus date of first study drug administration plus 1 day.
Relative to stop day = date of death minus date of last study drug administration plus 1 day.
Global Biostatistics: /by-sasp/patdb/projects/597939/14568/stat/prod/pgms/t-14-3-2-adds-death-listing.sas evmqe 07MAR2014 13:24
End of table
引用元：5.3.5.3.12 Integrated-J Table 14.3.2/1

表 2.7.4.7-49 死亡例一覧（試験 15960、安全性解析対象集団）

Actual Treatment for Period 01	Subject identifier/ age/sex/race	Study drug start date/stop date	Last dose [mg]	Date of death	Relative to start day/relative to stop day	MedDRA preferred term with fatal outcome	Relation ship to study drug	Cause of death
Rivaroxaban 15 mg BID/OD	200020003/76/M/A	12JUL2012 / 13JUL2012	15.0	21JUL2012	10 / 9	Shock haemorrhagic (出血性ショック)	N	OTHER CAUSE: BLEEDING
	200210001/79/M/A	02MAR2012 / 06JUL2012	15.0	02AUG2012	154 / 28	Cardiac failure (心不全)	N	CARDIOVASCULAR CAUSE: HEART FAILURE

Race: A=Asian B=Black W=White AI=American Indian or Alaska Native NH=Native Hawaiian or Other Pacific Islander NR=Not Reported MUL=Multiple
Sex: F=female M=male
Relative to start day = date of death minus date of first study drug administration plus 1 day.
Relative to stop day = date of death minus date of last study drug administration plus 1 day.
Global Biostatistics: /by-sasp/patdb/projects/597939/15960/stat/prod/pgms/t-14-3-2-adds-death-listing.sas erjli 07MAR2014 12:42
End of table
引用元：5.3.5.3.12 Integrated-J Table 14.3.2/1

表 2.7.4.7-50　すべての重篤な有害事象の一覧（試験 14568、割り付けられた被験者）

Subject ID	Sex/Age/Race/Country/Safety population	Adverse Events (AE) Preferred term	Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Start Date of AE	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
Treatment group: Rivaroxaban 15 mg BID/OD													
200050051	Male/64/ASIAN/JPN/YES	Ischaemic stroke（虚血性脳卒中）	15mg OD	F	MODERATE	YES	NO	30AUG2012	63	.	NO	Rivaroxaban:NOT APPLICABLE	RECOVERING/RESOLVING
200110054	Male/70/ASIAN/JPN/YES	Pulmonary oedema（肺水腫）	15mg OD	F	SEVERE	YES	NO	08DEC2012	186	1	NO	Rivaroxaban:NOT APPLICABLE	FATAL
		Ischaemic stroke（虚血性脳卒中）	15mg OD	F	MODERATE	YES	NO	25NOV2012	173	.	NO	Rivaroxaban:NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
		Decreased appetite（食欲減退）	15mg OD	F	MODERATE	YES	YES	07NOV2012	155	.	NO	Rivaroxaban:NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
200140053	Male/76/ASIAN/JPN/YES	Subileus（亜イレウス）	15mg OD	-	MODERATE	YES	YES	11DEC2012	48	11	NO	Rivaroxaban:DRUG INTERRUPTED	RECOVERING/RESOLVING
Treatment group: Rivaroxaban 10 mg BID/15 mg OD													
200090052	Male/59/ASIAN/JPN/YES	Metastases to lymph nodes（リンパ節転移）	15mg OD	-	MODERATE	YES	YES	10JAN2013	80	.	NO	Rivaroxaban:DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
		Lymphangitis（リンパ管炎）	10mg BID	-	MILD	YES	YES	09NOV2012	18	35	NO	Rivaroxaban:DOSE NOT CHANGED	RECOVERED/RESOLVED
200150051	Female/75/ASIAN/JPN/YES	Interstitial lung disease（間質性肺疾患）	15mg OD	-	MODERATE	YES	YES	20APR2012	23	88	YES	Rivaroxaban:DRUG WITHDRAWN	RECOVERING/RESOLVING
200350051	Female/71/ASIAN/JPN/YES	Colon cancer（結腸癌）	15mg OD	F	MILD	YES	NO	20NOV2012	163	2	NO	Rivaroxaban:NOT APPLICABLE	RECOVERED/RESOLVED

表 2.7.4.7-50　すべての重篤な有害事象の一覧（試験 14568、割り付けられた被験者）（続き）

Treatment group: Rivaroxaban 15 mg BID/OD

Subject ID	Sex/Age/Race/Country/Safety population	Adverse Events (AE) Preferred term	Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Start Date of AE	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
200380051	Female/61/ASIAN/JPN/YES	Renal cancer (腎癌)	15mg OD	-	MODERATE	YES	YES	19MAY2013	116	55	NO	Rivaroxaban:DRUG INTERRUPTED	RECOVERED/RESOLVED

Treatment group: UFH / Warfarin

Subject ID	Sex/Age/Race/Country/Safety population	Adverse Events (AE) Preferred term	Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Start Date of AE	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
200370051	Male/67/ASIAN/JPN/YES	Gastrointestinal stromal tumour (消化管間質性腫瘍)			SEVERE	YES	NO	28AUG2013	313	8	NO	Warfarin:NOT APPLICABLE , UFH:NOT APPLICABLE	RECOVERING/RESOLVING
		Gastroenteritis (胃腸炎)			MODERATE	YES	YES	31JUL2013	285	10	NO	Warfarin:DOSE NOT CHANGED , UFH:NOT APPLICABLE	RECOVERED/RESOLVED

Only All serious AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is (onset day of AE minus medication day) plus 1 day.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, "I" will be listed. If AE onset is after treatment phase, "F" will be listed.
GB: .../projects/597939/14568-15960/stat/prod/pgms/t-14-3-2-adae-j4-j7-individual-data-listing.sas erjli 07MAR2014 16:42
引用元：5.3.5.3.12 Integrated-J Table 14.3.2/2

表 2.7.4.7-51 すべての重篤な有害事象の一覧（試験 15960、割り付けられた被験者）

Treatment group: Rivaroxaban 15 mg BID/OD

Subject ID	Sex/Age/Race/Country/Safety population	Adverse Events (AE) Preferred term	Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Start Date of AE	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
200020003	Male/76/ASIAN/JPN/YES	Gastrointestinal haemorrhage (胃腸出血)	15mg OD	F	SEVERE	YES	NO	16JUL2012	5	.	NO	Rivaroxaban:NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
		Shock haemorrhagic (出血性ショック)	15mg OD	F	SEVERE	YES	NO	21JUL2012	10	1	NO	Rivaroxaban:NOT APPLICABLE	FATAL
200090002	Female/72/ASIAN/JPN/YES	Ischaemic stroke (虚血性脳卒中)	15mg OD	F	MILD	YES	NO	24OCT2012	139	18	NO	Rivaroxaban:NOT APPLICABLE	RECOVERED/RESOLVED
200100002	Female/78/ASIAN/JPN/YES	Cellulitis (蜂巣炎)	15mg BID	-	MODERATE	YES	YES	01SEP2012	5	9	NO	Rivaroxaban:DOSE NOT CHANGED	RECOVERING/RESOLVING
200130001	Male/44/ASIAN/JPN/YES	Atrial fibrillation (心房細動)	15mg OD	F	MODERATE	YES	NO	22FEB2013	366	8	NO	Rivaroxaban:NOT APPLICABLE	RECOVERING/RESOLVING
200180001	Female/77/ASIAN/JPN/NO	Cardiac failure (心不全)	15mg OD	-	SEVERE	YES	YES	24SEP2012	132	.	NO	Rivaroxaban:DRUG INTERRUPTED	RECOVERING/RESOLVING
200210001	Male/79/ASIAN/JPN/YES	Cardiac failure (心不全)	15mg OD	-	MODERATE	YES	YES	03JUL2012	124	31	NO	Rivaroxaban:DRUG WITHDRAWN	FATAL
		Pneumonia (肺炎)	15mg OD	-	MILD	YES	YES	22MAR2012	21	16	NO	Rivaroxaban:DOSE NOT CHANGED	RECOVERING/RESOLVING
		Pneumonia (肺炎)	15mg OD	-	MODERATE	YES	YES	03JUL2012	124	.	NO	Rivaroxaban:DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
200300002	Female/72/ASIAN/JPN/YES	Cellulitis (蜂巣炎)	15mg OD	-	MODERATE	YES	YES	29NOV2012	161	16	NO	Rivaroxaban:DOSE NOT CHANGED	RECOVERED/RESOLVED

表 2.7.4.7-51　すべての重篤な有害事象の一覧（試験 15960、割り付けられた被験者）（続き）

Treatment group: Rivaroxaban 15 mg BID/OD

Subject ID	Sex/Age/Race/Country/Safety population	Adverse Events (AE) Preferred term	Dose on AE onset	Dose status on AE onset	Intensity	SAE	TE	Start Date of AE	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
200330001	Male/71/ASIAN/JPN/YES	Hypopharyngeal cancer (下咽頭癌)	15mg OD	-	SEVERE	YES	YES	14SEP2012	29	35	NO	Rivaroxaban:DRUG INTERRUPTED	RECOVERING/RESOLVING
		Pleural effusion (胸水)	15mg OD	F	MODERATE	YES	NO	01MAR2013	197	.	NO	Rivaroxaban:NOT APPLICABLE	RECOVERING/RESOLVING

Only All serious AEs (TEAE and non-TEAE) are presented.
TE: Treatment emergent (time window: 2 days)
Relative day is calculated from the first day of study drug administration: The formula for this calculation is (onset day of AE minus medication day) plus 1 day.
Dose on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, dose just before the onset will be listed.
Dose status on AE onset: only rivaroxaban arm. If AE onset is during dose interruption, "I" will be listed. If AE onset is after treatment phase, "F" will be listed.
GB:.../projects/597939/14568-15960/stat/prod/pgms/t-14-3-2-adae-j4-j7-individual-data-listing.sas erjli 07MAR2014 16:42
End of table
引用元：5.3.5.3.12 Integrated-J Table 14.3.2/2

表 2.7.4.7-52　重篤な TEAE（治験薬投与終了後 2 日以内）（試験 14568、安全性解析対象集団）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID/15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID/OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)
Number (%) of subjects with at least one adverse event	3 (13.6%)	2 (8.0%)	5 (10.6%)	1 (8.3%)
Gastrointestinal disorders (胃腸障害)	0	1 (4.0%)	1 (2.1%)	0
Subileus (亜イレウス)	0	1 (4.0%)	1 (2.1%)	0
Infections and infestations (感染症および寄生虫症)	1 (4.5%)	0	1 (2.1%)	1 (8.3%)
Gastroenteritis (胃腸炎)	0	0	0	1 (8.3%)
Lymphangitis (リンパ管炎)	1 (4.5%)	0	1 (2.1%)	0
Metabolism and nutrition disorders (代謝および栄養障害)	0	1 (4.0%)	1 (2.1%)	0
Decreased appetite (食欲減退)	0	1 (4.0%)	1 (2.1%)	0
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))	2 (9.1%)	0	2 (4.3%)	0
Metastases to lymph nodes (リンパ節転移)	1 (4.5%)	0	1 (2.1%)	0
Renal cancer (腎癌)	1 (4.5%)	0	1 (2.1%)	0
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	1 (4.5%)	0	1 (2.1%)	0
Interstitial lung disease (間質性肺疾患)	1 (4.5%)	0	1 (2.1%)	0

SOC = System Organ Class
Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more clinical AEs, the subject is counted only once in a category.
The same subject may appear in different categories.
Percentages calculated with the number of subjects in each group as denominator. Sorted first by SOC (alphab. order) then by preferred term (alphab. order).
Treatment-emergent AE is defined as the AE occurred after the first dose and up to the respective time window after the last dose of study drug.
Global Biostatistics: /by-sasp/patdb/projects/597939/14568/stat/prod/pgms/t-14-3-1-adae-subjects-soc-pt.sas　evmqe　07MAR2014 12:03
End of table
引用元：5.3.5.1.20 PH-37602 Table 14.3.1/24

表 2.7.4.7-53 重篤な TEAE（治験薬投与終了後 2 日以内）（試験 15960、安全性解析対象集団）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 15 mg BID/OD N=30 (100%)	UFH / Warfarin N=7 (100%)
Number (%) of subjects with at least one adverse event	4 (13.3%)	0
Cardiac disorders (心臓障害)	1 (3.3%)	0
Cardiac failure (心不全)	1 (3.3%)	0
Infections and infestations (感染症および寄生虫症)	3 (10.0%)	0
Cellulitis (蜂巣炎)	2 (6.7%)	0
Pneumonia (肺炎)	1 (3.3%)	0
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))	1 (3.3%)	0
Hypopharyngeal cancer (下咽頭癌)	1 (3.3%)	0

SOC = System Organ Class
Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more clinical AEs, the subject is counted only once in a category. The same subject may appear in different categories.
Percentages calculated with the number of subjects in each group as denominator. Sorted first by SOC (alphab. order) then by preferred term (alphab. order).
Treatment-emergent AE is defined as the AE occurred after the first dose and up to the respective time window after the last dose of study drug.
Global Biostatistics: /by-sasp/patdb/projects/597939/15960/stat/prod/pgms/t-14-3-1-adae-subjects-soc-pt.sas erjli 07MAR2014 11:41
End of table
引用元：5.3.5.1.21 PH-37586 Table 14.3.1/24

表 2.7.4.7-54　治験薬との因果関係が否定できない重篤な TEAE（治験薬投与終了後 2 日以内）（試験 14568、安全性解析対象集団）

Primary system organ class Preferred term MedDRA version 16.1	Rivaroxaban 10 mg BID/15 mg OD N=22 (100%)	Rivaroxaban 15 mg BID/OD N=25 (100%)	Rivaroxaban Total N=47 (100%)	UFH / Warfarin N=12 (100%)
Number (%) of subjects with at least one adverse event	1 (4.5%)	0	1 (2.1%)	0
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	1 (4.5%)	0	1 (2.1%)	0
Interstitial lung disease (間質性肺疾患)	1 (4.5%)	0	1 (2.1%)	0

SOC = System Organ Class
Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more clinical AEs, the subject is counted only once in a category. The same subject may appear in different categories.
Percentages calculated with the number of subjects in each group as denominator. Sorted first by SOC (alphab. order) then by preferred term (alphab. order).
Treatment-emergent AE is defined as the AE occurred after the first dose and up to the respective time window after the last dose of study drug.
Global Biostatistics: /by-sasp/patdb/projects/597939/14568/stat/prod/pgms/t-14-3-1-adae-subjects-soc-pt.sas　evmqe　07MAR2014 12:03
End of table
引用元：5.3.5.1.20 PH-37602 Table 14.3.1/32

表 2.7.4.7- 55　治験薬投与後のその他の抗凝固療法（試験 14568、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）

ANTICOAGULANT MEDICATION	Rivaroxaban 10 mg BID/15 mg OD N=16 (100%)	Rivaroxaban 15 mg BID/OD N=20 (100%)	UFH / Warfarin N=11 (100%)	Total N=47 (100%)
Any medication	7 (43.8%)	8 (40.0%)	9 (81.8%)	24 (51.1%)
VKA	7 (43.8%)	7 (35.0%)	9 (81.8%)	23 (48.9%)
UFH	0	0	0	0
LMWH	0	0	0	0
Fondaparinux	0	1 (5.0%)	0	1 (2.1%)

Anticoagulant drugs are selected by ATC codes (see additional SAP).
If the above drugs meet the following condition, these drugs are treated as taken after study medication.
End date of study treatment < end date of the above concomitant medication drugs or end date of study treatment < start date of the above concomitant medication drugs.
Ongoing status at subject's last visit will be also considered.
'The patients who completed' means the patients completed intended treatment duration without primary efficacy outcome, death (scope: intended treatment duration) and/or termination by sponsor.
GB: .../projects/597939/14568-15960/stat/prod_query01/pgms/t-adcm-pmda-posthoc-other-anticoagulant.sas　erjli　06MAR2014 15:35
End of table
引用元：5.3.5.1.43 Additional_22 Table /25

表 2.7.4.7- 56　治験薬投与後のその他の抗凝固療法（試験 15960、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）

ANTICOAGULANT MEDICATION	Rivaroxaban 15 mg BID/OD N=23 (100%)	UFH / Warfarin N=6 (100%)	Total N=29 (100%)
Any medication	7 (30.4%)	6 (100.0%)	13 (44.8%)
VKA	6 (26.1%)	6 (100.0%)	12 (41.4%)
UFH	1 (4.3%)	0	1 (3.4%)
LMWH	0	0	0
Fondaparinux	0	0	0

Anticoagulant drugs are selected by ATC codes (see additional SAP).
If the above drugs meet the following condition, these drugs are treated as taken after study medication.
End date of study treatment < end date of the above concomitant medication drugs or end date of study treatment < start date of the above concomitant medication drugs.
Ongoing status at subject's last visit will be also considered.
'The patients who completed' means the patients completed intended treatment duration without primary efficacy outcome, death (scope: intended treatment duration) and/or termination by sponsor.
GB: .../projects/597939/14568-15960/stat/prod_query01/pgms/t-adcm-pmda-posthoc-other-anticoagulant.sas　erjli 06MAR2014 15:35
End of table
引用元：5.3.5.1.43 Additional_22 Table /26

表 2.7.4.7- 57　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 14568、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）

Other anticoagulant medication after stopping study medication: NO

	Rivaroxaban 10 mg BID/15 mg OD N=10 (100%)	Rivaroxaban 15 mg BID/OD N=15 (100%)	UFH / Warfarin N=2 (100%)	Total N=27 (100%)
Sex				
Male	8 (80.0%)	5 (33.3%)	1 (50.0%)	14 (51.9%)
Female	2 (20.0%)	10 (66.7%)	1 (50.0%)	13 (48.1%)
Age (years)				
n	10	15	2	27
Mean	64.5	76.1	77.0	71.9
SD	13.5	8.0	8.5	11.5
Min	41	51	71	41
Q1	61.0	74.0	71.0	69.0
Median	68.5	77.0	77.0	74.0
Q3	74.0	81.0	83.0	80.0
Max	80	85	83	85
Age Group 2				
<60 years	2 (20.0%)	1 (6.7%)	0	3 (11.1%)
>=60 years	8 (80.0%)	14 (93.3%)	2 (100.0%)	24 (88.9%)
Age Group 3				
<65 years	4 (40.0%)	1 (6.7%)	0	5 (18.5%)
65 - 75 years	5 (50.0%)	4 (26.7%)	1 (50.0%)	10 (37.0%)
>75 years	1 (10.0%)	10 (66.7%)	1 (50.0%)	12 (44.4%)

表 2.7.4.7- 57　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 14568、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: NO

	Rivaroxaban 10 mg BID/15 mg OD N=10 (100%)	Rivaroxaban 15 mg BID/OD N=15 (100%)	UFH / Warfarin N=2 (100%)	Total N=27 (100%)
Baseline Weight (kg)				
n	10	15	2	27
Mean	70.60	59.19	61.60	63.60
SD	11.54	15.39	17.54	14.69
Min	56.5	37.6	49.2	37.6
Q1	58.10	44.80	49.20	56.40
Median	71.25	62.00	61.60	62.10
Q3	77.10	65.00	74.00	74.00
Max	90.6	94.8	74.0	94.8
Weight Group 1				
<=70 kg	5 (50.0%)	13 (86.7%)	1 (50.0%)	19 (70.4%)
>70 - <=90 kg	4 (40.0%)	1 (6.7%)	1 (50.0%)	6 (22.2%)
>90 kg	1 (10.0%)	1 (6.7%)	0	2 (7.4%)
Weight Group 2				
<90 kg	9 (90.0%)	14 (93.3%)	2 (100.0%)	25 (92.6%)
>=90 kg	1 (10.0%)	1 (6.7%)	0	2 (7.4%)
Weight Group 3				
<=50 kg	0	4 (26.7%)	1 (50.0%)	5 (18.5%)
50 - <=70 kg	5 (50.0%)	9 (60.0%)	0	14 (51.9%)
70 - <=90 kg	4 (40.0%)	1 (6.7%)	1 (50.0%)	6 (22.2%)
>90 kg	1 (10.0%)	1 (6.7%)	0	2 (7.4%)

表 2.7.4.7- 57 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 14568、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: NO

	Rivaroxaban 10 mg BID/15 mg OD N=10 (100%)	Rivaroxaban 15 mg BID/OD N=15 (100%)	UFH / Warfarin N=2 (100%)	Total N=27 (100%)
Baseline Height (cm)				
n	10	15	2	27
Mean	164.1	156.5	153.3	159.1
SD	10.3	10.1	4.1	10.4
Min	147	140	150	140
Q1	154.0	150.0	150.4	150.4
Median	166.1	156.0	153.3	158.5
Q3	173.6	164.5	156.2	170.1
Max	175	173	156	175
Baseline Body Mass Index (kg/m2)				
n	10	15	2	27
Mean	26.30	24.03	26.05	25.02
SD	4.34	5.30	6.01	4.93
Min	21.7	16.7	21.8	16.7
Q1	23.10	20.10	21.80	21.20
Median	25.45	24.60	26.05	24.60
Q3	27.60	26.90	30.30	27.60
Max	36.2	36.3	30.3	36.3
Baseline Body Mass Index Group 2				
<30 kg/m2	8 (80.0%)	14 (93.3%)	1 (50.0%)	23 (85.2%)
>=30 kg/m2	2 (20.0%)	1 (6.7%)	1 (50.0%)	4 (14.8%)
Baseline Body Mass Index Group 3				
<=18.5 kg/m2	0	2 (13.3%)	0	2 (7.4%)
18.5 - <=25 kg/m2	5 (50.0%)	6 (40.0%)	1 (50.0%)	12 (44.4%)
25 - <=30 kg/m2	3 (30.0%)	6 (40.0%)	0	9 (33.3%)
30 - <=35 kg/m2	1 (10.0%)	0	1 (50.0%)	2 (7.4%)
>35 kg/m2	1 (10.0%)	1 (6.7%)	0	2 (7.4%)

表 2.7.4.7- 57　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 14568、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: NO				
	Rivaroxaban 10 mg BID/15 mg OD N=10 (100%)	Rivaroxaban 15 mg BID/OD N=15 (100%)	UFH / Warfarin N=2 (100%)	Total N=27 (100%)
Creatinine Clearance Group 2				
<50 mL/min	0	3 (20.0%)	0	3 (11.1%)
50 - <80 mL/min	2 (20.0%)	8 (53.3%)	2 (100.0%)	12 (44.4%)
>=80 mL/min	8 (80.0%)	4 (26.7%)	0	12 (44.4%)
Creatinine Clearance Group 3				
30 - <50 mL/min	0	3 (20.0%)	0	3 (11.1%)
50 - <80 mL/min	2 (20.0%)	8 (53.3%)	2 (100.0%)	12 (44.4%)
>=80 mL/min	8 (80.0%)	4 (26.7%)	0	12 (44.4%)
Systolic Blood Pressure (mmhg)				
n	10	15	2	27
Mean	139.50	137.27	142.50	138.48
SD	24.20	24.11	7.78	22.82
Min	99.0	100.0	137.0	99.0
Q1	122.00	120.00	137.00	122.00
Median	138.00	130.00	142.50	137.00
Q3	164.00	162.00	148.00	162.00
Max	172.0	178.0	148.0	178.0

表 2.7.4.7- 57　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 14568、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: NO

	Rivaroxaban 10 mg BID/15 mg OD N=10 (100%)	Rivaroxaban 15 mg BID/OD N=15 (100%)	UFH / Warfarin N=2 (100%)	Total N=27 (100%)
Diastolic Blood Pressure (mmHg)				
n	10	15	2	27
Mean	75.80	76.13	82.00	76.44
SD	13.62	14.81	1.41	13.60
Min	54.0	52.0	81.0	52.0
Q1	67.00	65.00	81.00	67.00
Median	74.00	71.00	82.00	76.00
Q3	90.00	90.00	83.00	90.00
Max	93.0	102.0	83.0	102.0

Creatinine clearance levels were calculated using the equation of Cockroft and Gault, using the last value up to the day of randomization.
Percentages are calculated including missing values.
Q1 = 25th percentile, Q3 = 75th percentile.
Anticoagulant drugs are selected by ATC codes (see additional SAP).
If the above drugs meet the following condition, these drugs are treated as taken after study medication.
End date of study treatment < end date of the above concomitant medication drugs or end date of study treatment < start date of the above concomitant medication drugs.
Ongoing status at subject's last visit will be also considered.
'The patients who completed' means the patients completed intended treatment duration without primary efficacy outcome,
death (scope: intended treatment duration) and/or termination by sponsor.
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表 2.7.4.7- 57 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 14568、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: YES

	Rivaroxaban 10 mg BID/15 mg OD N=6 (100%)	Rivaroxaban 15 mg BID/OD N=5 (100%)	UFH / Warfarin N=9 (100%)	Total N=20 (100%)
Sex				
Male	4 (66.7%)	4 (80.0%)	6 (66.7%)	14 (70.0%)
Female	2 (33.3%)	1 (20.0%)	3 (33.3%)	6 (30.0%)
Age (years)				
n	6	5	9	20
Mean	64.7	69.8	58.9	63.4
SD	8.3	16.2	19.5	16.0
Min	52	50	33	33
Q1	61.0	59.0	38.0	55.5
Median	64.0	72.0	60.0	64.0
Q3	71.0	76.0	75.0	75.5
Max	76	92	82	92
Age Group 2				
<60 years	1 (16.7%)	2 (40.0%)	3 (33.3%)	6 (30.0%)
>=60 years	5 (83.3%)	3 (60.0%)	6 (66.7%)	14 (70.0%)
Age Group 3				
<65 years	3 (50.0%)	2 (40.0%)	5 (55.6%)	10 (50.0%)
65 - 75 years	2 (33.3%)	1 (20.0%)	2 (22.2%)	5 (25.0%)
>75 years	1 (16.7%)	2 (40.0%)	2 (22.2%)	5 (25.0%)

表 2.7.4.7- 57　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 14568、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: YES

	Rivaroxaban 10 mg BID/15 mg OD N=6 (100%)	Rivaroxaban 15 mg BID/OD N=5 (100%)	UFH / Warfarin N=9 (100%)	Total N=20 (100%)
Baseline Weight (kg)				
n	6	5	9	20
Mean	65.20	64.16	57.48	61.47
SD	11.10	12.05	10.54	11.12
Min	48.0	46.9	38.0	38.0
Q1	58.00	56.40	52.00	54.05
Median	66.65	70.00	58.00	61.20
Q3	71.90	72.20	62.40	70.95
Max	80.0	75.3	76.8	80.0
Weight Group 1				
<=70 kg	4 (66.7%)	3 (60.0%)	8 (88.9%)	15 (75.0%)
>70 - <=90 kg	2 (33.3%)	2 (40.0%)	1 (11.1%)	5 (25.0%)
>90 kg	0	0	0	0
Weight Group 2				
<90 kg	6 (100.0%)	5 (100.0%)	9 (100.0%)	20 (100.0%)
>=90 kg	0	0	0	0
Weight Group 3				
<=50 kg	1 (16.7%)	1 (20.0%)	1 (11.1%)	3 (15.0%)
50 - <=70 kg	3 (50.0%)	2 (40.0%)	7 (77.8%)	12 (60.0%)
70 - <=90 kg	2 (33.3%)	2 (40.0%)	1 (11.1%)	5 (25.0%)
>90 kg	0	0	0	0

表 2.7.4.7- 57 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 14568、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: YES

	Rivaroxaban 10 mg BID/15 mg OD N=6 (100%)	Rivaroxaban 15 mg BID/OD N=5 (100%)	UFH / Warfarin N=9 (100%)	Total N=20 (100%)
Baseline Height (cm)				
n	6	5	9	20
Mean	160.6	166.2	164.5	163.7
SD	18.2	13.0	10.2	13.1
Min	126	144	145	126
Q1	155.8	169.0	158.9	157.4
Median	167.5	169.5	168.0	168.5
Q3	170.0	170.0	172.0	171.5
Max	177	179	174	179
Baseline Body Mass Index (kg/m2)				
n	6	5	9	20
Mean	25.50	23.04	21.12	22.92
SD	3.75	2.08	2.52	3.30
Min	20.1	19.7	17.6	17.6
Q1	23.10	22.60	20.50	20.50
Median	25.65	23.60	20.50	22.60
Q3	28.30	24.20	22.20	24.65
Max	30.2	25.1	26.0	30.2
Baseline Body Mass Index Group 2				
<30 kg/m2	5 (83.3%)	5 (100.0%)	9 (100.0%)	19 (95.0%)
>=30 kg/m2	1 (16.7%)	0	0	1 (5.0%)
Baseline Body Mass Index Group 3				
<=18.5 kg/m2	0	0	2 (22.2%)	2 (10.0%)
18.5 - <=25 kg/m2	3 (50.0%)	4 (80.0%)	6 (66.7%)	13 (65.0%)
25 - <=30 kg/m2	2 (33.3%)	1 (20.0%)	1 (11.1%)	4 (20.0%)
30 - <=35 kg/m2	1 (16.7%)	0	0	1 (5.0%)
>35 kg/m2	0	0	0	0

表 2.7.4.7- 57　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 14568、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: YES				
	Rivaroxaban 10 mg BID/15 mg OD N=6 (100%)	Rivaroxaban 15 mg BID/OD N=5 (100%)	UFH / Warfarin N=9 (100%)	Total N=20 (100%)
Creatinine Clearance Group 2				
<50 mL/min	0	1 (20.0%)	0	1 (5.0%)
50 - <80 mL/min	1 (16.7%)	2 (40.0%)	4 (44.4%)	7 (35.0%)
>=80 mL/min	5 (83.3%)	2 (40.0%)	5 (55.6%)	12 (60.0%)
Creatinine Clearance Group 3				
30 - <50 mL/min	0	1 (20.0%)	0	1 (5.0%)
50 - <80 mL/min	1 (16.7%)	2 (40.0%)	4 (44.4%)	7 (35.0%)
>=80 mL/min	5 (83.3%)	2 (40.0%)	5 (55.6%)	12 (60.0%)
Systolic Blood Pressure (mmhg)				
n	6	5	9	20
Mean	140.50	127.40	126.67	131.00
SD	21.44	13.20	9.71	15.43
Min	120.0	112.0	109.0	109.0
Q1	127.00	119.00	122.00	121.00
Median	133.50	124.00	133.00	131.50
Q3	150.00	139.00	133.00	135.50
Max	179.0	143.0	134.0	179.0

表 2.7.4.7- 57　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 14568、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: YES

	Rivaroxaban 10 mg BID/15 mg OD N=6 (100%)	Rivaroxaban 15 mg BID/OD N=5 (100%)	UFH / Warfarin N=9 (100%)	Total N=20 (100%)
Diastolic Blood Pressure (mmHg)				
n	6	5	9	20
Mean	82.17	72.40	80.44	78.95
SD	13.39	9.74	11.35	11.70
Min	70.0	60.0	64.0	60.0
Q1	76.00	64.00	68.00	69.00
Median	78.00	78.00	86.00	79.00
Q3	83.00	78.00	89.00	86.50
Max	108.0	82.0	93.0	108.0

Creatinine clearance levels were calculated using the equation of Cockroft and Gault, using the last value up to the day of randomization.
Percentages are calculated including missing values.
Q1 = 25th percentile, Q3 = 75th percentile.
Anticoagulant drugs are selected by ATC codes (see additional SAP).
If the above drugs meet the following condition, these drugs are treated as taken after study medication.
End date of study treatment < end date of the above concomitant medication drugs or end date of study treatment < start date of the above concomitant medication drugs.
Ongoing status at subject's last visit will be also considered.
'The patients who completed' means the patients completed intended treatment duration without primary efficacy outcome,
death (scope: intended treatment duration) and/or termination by sponsor.
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表 2.7.4.7- 58　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 15960、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）

Other anticoagulant medication after stopping study medication: NO			
	Rivaroxaban 15 mg BID/OD N=18 (100%)	UFH / Warfarin N=0 (100%)	Total N=18 (100%)
Sex			
Male	8 (44.4%)	0	8 (44.4%)
Female	10 (55.6%)	0	10 (55.6%)
Age (years)			
n	18		18
Mean	65.3		65.3
SD	10.8		10.8
Min	41		41
Q1	61.0		61.0
Median	69.0		69.0
Q3	72.0		72.0
Max	78		78
Age Group 2			
<60 years	3 (16.7%)	0	3 (16.7%)
>=60 years	15 (83.3%)	0	15 (83.3%)
Age Group 3			
<65 years	7 (38.9%)	0	7 (38.9%)
65 - 75 years	9 (50.0%)	0	9 (50.0%)
>75 years	2 (11.1%)	0	2 (11.1%)

表 2.7.4.7- 58　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 15960、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: NO			
	Rivaroxaban 15 mg BID/OD N=18 (100%)	UFH / Warfarin N=0 (100%)	Total N=18 (100%)
Baseline Weight (kg)			
n	18		18
Mean	60.43		60.43
SD	13.67		13.67
Min	37.9		37.9
Q1	52.70		52.70
Median	57.05		57.05
Q3	71.80		71.80
Max	92.7		92.7
Weight Group 1			
<=70 kg	13 (72.2%)	0	13 (72.2%)
>70 - <=90 kg	4 (22.2%)	0	4 (22.2%)
>90 kg	1 (5.6%)	0	1 (5.6%)
Weight Group 2			
<90 kg	17 (94.4%)	0	17 (94.4%)
>=90 kg	1 (5.6%)	0	1 (5.6%)
Weight Group 3			
<=50 kg	3 (16.7%)	0	3 (16.7%)
50 - <=70 kg	10 (55.6%)	0	10 (55.6%)
70 - <=90 kg	4 (22.2%)	0	4 (22.2%)
>90 kg	1 (5.6%)	0	1 (5.6%)

表 2.7.4.7- 58　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 15960、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: NO			
	Rivaroxaban 15 mg BID/OD N=18 (100%)	UFH / Warfarin N=0 (100%)	Total N=18 (100%)
Baseline Height (cm)			
n	18		18
Mean	158.7		158.7
SD	10.3		10.3
Min	143		143
Q1	151.5		151.5
Median	157.5		157.5
Q3	165.7		165.7
Max	183		183
Baseline Body Mass Index (kg/m2)			
n	18		18
Mean	23.76		23.76
SD	3.46		3.46
Min	18.6		18.6
Q1	21.60		21.60
Median	22.60		22.60
Q3	26.80		26.80
Max	30.2		30.2
Baseline Body Mass Index Group 2			
<30 kg/m2	17 (94.4%)	0	17 (94.4%)
>=30 kg/m2	1 (5.6%)	0	1 (5.6%)
Baseline Body Mass Index Group 3			
18.5 - <=25 kg/m2	11 (61.1%)	0	11 (61.1%)
25 - <=30 kg/m2	6 (33.3%)	0	6 (33.3%)
30 - <=35 kg/m2	1 (5.6%)	0	1 (5.6%)
>35 kg/m2	0	0	0

表 2.7.4.7- 58　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 15960、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: NO			
	Rivaroxaban 15 mg BID/OD N=18 (100%)	UFH / Warfarin N=0 (100%)	Total N=18 (100%)
Creatinine Clearance Group 2			
<50 mL/min	2 (11.1%)	0	2 (11.1%)
50 - <80 mL/min	11 (61.1%)	0	11 (61.1%)
>=80 mL/min	5 (27.8%)	0	5 (27.8%)
Creatinine Clearance Group 3			
30 - <50 mL/min	2 (11.1%)	0	2 (11.1%)
50 - <80 mL/min	11 (61.1%)	0	11 (61.1%)
>=80 mL/min	5 (27.8%)	0	5 (27.8%)
Systolic Blood Pressure (mmhg)			
n	18		18
Mean	120.83		120.83
SD	19.80		19.80
Min	90.0		90.0
Q1	110.00		110.00
Median	117.50		117.50
Q3	140.00		140.00
Max	160.0		160.0

表 2.7.4.7- 58　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 15960、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: NO

	Rivaroxaban 15 mg BID/OD N=18 (100%)	UFH / Warfarin N=0 (100%)	Total N=18 (100%)
Diastolic Blood Pressure (mmHg)			
n	18		18
Mean	66.17		66.17
SD	7.50		7.50
Min	49.0		49.0
Q1	61.00		61.00
Median	67.50		67.50
Q3	72.00		72.00
Max	76.0		76.0

Creatinine clearance levels were calculated using the equation of Cockroft and Gault, using the last value up to the day of randomization.
Percentages are calculated including missing values.
Q1 = 25th percentile, Q3 = 75th percentile.
Anticoagulant drugs are selected by ATC codes (see additional SAP).
If the above drugs meet the following condition, these drugs are treated as taken after study medication.
End date of study treatment < end date of the above concomitant medication drugs or end date of study treatment < start date of the above concomitant medication drugs.
Ongoing status at subject's last visit will be also considered.
'The patients who completed' means the patients completed intended treatment duration without primary
efficacy outcome, death (scope: intended treatment duration) and/or termination by sponsor.
GB:.../t-adsl-pmda-posthoc-demographic-anticoagulant.sas erjli 06MAR2014 15:36
引用元：5.3.5.1.43 Additional_22 Table /32

表 2.7.4.7- 58　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 15960、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: YES			
	Rivaroxaban 15 mg BID/OD N=5 (100%)	UFH / Warfarin N=6 (100%)	Total N=11 (100%)
Sex			
Male	1 (20.0%)	2 (33.3%)	3 (27.3%)
Female	4 (80.0%)	4 (66.7%)	8 (72.7%)
Age (years)			
n	5	6	11
Mean	69.8	64.5	66.9
SD	14.8	21.6	18.1
Min	44	25	25
Q1	72.0	55.0	55.0
Median	74.0	73.5	74.0
Q3	79.0	78.0	79.0
Max	80	82	82
Age Group 2			
<60 years	1 (20.0%)	2 (33.3%)	3 (27.3%)
>=60 years	4 (80.0%)	4 (66.7%)	8 (72.7%)
Age Group 3			
<65 years	1 (20.0%)	2 (33.3%)	3 (27.3%)
65 - 75 years	2 (40.0%)	1 (16.7%)	3 (27.3%)
>75 years	2 (40.0%)	3 (50.0%)	5 (45.5%)

表 2.7.4.7- 58 治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 15960、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: YES			
	Rivaroxaban 15 mg BID/OD N=5 (100%)	UFH / Warfarin N=6 (100%)	Total N=11 (100%)
Baseline Weight (kg)			
n	5	6	11
Mean	69.16	65.65	67.25
SD	18.98	13.59	15.49
Min	53.0	52.6	52.6
Q1	53.80	53.90	53.80
Median	62.00	64.60	63.00
Q3	80.00	68.00	80.00
Max	97.0	90.2	97.0
Weight Group 1			
<=70 kg	3 (60.0%)	5 (83.3%)	8 (72.7%)
>70 - <=90 kg	1 (20.0%)	0	1 (9.1%)
>90 kg	1 (20.0%)	1 (16.7%)	2 (18.2%)
Weight Group 2			
<90 kg	4 (80.0%)	5 (83.3%)	9 (81.8%)
>=90 kg	1 (20.0%)	1 (16.7%)	2 (18.2%)
Weight Group 3			
<=50 kg	0	0	0
50 - <=70 kg	3 (60.0%)	5 (83.3%)	8 (72.7%)
70 - <=90 kg	1 (20.0%)	0	1 (9.1%)
>90 kg	1 (20.0%)	1 (16.7%)	2 (18.2%)

表 2.7.4.7- 58　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 15960、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: YES			
	Rivaroxaban 15 mg BID/OD N=5 (100%)	UFH / Warfarin N=6 (100%)	Total N=11 (100%)
Baseline Height (cm)			
n	5	6	11
Mean	157.0	158.3	157.7
SD	17.7	7.5	12.4
Min	138	148	138
Q1	151.8	150.8	150.8
Median	152.0	160.0	157.0
Q3	157.0	164.5	164.5
Max	186	166	186
Baseline Body Mass Index (kg/m2)			
n	5	6	11
Mean	28.28	26.13	27.11
SD	7.90	4.57	6.06
Min	23.1	21.6	21.6
Q1	23.30	23.10	23.10
Median	25.20	24.30	24.60
Q3	27.80	30.20	30.20
Max	42.0	33.3	42.0
Baseline Body Mass Index Group 2			
<30 kg/m2	4 (80.0%)	4 (66.7%)	8 (72.7%)
>=30 kg/m2	1 (20.0%)	2 (33.3%)	3 (27.3%)
Baseline Body Mass Index Group 3			
18.5 - <=25 kg/m2	2 (40.0%)	4 (66.7%)	6 (54.5%)
25 - <=30 kg/m2	2 (40.0%)	0	2 (18.2%)
30 - <=35 kg/m2	0	2 (33.3%)	2 (18.2%)
>35 kg/m2	1 (20.0%)	0	1 (9.1%)

表 2.7.4.7- 58　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 15960、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: YES			
	Rivaroxaban 15 mg BID/OD N=5 (100%)	UFH / Warfarin N=6 (100%)	Total N=11 (100%)
Creatinine Clearance Group 2			
<50 mL/min	1 (20.0%)	0	1 (9.1%)
50 - <80 mL/min	2 (40.0%)	3 (50.0%)	5 (45.5%)
>=80 mL/min	2 (40.0%)	3 (50.0%)	5 (45.5%)
Creatinine Clearance Group 3			
30 - <50 mL/min	1 (20.0%)	0	1 (9.1%)
50 - <80 mL/min	2 (40.0%)	3 (50.0%)	5 (45.5%)
>=80 mL/min	2 (40.0%)	3 (50.0%)	5 (45.5%)
Systolic Blood Pressure (mmhg)			
n	5	6	11
Mean	124.20	122.17	123.09
SD	13.05	14.74	13.34
Min	110.0	95.0	95.0
Q1	112.00	118.00	112.00
Median	125.00	127.00	127.00
Q3	136.00	128.00	136.00
Max	138.0	138.0	138.0

表 2.7.4.7- 58　治験薬投与後のその他の抗凝固療法の有無別による人口統計学的データ（試験 15960、安全性解析対象集団：予定投与期間を完了し、予定投与期間終了までに治験依頼者による治験中止、又は有効性主要評価項目の発現や死亡がみとめられなかった被験者）（続き）

Other anticoagulant medication after stopping study medication: YES			
	Rivaroxaban 15 mg BID/OD N=5 (100%)	UFH / Warfarin N=6 (100%)	Total N=11 (100%)
Diastolic Blood Pressure (mmHg)			
n	5	6	11
Mean	80.00	70.50	74.82
SD	14.09	5.50	10.92
Min	60.0	61.0	60.0
Q1	72.00	70.00	70.00
Median	85.00	71.00	72.00
Q3	87.00	72.00	85.00
Max	96.0	78.0	96.0

Creatinine clearance levels were calculated using the equation of Cockroft and Gault, using the last value up to the day of randomization.
Percentages are calculated including missing values.
Q1 = 25th percentile, Q3 = 75th percentile.
Anticoagulant drugs are selected by ATC codes (see additional SAP).
If the above drugs meet the following condition, these drugs are treated as taken after study medication.
End date of study treatment < end date of the above concomitant medication drugs or end date of study treatment < start date of the above concomitant medication drugs.
Ongoing status at subject's last visit will be also considered.
'The patients who completed' means the patients completed intended treatment duration without primary
efficacy outcome, death (scope: intended treatment duration) and/or termination by sponsor.
GB: .../t-adsl-pmda-posthoc-demographic-anticoagulant.sas erjli 06MAR2014 15:36
End of table
引用元：5.3.5.1.43 Additional_22 Table /32

表 2.7.4.7- 59 治験薬投与期間における併用薬別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
ASA (incl. Acetylsalicylates)	NO	17/52 (32.7%)	8/22 (36.4%)	8/19 (42.1%)
	YES	0/3 (0.0%)		
CYP3A4 Inhibitors	NO	15/50 (30.0%)	6/18 (33.3%)	8/19 (42.1%)
	YES	2/5 (40.0%)	2/4 (50.0%)	
Clopidogrel or Ticlopidine	NO	16/54 (29.6%)	8/22 (36.4%)	7/18 (38.9%)
	YES	1/1 (100.0%)		1/1 (100.0%)
NSAID (ATC code M01A)	NO	10/36 (27.8%)	5/11 (45.5%)	4/10 (40.0%)
	YES	7/19 (36.8%)	3/11 (27.3%)	4/9 (44.4%)
NSAID (excl. M01AH and M01AX)	NO	11/39 (28.2%)	5/12 (41.7%)	4/11 (36.4%)
	YES	6/16 (37.5%)	3/10 (30.0%)	4/8 (50.0%)
NSAID and PAI/ASA	NO	17/54 (31.5%)	8/21 (38.1%)	7/18 (38.9%)
	YES	0/1 (0.0%)	0/1 (0.0%)	1/1 (100.0%)
NSAID or PAI/ASA	NO	9/32 (28.1%)	5/11 (45.5%)	3/9 (33.3%)
	YES	8/23 (34.8%)	3/11 (27.3%)	5/10 (50.0%)
P-GP Inhibitors	NO	17/53 (32.1%)	8/20 (40.0%)	8/19 (42.1%)
	YES	0/2 (0.0%)	0/2 (0.0%)	
P-GP or Strong CYP3A4 Inhibitors	NO	16/52 (30.8%)	8/20 (40.0%)	8/19 (42.1%)
	YES	1/3 (33.3%)	0/2 (0.0%)	
PAI or ASA	NO	16/50 (32.0%)	8/21 (38.1%)	6/17 (35.3%)
	YES	1/5 (20.0%)	0/1 (0.0%)	2/2 (100.0%)

表 2.7.4.7- 59 治験薬投与期間における併用薬別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Statin	NO	15/48 (31.3%)	8/19 (42.1%)	7/16 (43.8%)
	YES	2/7 (28.6%)	0/3 (0.0%)	1/3 (33.3%)
Steroids	NO	13/47 (27.7%)	6/17 (35.3%)	7/17 (41.2%)
	YES	4/8 (50.0%)	2/5 (40.0%)	1/2 (50.0%)
Steroids (systemic use)	NO	14/51 (27.5%)	7/18 (38.9%)	8/18 (44.4%)
	YES	3/4 (75.0%)	1/4 (25.0%)	0/1 (0.0%)
Strong CYP3A4 Inhibitors	NO	16/54 (29.6%)	8/21 (38.1%)	8/19 (42.1%)
	YES	1/1 (100.0%)	0/1 (0.0%)	

Judgement yes/no of co-medications by the following conditions.
Start date of study medication <= start or end date of the concomitant medication <= first onset or censoring date of any treatment emergent confirmed bleeding event.
If there are concomitant medications with missing start or end date of concomitant medication, any imputation isn't applied in this analysis.
GB: .../projects/597939/14568-15960/stat/prod_query01/pgms/t-adtte-adcm-pmda-posthoc-co-medication.sas erjli 06MAR2014 15:37
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引用元：5.3.5.1.43 Additional_22 Table /40

表 2.7.4.7- 60　部分集団別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Age Group 2	<60 years	0/9 (0.0%)	0/4 (0.0%)	0/13 (0.0%)	0/5 (0.0%)
	>=60 years	3/46 (6.5%)	3/18 (16.7%)	6/64 (9.4%)	1/14 (7.1%)
Age Group 3	<65 years	0/15 (0.0%)	0/10 (0.0%)	0/25 (0.0%)	0/7 (0.0%)
	65 - 75 years	2/22 (9.1%)	3/10 (30.0%)	5/32 (15.6%)	1/6 (16.7%)
	>75 years	1/18 (5.6%)	0/2 (0.0%)	1/20 (5.0%)	0/6 (0.0%)
Baseline Body Mass Index Group 2	<30 kg/m2	3/51 (5.9%)	3/19 (15.8%)	6/70 (8.6%)	1/15 (6.7%)
	>=30 kg/m2	0/4 (0.0%)	0/3 (0.0%)	0/7 (0.0%)	0/4 (0.0%)
Baseline Body Mass Index Group 3	<=18.5 kg/m2	0/3 (0.0%)	0/1 (0.0%)	0/4 (0.0%)	0/2 (0.0%)
	18.5 - <=25 kg/m2	0/29 (0.0%)	2/13 (15.4%)	2/42 (4.8%)	1/12 (8.3%)
	25 - <=30 kg/m2	3/19 (15.8%)	1/5 (20.0%)	4/24 (16.7%)	0/1 (0.0%)
	30 - <=35 kg/m2	0/1 (0.0%)	0/2 (0.0%)	0/3 (0.0%)	0/4 (0.0%)
	>35 kg/m2	0/3 (0.0%)	0/1 (0.0%)	0/4 (0.0%)	
Unfractioned heparin/fondaparinux or warfarin treatment before randomization	NO	1/12 (8.3%)	1/9 (11.1%)	2/21 (9.5%)	1/6 (16.7%)
	YES	2/43 (4.7%)	2/13 (15.4%)	4/56 (7.1%)	0/13 (0.0%)
Creatinine Clearance Group 2	<50 mL/min	1/9 (11.1%)		1/9 (11.1%)	
	50 - <80 mL/min	2/27 (7.4%)	1/8 (12.5%)	3/35 (8.6%)	1/11 (9.1%)
	>=80 mL/min	0/19 (0.0%)	2/14 (14.3%)	2/33 (6.1%)	0/8 (0.0%)
Creatinine Clearance Group 3	30 - <50 mL/min	1/9 (11.1%)		1/9 (11.1%)	
	50 - <80 mL/min	2/27 (7.4%)	1/8 (12.5%)	3/35 (8.6%)	1/11 (9.1%)
	>=80 mL/min	0/19 (0.0%)	2/14 (14.3%)	2/33 (6.1%)	0/8 (0.0%)
Sex	Male	1/25 (4.0%)	0/15 (0.0%)	1/40 (2.5%)	0/10 (0.0%)
	Female	2/30 (6.7%)	3/7 (42.9%)	5/37 (13.5%)	1/9 (11.1%)

表 2.7.4.7- 60 部分集団別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Weight Group 2	<90 kg	3/51 (5.9%)	3/21 (14.3%)	6/72 (8.3%)	1/18 (5.6%)
	>=90 kg	0/4 (0.0%)	0/1 (0.0%)	0/5 (0.0%)	0/1 (0.0%)
Weight Group 1	<=70 kg	3/41 (7.3%)	3/14 (21.4%)	6/55 (10.9%)	1/15 (6.7%)
	>70 - <=90 kg	0/10 (0.0%)	0/7 (0.0%)	0/17 (0.0%)	0/3 (0.0%)
	>90 kg	0/4 (0.0%)	0/1 (0.0%)	0/5 (0.0%)	0/1 (0.0%)
Weight Group 3	<=50 kg	0/10 (0.0%)	1/3 (33.3%)	1/13 (7.7%)	0/3 (0.0%)
	50 - <=70 kg	3/31 (9.7%)	2/11 (18.2%)	5/42 (11.9%)	1/12 (8.3%)
	70 - <=90 kg	0/10 (0.0%)	0/7 (0.0%)	0/17 (0.0%)	0/3 (0.0%)
	>90 kg	0/4 (0.0%)	0/1 (0.0%)	0/5 (0.0%)	0/1 (0.0%)
Location of index DVT	.	1/20 (5.0%)		1/20 (5.0%)	0/5 (0.0%)
	Femoral or more proximal	2/28 (7.1%)	2/16 (12.5%)	4/44 (9.1%)	0/10 (0.0%)
	Popliteal or more distal	0/7 (0.0%)	1/6 (16.7%)	1/13 (7.7%)	1/4 (25.0%)
Index DVT/PE	Spontaneous DVT/PE	1/38 (2.6%)	1/12 (8.3%)	2/50 (4.0%)	0/11 (0.0%)
	Secondary DVT/PE	2/17 (11.8%)	2/10 (20.0%)	4/27 (14.8%)	1/8 (12.5%)
Previous episode(s) of DVT/PE	NO	2/47 (4.3%)	3/22 (13.6%)	5/69 (7.2%)	1/18 (5.6%)
	YES	1/8 (12.5%)		1/8 (12.5%)	0/1 (0.0%)
Idiopathic VTE	NO	2/27 (7.4%)	3/13 (23.1%)	5/40 (12.5%)	1/11 (9.1%)
	YES	1/28 (3.6%)	0/9 (0.0%)	1/37 (2.7%)	0/8 (0.0%)
Recent surgery or trauma	NO	2/44 (4.5%)	2/17 (11.8%)	4/61 (6.6%)	1/17 (5.9%)
	YES	1/11 (9.1%)	1/5 (20.0%)	2/16 (12.5%)	0/2 (0.0%)
Prolonged immobilization	NO	3/47 (6.4%)	3/19 (15.8%)	6/66 (9.1%)	0/15 (0.0%)
	YES	0/8 (0.0%)	0/3 (0.0%)	0/11 (0.0%)	1/4 (25.0%)

表 2.7.4.7- 60 部分集団別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Use of estrogen containing drugs	NO	3/55 (5.5%)	3/22 (13.6%)	6/77 (7.8%)	1/18 (5.6%)
	YES				0/1 (0.0%)
Puerperium	NO	3/55 (5.5%)	3/22 (13.6%)	6/77 (7.8%)	1/19 (5.3%)
Active cancer	NO	2/52 (3.8%)	2/20 (10.0%)	4/72 (5.6%)	0/17 (0.0%)
	YES	1/3 (33.3%)	1/2 (50.0%)	2/5 (40.0%)	1/2 (50.0%)
Antithrombin deficiency	NO	3/55 (5.5%)	2/21 (9.5%)	5/76 (6.6%)	1/19 (5.3%)
	YES		1/1 (100.0%)	1/1 (100.0%)	
Factor V Leiden gene mutation	NO	3/55 (5.5%)	3/22 (13.6%)	6/77 (7.8%)	1/19 (5.3%)
Hyperhomocysteinaemia	NO	3/55 (5.5%)	3/22 (13.6%)	6/77 (7.8%)	1/19 (5.3%)
Antiphospholipid antibodies	NO	3/55 (5.5%)	3/22 (13.6%)	6/77 (7.8%)	1/19 (5.3%)
Protein C deficiency	NO	3/54 (5.6%)	2/21 (9.5%)	5/75 (6.7%)	1/17 (5.9%)
	YES	0/1 (0.0%)	1/1 (100.0%)	1/2 (50.0%)	0/2 (0.0%)
Protein S deficiency	NO	3/55 (5.5%)	3/22 (13.6%)	6/77 (7.8%)	1/18 (5.6%)
	YES				0/1 (0.0%)
Prothrombin gene mutation	NO	3/55 (5.5%)	3/22 (13.6%)	6/77 (7.8%)	1/19 (5.3%)
Pulmonary disease	No pulmonary disease	2/47 (4.3%)	3/18 (16.7%)	5/65 (7.7%)	1/17 (5.9%)
	Pulmonary disease	1/8 (12.5%)	0/4 (0.0%)	1/12 (8.3%)	0/2 (0.0%)

表 2.7.4.7- 60　部分集団別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Cardiac disease	No cardiac disease	1/44 (2.3%)	3/21 (14.3%)	4/65 (6.2%)	1/19 (5.3%)
	Cardiac disease	2/11 (18.2%)	0/1 (0.0%)	2/12 (16.7%)	

Incidence = # of events / # at risk, where:
# of events = # of subjects reporting the event after randomization up to 2 days after stop of study treatment.
# at risk = # of subjects in reference population.
GB: /by-sasp/patdb/projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adtte-incidence-safety-subgroup.sas erjli 07MAR2014 16:16
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引用元：5.3.5.3.12 Integrated-J Table 14.3.1/174

表 2.7.4.7- 61 部分集団別及び予定投与期間別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）

Intended treatment duration: 3 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Age Group 2	<60 years		0/1 (0.0%)	0/1 (0.0%)	
	>=60 years	1/10 (10.0%)	0/2 (0.0%)	1/12 (8.3%)	0/4 (0.0%)
Age Group 3	<65 years	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	0/1 (0.0%)
	65 - 75 years	1/3 (33.3%)	0/2 (0.0%)	1/5 (20.0%)	0/1 (0.0%)
	>75 years	0/6 (0.0%)		0/6 (0.0%)	0/2 (0.0%)
Baseline Body Mass Index Group 2	<30 kg/m2	1/10 (10.0%)	0/3 (0.0%)	1/13 (7.7%)	0/4 (0.0%)
Baseline Body Mass Index Group 3	<=18.5 kg/m2				0/1 (0.0%)
	18.5 - <=25 kg/m2	0/6 (0.0%)	0/1 (0.0%)	0/7 (0.0%)	0/2 (0.0%)
	25 - <=30 kg/m2	1/4 (25.0%)	0/2 (0.0%)	1/6 (16.7%)	0/1 (0.0%)
Unfractioned heparin/fondaparinux or warfarin treatment before randomization	NO	1/5 (20.0%)	0/2 (0.0%)	1/7 (14.3%)	0/2 (0.0%)
	YES	0/5 (0.0%)	0/1 (0.0%)	0/6 (0.0%)	0/2 (0.0%)
Creatinine Clearance Group 2	<50 mL/min	1/4 (25.0%)		1/4 (25.0%)	
	50 - <80 mL/min	0/3 (0.0%)	0/1 (0.0%)	0/4 (0.0%)	0/3 (0.0%)
	>=80 mL/min	0/3 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/1 (0.0%)
Creatinine Clearance Group 3	30 - <50 mL/min	1/4 (25.0%)		1/4 (25.0%)	
	50 - <80 mL/min	0/3 (0.0%)	0/1 (0.0%)	0/4 (0.0%)	0/3 (0.0%)
	>=80 mL/min	0/3 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/1 (0.0%)
Sex	Male	1/4 (25.0%)	0/2 (0.0%)	1/6 (16.7%)	0/1 (0.0%)
	Female	0/6 (0.0%)	0/1 (0.0%)	0/7 (0.0%)	0/3 (0.0%)

表 2.7.4.7- 61 部分集団別及び予定投与期間別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Weight Group 2	<90 kg	1/10 (10.0%)	0/3 (0.0%)	1/13 (7.7%)	0/4 (0.0%)
Weight Group 1	<=70 kg	1/10 (10.0%)	0/1 (0.0%)	1/11 (9.1%)	0/3 (0.0%)
	>70 - <=90 kg		0/2 (0.0%)	0/2 (0.0%)	0/1 (0.0%)
Weight Group 3	<=50 kg	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)
	50 - <=70 kg	1/9 (11.1%)		1/9 (11.1%)	0/1 (0.0%)
	70 - <=90 kg		0/2 (0.0%)	0/2 (0.0%)	0/1 (0.0%)
Location of index DVT	.	0/4 (0.0%)		0/4 (0.0%)	0/1 (0.0%)
	Femoral or more proximal	1/5 (20.0%)	0/1 (0.0%)	1/6 (16.7%)	0/2 (0.0%)
	Popliteal or more distal	0/1 (0.0%)	0/2 (0.0%)	0/3 (0.0%)	0/1 (0.0%)
Index DVT/PE	Spontaneous DVT/PE	0/3 (0.0%)	0/1 (0.0%)	0/4 (0.0%)	0/1 (0.0%)
	Secondary DVT/PE	1/7 (14.3%)	0/2 (0.0%)	1/9 (11.1%)	0/3 (0.0%)
Previous episode(s) of DVT/PE	NO	0/9 (0.0%)	0/3 (0.0%)	0/12 (0.0%)	0/4 (0.0%)
	YES	1/1 (100.0%)		1/1 (100.0%)	
Idiopathic VTE	NO	1/8 (12.5%)	0/2 (0.0%)	1/10 (10.0%)	0/3 (0.0%)
	YES	0/2 (0.0%)	0/1 (0.0%)	0/3 (0.0%)	0/1 (0.0%)
Recent surgery or trauma	NO	1/8 (12.5%)	0/2 (0.0%)	1/10 (10.0%)	0/3 (0.0%)
	YES	0/2 (0.0%)	0/1 (0.0%)	0/3 (0.0%)	0/1 (0.0%)
Prolonged immobilization	NO	1/6 (16.7%)	0/2 (0.0%)	1/8 (12.5%)	0/3 (0.0%)
	YES	0/4 (0.0%)	0/1 (0.0%)	0/5 (0.0%)	0/1 (0.0%)
Use of estrogen containing drugs	NO	1/10 (10.0%)	0/3 (0.0%)	1/13 (7.7%)	0/4 (0.0%)

表 2.7.4.7- 61　部分集団別及び予定投与期間別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Puerperium	NO	1/10 (10.0%)	0/3 (0.0%)	1/13 (7.7%)	0/4 (0.0%)
Active cancer	NO	0/7 (0.0%)	0/3 (0.0%)	0/10 (0.0%)	0/3 (0.0%)
	YES	1/3 (33.3%)		1/3 (33.3%)	0/1 (0.0%)
Antithrombin deficiency	NO	1/10 (10.0%)	0/3 (0.0%)	1/13 (7.7%)	0/4 (0.0%)
Factor V Leiden gene mutation	NO	1/10 (10.0%)	0/3 (0.0%)	1/13 (7.7%)	0/4 (0.0%)
Hyperhomocysteinaemia	NO	1/10 (10.0%)	0/3 (0.0%)	1/13 (7.7%)	0/4 (0.0%)
Antiphospholipid antibodies	NO	1/10 (10.0%)	0/3 (0.0%)	1/13 (7.7%)	0/4 (0.0%)
Protein C deficiency	NO	1/10 (10.0%)	0/3 (0.0%)	1/13 (7.7%)	0/4 (0.0%)
Protein S deficiency	NO	1/10 (10.0%)	0/3 (0.0%)	1/13 (7.7%)	0/4 (0.0%)
Prothrombin gene mutation	NO	1/10 (10.0%)	0/3 (0.0%)	1/13 (7.7%)	0/4 (0.0%)
Pulmonary disease	No pulmonary disease	1/10 (10.0%)	0/2 (0.0%)	1/12 (8.3%)	0/4 (0.0%)
	Pulmonary disease		0/1 (0.0%)	0/1 (0.0%)	

表 2.7.4.7- 61　部分集団別及び予定投与期間別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Cardiac disease	No cardiac disease	0/7 (0.0%)	0/3 (0.0%)	0/10 (0.0%)	0/4 (0.0%)
	Cardiac disease	1/3 (33.3%)		1/3 (33.3%)	

Incidence = # of events / # at risk, where:
# of events = # of subjects reporting the event after randomization up to 2 days after stop of study treatment.
# at risk = # of subjects in reference population.
GB: /by-sasp/patdb/projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adtte-incidence-safety-subgroup.sas erjli 07MAR2014 16:16
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/175

表 2.7.4.7- 61 部分集団別及び予定投与期間別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Age Group 2	<60 years	0/2 (0.0%)	0/1 (0.0%)	0/3 (0.0%)	0/4 (0.0%)
	>=60 years	2/24 (8.3%)	3/11 (27.3%)	5/35 (14.3%)	0/5 (0.0%)
Age Group 3	<65 years	0/5 (0.0%)	0/4 (0.0%)	0/9 (0.0%)	0/5 (0.0%)
	65 - 75 years	1/11 (9.1%)	3/6 (50.0%)	4/17 (23.5%)	0/2 (0.0%)
	>75 years	1/10 (10.0%)	0/2 (0.0%)	1/12 (8.3%)	0/2 (0.0%)
Baseline Body Mass Index Group 2	<30 kg/m2	2/24 (8.3%)	3/9 (33.3%)	5/33 (15.2%)	0/8 (0.0%)
	>=30 kg/m2	0/2 (0.0%)	0/3 (0.0%)	0/5 (0.0%)	0/1 (0.0%)
Baseline Body Mass Index Group 3	<=18.5 kg/m2	0/3 (0.0%)		0/3 (0.0%)	0/1 (0.0%)
	18.5 - <=25 kg/m2	0/14 (0.0%)	2/6 (33.3%)	2/20 (10.0%)	0/7 (0.0%)
	25 - <=30 kg/m2	2/7 (28.6%)	1/3 (33.3%)	3/10 (30.0%)	
	30 - <=35 kg/m2		0/2 (0.0%)	0/2 (0.0%)	0/1 (0.0%)
	>35 kg/m2	0/2 (0.0%)	0/1 (0.0%)	0/3 (0.0%)	
Unfractioned heparin/fondaparinux or warfarin treatment before randomization	NO	0/3 (0.0%)	1/5 (20.0%)	1/8 (12.5%)	0/2 (0.0%)
	YES	2/23 (8.7%)	2/7 (28.6%)	4/30 (13.3%)	0/7 (0.0%)
Creatinine Clearance Group 2	<50 mL/min	0/4 (0.0%)		0/4 (0.0%)	
	50 - <80 mL/min	2/15 (13.3%)	1/3 (33.3%)	3/18 (16.7%)	0/4 (0.0%)
	>=80 mL/min	0/7 (0.0%)	2/9 (22.2%)	2/16 (12.5%)	0/5 (0.0%)
Creatinine Clearance Group 3	30 - <50 mL/min	0/4 (0.0%)		0/4 (0.0%)	
	50 - <80 mL/min	2/15 (13.3%)	1/3 (33.3%)	3/18 (16.7%)	0/4 (0.0%)
	>=80 mL/min	0/7 (0.0%)	2/9 (22.2%)	2/16 (12.5%)	0/5 (0.0%)

表 2.7.4.7- 61 部分集団別及び予定投与期間別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Sex	Male	0/11 (0.0%)	0/7 (0.0%)	0/18 (0.0%)	0/6 (0.0%)
	Female	2/15 (13.3%)	3/5 (60.0%)	5/20 (25.0%)	0/3 (0.0%)
Weight Group 2	<90 kg	2/24 (8.3%)	3/11 (27.3%)	5/35 (14.3%)	0/9 (0.0%)
	>=90 kg	0/2 (0.0%)	0/1 (0.0%)	0/3 (0.0%)	
Weight Group 1	<=70 kg	2/22 (9.1%)	3/8 (37.5%)	5/30 (16.7%)	0/9 (0.0%)
	>70 - <=90 kg	0/2 (0.0%)	0/3 (0.0%)	0/5 (0.0%)	
	>90 kg	0/2 (0.0%)	0/1 (0.0%)	0/3 (0.0%)	
Weight Group 3	<=50 kg	0/7 (0.0%)	1/2 (50.0%)	1/9 (11.1%)	
	50 - <=70 kg	2/15 (13.3%)	2/6 (33.3%)	4/21 (19.0%)	0/9 (0.0%)
	70 - <=90 kg	0/2 (0.0%)	0/3 (0.0%)	0/5 (0.0%)	
	>90 kg	0/2 (0.0%)	0/1 (0.0%)	0/3 (0.0%)	
Location of index DVT	.	1/10 (10.0%)		1/10 (10.0%)	0/2 (0.0%)
	Femoral or more proximal	1/13 (7.7%)	2/9 (22.2%)	3/22 (13.6%)	0/7 (0.0%)
	Popliteal or more distal	0/3 (0.0%)	1/3 (33.3%)	1/6 (16.7%)	
Index DVT/PE	Spontaneous DVT/PE	1/20 (5.0%)	1/6 (16.7%)	2/26 (7.7%)	0/6 (0.0%)
	Secondary DVT/PE	1/6 (16.7%)	2/6 (33.3%)	3/12 (25.0%)	0/3 (0.0%)
Previous episode(s) of DVT/PE	NO	2/25 (8.0%)	3/12 (25.0%)	5/37 (13.5%)	0/9 (0.0%)
	YES	0/1 (0.0%)		0/1 (0.0%)	
Idiopathic VTE	NO	1/11 (9.1%)	3/8 (37.5%)	4/19 (21.1%)	0/3 (0.0%)
	YES	1/15 (6.7%)	0/4 (0.0%)	1/19 (5.3%)	0/6 (0.0%)
Recent surgery or trauma	NO	1/21 (4.8%)	2/9 (22.2%)	3/30 (10.0%)	0/8 (0.0%)
	YES	1/5 (20.0%)	1/3 (33.3%)	2/8 (25.0%)	0/1 (0.0%)

表 2.7.4.7- 61 部分集団別及び予定投与期間別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Prolonged immobilization	NO	2/25 (8.0%)	3/10 (30.0%)	5/35 (14.3%)	0/7 (0.0%)
	YES	0/1 (0.0%)	0/2 (0.0%)	0/3 (0.0%)	0/2 (0.0%)
Use of estrogen containing drugs	NO	2/26 (7.7%)	3/12 (25.0%)	5/38 (13.2%)	0/9 (0.0%)
Puerperium	NO	2/26 (7.7%)	3/12 (25.0%)	5/38 (13.2%)	0/9 (0.0%)
Active cancer	NO	2/26 (7.7%)	2/11 (18.2%)	4/37 (10.8%)	0/9 (0.0%)
	YES		1/1 (100.0%)	1/1 (100.0%)	
Antithrombin deficiency	NO	2/26 (7.7%)	2/11 (18.2%)	4/37 (10.8%)	0/9 (0.0%)
	YES		1/1 (100.0%)	1/1 (100.0%)	
Factor V Leiden gene mutation	NO	2/26 (7.7%)	3/12 (25.0%)	5/38 (13.2%)	0/9 (0.0%)
Hyperhomocysteinaemia	NO	2/26 (7.7%)	3/12 (25.0%)	5/38 (13.2%)	0/9 (0.0%)
Antiphospholipid antibodies	NO	2/26 (7.7%)	3/12 (25.0%)	5/38 (13.2%)	0/9 (0.0%)
Protein C deficiency	NO	2/25 (8.0%)	2/11 (18.2%)	4/36 (11.1%)	0/8 (0.0%)
	YES	0/1 (0.0%)	1/1 (100.0%)	1/2 (50.0%)	0/1 (0.0%)
Protein S deficiency	NO	2/26 (7.7%)	3/12 (25.0%)	5/38 (13.2%)	0/8 (0.0%)
	YES				0/1 (0.0%)
Prothrombin gene mutation	NO	2/26 (7.7%)	3/12 (25.0%)	5/38 (13.2%)	0/9 (0.0%)
Pulmonary disease	No pulmonary disease	1/23 (4.3%)	3/10 (30.0%)	4/33 (12.1%)	0/8 (0.0%)
	Pulmonary disease	1/3 (33.3%)	0/2 (0.0%)	1/5 (20.0%)	0/1 (0.0%)

表 2.7.4.7- 61　部分集団別及び予定投与期間別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Cardiac disease	No cardiac disease	1/19 (5.3%)	3/11 (27.3%)	4/30 (13.3%)	0/9 (0.0%)
	Cardiac disease	1/7 (14.3%)	0/1 (0.0%)	1/8 (12.5%)	

Incidence = # of events / # at risk, where:
# of events = # of subjects reporting the event after randomization up to 2 days after stop of study treatment.
# at risk = # of subjects in reference population.
GB: /by-sasp/patdb/projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adtte-incidence-safety-subgroup.sas erjli 07MAR2014 16:16
引用元：5.3.5.3.12 Integrated-J Table 14.3.1/175

表 2.7.4.7- 61 部分集団別及び予定投与期間別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Age Group 2	<60 years	0/7 (0.0%)	0/2 (0.0%)	0/9 (0.0%)	0/1 (0.0%)
	>=60 years	0/12 (0.0%)	0/5 (0.0%)	0/17 (0.0%)	1/5 (20.0%)
Age Group 3	<65 years	0/9 (0.0%)	0/5 (0.0%)	0/14 (0.0%)	0/1 (0.0%)
	65 - 75 years	0/8 (0.0%)	0/2 (0.0%)	0/10 (0.0%)	1/3 (33.3%)
	>75 years	0/2 (0.0%)		0/2 (0.0%)	0/2 (0.0%)
Baseline Body Mass Index Group 2	<30 kg/m2	0/17 (0.0%)	0/7 (0.0%)	0/24 (0.0%)	1/3 (33.3%)
	>=30 kg/m2	0/2 (0.0%)		0/2 (0.0%)	0/3 (0.0%)
Baseline Body Mass Index Group 3	<=18.5 kg/m2		0/1 (0.0%)	0/1 (0.0%)	
	18.5 - <=25 kg/m2	0/9 (0.0%)	0/6 (0.0%)	0/15 (0.0%)	1/3 (33.3%)
	25 - <=30 kg/m2	0/8 (0.0%)		0/8 (0.0%)	
	30 - <=35 kg/m2	0/1 (0.0%)		0/1 (0.0%)	0/3 (0.0%)
	>35 kg/m2	0/1 (0.0%)		0/1 (0.0%)	
Unfractioned heparin/fondaparinux or warfarin treatment before randomization	NO	0/4 (0.0%)	0/2 (0.0%)	0/6 (0.0%)	1/2 (50.0%)
	YES	0/15 (0.0%)	0/5 (0.0%)	0/20 (0.0%)	0/4 (0.0%)
Creatinine Clearance Group 2	<50 mL/min	0/1 (0.0%)		0/1 (0.0%)	
	50 - <80 mL/min	0/9 (0.0%)	0/4 (0.0%)	0/13 (0.0%)	1/4 (25.0%)
	>=80 mL/min	0/9 (0.0%)	0/3 (0.0%)	0/12 (0.0%)	0/2 (0.0%)
Creatinine Clearance Group 3	30 - <50 mL/min	0/1 (0.0%)		0/1 (0.0%)	
	50 - <80 mL/min	0/9 (0.0%)	0/4 (0.0%)	0/13 (0.0%)	1/4 (25.0%)
	>=80 mL/min	0/9 (0.0%)	0/3 (0.0%)	0/12 (0.0%)	0/2 (0.0%)

表 2.7.4.7- 61 部分集団別及び予定投与期間別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Sex	Male	0/10 (0.0%)	0/6 (0.0%)	0/16 (0.0%)	0/3 (0.0%)
	Female	0/9 (0.0%)	0/1 (0.0%)	0/10 (0.0%)	1/3 (33.3%)
Weight Group 2	<90 kg	0/17 (0.0%)	0/7 (0.0%)	0/24 (0.0%)	1/5 (20.0%)
	>=90 kg	0/2 (0.0%)		0/2 (0.0%)	0/1 (0.0%)
Weight Group 1	<=70 kg	0/9 (0.0%)	0/5 (0.0%)	0/14 (0.0%)	1/3 (33.3%)
	>70 - <=90 kg	0/8 (0.0%)	0/2 (0.0%)	0/10 (0.0%)	0/2 (0.0%)
	>90 kg	0/2 (0.0%)		0/2 (0.0%)	0/1 (0.0%)
Weight Group 3	<=50 kg	0/2 (0.0%)		0/2 (0.0%)	0/1 (0.0%)
	50 - <=70 kg	0/7 (0.0%)	0/5 (0.0%)	0/12 (0.0%)	1/2 (50.0%)
	70 - <=90 kg	0/8 (0.0%)	0/2 (0.0%)	0/10 (0.0%)	0/2 (0.0%)
	>90 kg	0/2 (0.0%)		0/2 (0.0%)	0/1 (0.0%)
Location of index DVT	.	0/6 (0.0%)		0/6 (0.0%)	0/2 (0.0%)
	Femoral or more proximal	0/10 (0.0%)	0/6 (0.0%)	0/16 (0.0%)	0/1 (0.0%)
	Popliteal or more distal	0/3 (0.0%)	0/1 (0.0%)	0/4 (0.0%)	1/3 (33.3%)
Index DVT/PE	Spontaneous DVT/PE	0/15 (0.0%)	0/5 (0.0%)	0/20 (0.0%)	0/4 (0.0%)
	Secondary DVT/PE	0/4 (0.0%)	0/2 (0.0%)	0/6 (0.0%)	1/2 (50.0%)
Previous episode(s) of DVT/PE	NO	0/13 (0.0%)	0/7 (0.0%)	0/20 (0.0%)	1/5 (20.0%)
	YES	0/6 (0.0%)		0/6 (0.0%)	0/1 (0.0%)
Idiopathic VTE	NO	0/8 (0.0%)	0/3 (0.0%)	0/11 (0.0%)	1/5 (20.0%)
	YES	0/11 (0.0%)	0/4 (0.0%)	0/15 (0.0%)	0/1 (0.0%)
Recent surgery or trauma	NO	0/15 (0.0%)	0/6 (0.0%)	0/21 (0.0%)	1/6 (16.7%)
	YES	0/4 (0.0%)	0/1 (0.0%)	0/5 (0.0%)	

表 2.7.4.7- 61 部分集団別及び予定投与期間別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Prolonged immobilization	NO	0/16 (0.0%)	0/7 (0.0%)	0/23 (0.0%)	0/5 (0.0%)
	YES	0/3 (0.0%)		0/3 (0.0%)	1/1 (100.0%)
Use of estrogen containing drugs	NO	0/19 (0.0%)	0/7 (0.0%)	0/26 (0.0%)	1/5 (20.0%)
	YES				0/1 (0.0%)
Puerperium	NO	0/19 (0.0%)	0/7 (0.0%)	0/26 (0.0%)	1/6 (16.7%)
Active cancer	NO	0/19 (0.0%)	0/6 (0.0%)	0/25 (0.0%)	0/5 (0.0%)
	YES		0/1 (0.0%)	0/1 (0.0%)	1/1 (100.0%)
Antithrombin deficiency	NO	0/19 (0.0%)	0/7 (0.0%)	0/26 (0.0%)	1/6 (16.7%)
Factor V Leiden gene mutation	NO	0/19 (0.0%)	0/7 (0.0%)	0/26 (0.0%)	1/6 (16.7%)
Hyperhomocysteinaemia	NO	0/19 (0.0%)	0/7 (0.0%)	0/26 (0.0%)	1/6 (16.7%)
Antiphospholipid antibodies	NO	0/19 (0.0%)	0/7 (0.0%)	0/26 (0.0%)	1/6 (16.7%)
Protein C deficiency	NO	0/19 (0.0%)	0/7 (0.0%)	0/26 (0.0%)	1/5 (20.0%)
	YES				0/1 (0.0%)
Protein S deficiency	NO	0/19 (0.0%)	0/7 (0.0%)	0/26 (0.0%)	1/6 (16.7%)
Prothrombin gene mutation	NO	0/19 (0.0%)	0/7 (0.0%)	0/26 (0.0%)	1/6 (16.7%)
Pulmonary disease	No pulmonary disease	0/14 (0.0%)	0/6 (0.0%)	0/20 (0.0%)	1/5 (20.0%)
	Pulmonary disease	0/5 (0.0%)	0/1 (0.0%)	0/6 (0.0%)	0/1 (0.0%)

表 2.7.4.7- 61　部分集団別及び予定投与期間別の治験薬投与下で発現した安全性主要評価項目（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	Rivaroxaban Total n/N(%)	UFH / Warfarin n/N(%)
Cardiac disease	No cardiac disease	0/18 (0.0%)	0/7 (0.0%)	0/25 (0.0%)	1/6 (16.7%)
	Cardiac disease	0/1 (0.0%)		0/1 (0.0%)	

Incidence = # of events / # at risk, where:
# of events = # of subjects reporting the event after randomization up to 2 days after stop of study treatment.
# at risk = # of subjects in reference population.
GB: /by-sasp/patdb/projects/597939/14568-15960/stat/prod/pgms/t-14-3-1-adtte-incidence-safety-subgroup.sas erjli 07MAR2014 16:16
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引用元：5.3.5.3.12 Integrated-J Table 14.3.1/175

表 2.7.4.7- 62 部分集団別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Age Group 2	<60 years	1/9 (11.1%)	2/4 (50.0%)	3/5 (60.0%)
	>=60 years	16/46 (34.8%)	6/18 (33.3%)	5/14 (35.7%)
Age Group 3	<65 years	3/15 (20.0%)	4/10 (40.0%)	3/7 (42.9%)
	65 - 75 years	10/22 (45.5%)	4/10 (40.0%)	4/6 (66.7%)
	>75 years	4/18 (22.2%)	0/2 (0.0%)	1/6 (16.7%)
Age (supp)	<75 years	13/37 (35.1%)	7/19 (36.8%)	7/12 (58.3%)
	>=75 years	4/18 (22.2%)	1/3 (33.3%)	1/7 (14.3%)
Baseline Body Mass Index Group 2	<30 kg/m2	16/51 (31.4%)	7/19 (36.8%)	6/15 (40.0%)
	>=30 kg/m2	1/4 (25.0%)	1/3 (33.3%)	2/4 (50.0%)
Baseline Body Mass Index Group 3	<=18.5 kg/m2	0/3 (0.0%)	1/1 (100.0%)	0/2 (0.0%)
	18.5 - <=25 kg/m2	9/29 (31.0%)	4/13 (30.8%)	6/12 (50.0%)
	25 - <=30 kg/m2	7/19 (36.8%)	2/5 (40.0%)	0/1 (0.0%)
	30 - <=35 kg/m2	0/1 (0.0%)	1/2 (50.0%)	2/4 (50.0%)
	>35 kg/m2	1/3 (33.3%)	0/1 (0.0%)	
Unfractioned heparin/fondaparinux or warfarin treatment before randomization	NO	3/12 (25.0%)	4/9 (44.4%)	3/6 (50.0%)
	YES	14/43 (32.6%)	4/13 (30.8%)	5/13 (38.5%)
Creatinine Clearance Group 2	<50 mL/min	3/9 (33.3%)		
	50 - <80 mL/min	11/27 (40.7%)	4/8 (50.0%)	5/11 (45.5%)
	>=80 mL/min	3/19 (15.8%)	4/14 (28.6%)	3/8 (37.5%)
Creatinine Clearance Group 3	30 - <50 mL/min	3/9 (33.3%)		
	50 - <80 mL/min	11/27 (40.7%)	4/8 (50.0%)	5/11 (45.5%)
	>=80 mL/min	3/19 (15.8%)	4/14 (28.6%)	3/8 (37.5%)

表 2.7.4.7- 62 部分集団別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Sex	Male	6/25 (24.0%)	3/15 (20.0%)	3/10 (30.0%)
	Female	11/30 (36.7%)	5/7 (71.4%)	5/9 (55.6%)
Weight Group 2	<90 kg	16/51 (31.4%)	7/21 (33.3%)	7/18 (38.9%)
	>=90 kg	1/4 (25.0%)	1/1 (100.0%)	1/1 (100.0%)
Weight Group 1	<=70 kg	14/41 (34.1%)	6/14 (42.9%)	6/15 (40.0%)
	>70 - <=90 kg	2/10 (20.0%)	1/7 (14.3%)	1/3 (33.3%)
	>90 kg	1/4 (25.0%)	1/1 (100.0%)	1/1 (100.0%)
Weight Group 3	<=50 kg	0/10 (0.0%)	2/3 (66.7%)	2/3 (66.7%)
	50 - <=70 kg	14/31 (45.2%)	4/11 (36.4%)	4/12 (33.3%)
	70 - <=90 kg	2/10 (20.0%)	1/7 (14.3%)	1/3 (33.3%)
	>90 kg	1/4 (25.0%)	1/1 (100.0%)	1/1 (100.0%)
Weight (supp)	<50 kg	0/10 (0.0%)	2/3 (66.7%)	2/3 (66.7%)
	>=50 kg	17/45 (37.8%)	6/19 (31.6%)	6/16 (37.5%)
Location of index DVT	.	10/20 (50.0%)		2/5 (40.0%)
	Femoral or more proximal	7/28 (25.0%)	6/16 (37.5%)	3/10 (30.0%)
	Popliteal or more distal	0/7 (0.0%)	2/6 (33.3%)	3/4 (75.0%)
Index DVT/PE	Spontaneous DVT/PE	14/38 (36.8%)	6/12 (50.0%)	5/11 (45.5%)
	Secondary DVT/PE	3/17 (17.6%)	2/10 (20.0%)	3/8 (37.5%)
Previous episode(s) of DVT/PE	NO	15/47 (31.9%)	8/22 (36.4%)	7/18 (38.9%)
	YES	2/8 (25.0%)		1/1 (100.0%)
Idiopathic VTE	NO	7/27 (25.9%)	4/13 (30.8%)	5/11 (45.5%)
	YES	10/28 (35.7%)	4/9 (44.4%)	3/8 (37.5%)

表 2.7.4.7- 62 部分集団別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Recent surgery or trauma	NO	15/44 (34.1%)	7/17 (41.2%)	8/17 (47.1%)
	YES	2/11 (18.2%)	1/5 (20.0%)	0/2 (0.0%)
Prolonged immobilization	NO	16/47 (34.0%)	8/19 (42.1%)	7/15 (46.7%)
	YES	1/8 (12.5%)	0/3 (0.0%)	1/4 (25.0%)
Use of estrogen containing drugs	NO	17/55 (30.9%)	8/22 (36.4%)	7/18 (38.9%)
	YES			1/1 (100.0%)
Puerperium	NO	17/55 (30.9%)	8/22 (36.4%)	8/19 (42.1%)
Active cancer	NO	16/52 (30.8%)	7/20 (35.0%)	6/17 (35.3%)
	YES	1/3 (33.3%)	1/2 (50.0%)	2/2 (100.0%)
Antithrombin deficiency	NO	17/55 (30.9%)	7/21 (33.3%)	8/19 (42.1%)
	YES		1/1 (100.0%)	
Factor V Leiden gene mutation	NO	17/55 (30.9%)	8/22 (36.4%)	8/19 (42.1%)
Hyperhomocysteinaemia	NO	17/55 (30.9%)	8/22 (36.4%)	8/19 (42.1%)
Antiphospholipid antibodies	NO	17/55 (30.9%)	8/22 (36.4%)	8/19 (42.1%)
Protein C deficiency	NO	17/54 (31.5%)	7/21 (33.3%)	7/17 (41.2%)
	YES	0/1 (0.0%)	1/1 (100.0%)	1/2 (50.0%)
Protein S deficiency	NO	17/55 (30.9%)	8/22 (36.4%)	7/18 (38.9%)
	YES			1/1 (100.0%)
Prothrombin gene mutation	NO	17/55 (30.9%)	8/22 (36.4%)	8/19 (42.1%)

表 2.7.4.7- 62　部分集団別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Pulmonary disease	No pulmonary disease	14/47 (29.8%)	7/18 (38.9%)	8/17 (47.1%)
	Pulmonary disease	3/8 (37.5%)	1/4 (25.0%)	0/2 (0.0%)
Cardiac disease	No cardiac disease	11/44 (25.0%)	8/21 (38.1%)	8/19 (42.1%)
	Cardiac disease	6/11 (54.5%)	0/1 (0.0%)	
Baseline ALT	<= upper limit of normal range	15/43 (34.9%)	7/21 (33.3%)	7/16 (43.8%)
	> upper limit of normal range	2/12 (16.7%)	1/1 (100.0%)	1/3 (33.3%)

Incidence = # of events / # at risk, where:
# of events = # of subjects reporting the event after randomization up to end of intended treatment time.
# at risk = # of subjects in reference population.
GB: .../t-adtte-pmda-posthoc-incidence-safety-subgroup-newgroup.sas erjli 06MAR2014 16:01
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引用元：5.3.5.1.43 Additional_22 Table /85

表 2.7.4.7- 63 部分集団別及び予定投与期間別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）

Intended treatment duration: 3 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Age Group 2	<60 years		0/1 (0.0%)	
	>=60 years	3/10 (30.0%)	1/2 (50.0%)	1/4 (25.0%)
Age Group 3	<65 years	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)
	65 - 75 years	2/3 (66.7%)	1/2 (50.0%)	1/1 (100.0%)
	>75 years	1/6 (16.7%)		0/2 (0.0%)
Age (supp)	<75 years	2/4 (50.0%)	0/2 (0.0%)	1/2 (50.0%)
	>=75 years	1/6 (16.7%)	1/1 (100.0%)	0/2 (0.0%)
Baseline Body Mass Index Group 2	<30 kg/m2	3/10 (30.0%)	1/3 (33.3%)	1/4 (25.0%)
Baseline Body Mass Index Group 3	<=18.5 kg/m2			0/1 (0.0%)
	18.5 - <=25 kg/m2	1/6 (16.7%)	1/1 (100.0%)	1/2 (50.0%)
	25 - <=30 kg/m2	2/4 (50.0%)	0/2 (0.0%)	0/1 (0.0%)
Unfractioned heparin/fondaparinux or warfarin treatment before randomization	NO	2/5 (40.0%)	1/2 (50.0%)	1/2 (50.0%)
	YES	1/5 (20.0%)	0/1 (0.0%)	0/2 (0.0%)
Creatinine Clearance Group 2	<50 mL/min	2/4 (50.0%)		
	50 - <80 mL/min	1/3 (33.3%)	1/1 (100.0%)	1/3 (33.3%)
	>=80 mL/min	0/3 (0.0%)	0/2 (0.0%)	0/1 (0.0%)
Creatinine Clearance Group 3	30 - <50 mL/min	2/4 (50.0%)		
	50 - <80 mL/min	1/3 (33.3%)	1/1 (100.0%)	1/3 (33.3%)
	>=80 mL/min	0/3 (0.0%)	0/2 (0.0%)	0/1 (0.0%)
Sex	Male	1/4 (25.0%)	0/2 (0.0%)	0/1 (0.0%)
	Female	2/6 (33.3%)	1/1 (100.0%)	1/3 (33.3%)

表 2.7.4.7- 63 部分集団別及び予定投与期間別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Weight Group 2	<90 kg	3/10 (30.0%)	1/3 (33.3%)	1/4 (25.0%)
Weight Group 1	<=70 kg	3/10 (30.0%)	1/1 (100.0%)	1/3 (33.3%)
	>70 - <=90 kg		0/2 (0.0%)	0/1 (0.0%)
Weight Group 3	<=50 kg	0/1 (0.0%)	1/1 (100.0%)	1/2 (50.0%)
	50 - <=70 kg	3/9 (33.3%)		0/1 (0.0%)
	70 - <=90 kg		0/2 (0.0%)	0/1 (0.0%)
Weight (supp)	<50 kg	0/1 (0.0%)	1/1 (100.0%)	1/2 (50.0%)
	>=50 kg	3/9 (33.3%)	0/2 (0.0%)	0/2 (0.0%)
Location of index DVT	.	1/4 (25.0%)		0/1 (0.0%)
	Femoral or more proximal	2/5 (40.0%)	1/1 (100.0%)	1/2 (50.0%)
	Popliteal or more distal	0/1 (0.0%)	0/2 (0.0%)	0/1 (0.0%)
Index DVT/PE	Spontaneous DVT/PE	2/3 (66.7%)	1/1 (100.0%)	0/1 (0.0%)
	Secondary DVT/PE	1/7 (14.3%)	0/2 (0.0%)	1/3 (33.3%)
Previous episode(s) of DVT/PE	NO	2/9 (22.2%)	1/3 (33.3%)	1/4 (25.0%)
	YES	1/1 (100.0%)		
Idiopathic VTE	NO	2/8 (25.0%)	0/2 (0.0%)	1/3 (33.3%)
	YES	1/2 (50.0%)	1/1 (100.0%)	0/1 (0.0%)
Recent surgery or trauma	NO	3/8 (37.5%)	1/2 (50.0%)	1/3 (33.3%)
	YES	0/2 (0.0%)	0/1 (0.0%)	0/1 (0.0%)

表 2.7.4.7- 63 部分集団別及び予定投与期間別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Prolonged immobilization	NO	3/6 (50.0%)	1/2 (50.0%)	1/3 (33.3%)
	YES	0/4 (0.0%)	0/1 (0.0%)	0/1 (0.0%)
Use of estrogen containing drugs	NO	3/10 (30.0%)	1/3 (33.3%)	1/4 (25.0%)
Puerperium	NO	3/10 (30.0%)	1/3 (33.3%)	1/4 (25.0%)
Active cancer	NO	2/7 (28.6%)	1/3 (33.3%)	0/3 (0.0%)
	YES	1/3 (33.3%)		1/1 (100.0%)
Antithrombin deficiency	NO	3/10 (30.0%)	1/3 (33.3%)	1/4 (25.0%)
Factor V Leiden gene mutation	NO	3/10 (30.0%)	1/3 (33.3%)	1/4 (25.0%)
Hyperhomocysteinaemia	NO	3/10 (30.0%)	1/3 (33.3%)	1/4 (25.0%)
Antiphospholipid antibodies	NO	3/10 (30.0%)	1/3 (33.3%)	1/4 (25.0%)
Protein C deficiency	NO	3/10 (30.0%)	1/3 (33.3%)	1/4 (25.0%)
Protein S deficiency	NO	3/10 (30.0%)	1/3 (33.3%)	1/4 (25.0%)
Prothrombin gene mutation	NO	3/10 (30.0%)	1/3 (33.3%)	1/4 (25.0%)
Pulmonary disease	No pulmonary disease	3/10 (30.0%)	0/2 (0.0%)	1/4 (25.0%)
	Pulmonary disease		1/1 (100.0%)	
Cardiac disease	No cardiac disease	1/7 (14.3%)	1/3 (33.3%)	1/4 (25.0%)
	Cardiac disease	2/3 (66.7%)		

表 2.7.4.7- 63　部分集団別及び予定投与期間別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 3 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Baseline ALT	<= upper limit of normal range	3/7 (42.9%)	1/3 (33.3%)	0/3 (0.0%)
	> upper limit of normal range	0/3 (0.0%)		1/1 (100.0%)

Incidence = # of events / # at risk, where:
# of events = # of subjects reporting the event after randomization up to end of intended treatment time.
# at risk = # of subjects in reference population.
GB:.../t-adtte-pmda-posthoc-incidence-safety-subgroup-newgroup.sas erjli 06MAR2014 16:01
引用元：5.3.5.1.43 Additional_22 Table /86

表 2.7.4.7- 63 部分集団別及び予定投与期間別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Age Group 2	<60 years	0/2 (0.0%)	1/1 (100.0%)	2/4 (50.0%)
	>=60 years	7/24 (29.2%)	4/11 (36.4%)	1/5 (20.0%)
Age Group 3	<65 years	0/5 (0.0%)	2/4 (50.0%)	2/5 (40.0%)
	65 - 75 years	5/11 (45.5%)	3/6 (50.0%)	1/2 (50.0%)
	>75 years	2/10 (20.0%)	0/2 (0.0%)	0/2 (0.0%)
Age (supp)	<75 years	5/16 (31.3%)	5/10 (50.0%)	3/6 (50.0%)
	>=75 years	2/10 (20.0%)	0/2 (0.0%)	0/3 (0.0%)
Baseline Body Mass Index Group 2	<30 kg/m2	6/24 (25.0%)	4/9 (44.4%)	3/8 (37.5%)
	>=30 kg/m2	1/2 (50.0%)	1/3 (33.3%)	0/1 (0.0%)
Baseline Body Mass Index Group 3	<=18.5 kg/m2	0/3 (0.0%)		0/1 (0.0%)
	18.5 - <=25 kg/m2	3/14 (21.4%)	2/6 (33.3%)	3/7 (42.9%)
	25 - <=30 kg/m2	3/7 (42.9%)	2/3 (66.7%)	
	30 - <=35 kg/m2		1/2 (50.0%)	0/1 (0.0%)
	>35 kg/m2	1/2 (50.0%)	0/1 (0.0%)	
Unfractioned heparin/fondaparinux or warfarin treatment before randomization	NO	1/3 (33.3%)	3/5 (60.0%)	1/2 (50.0%)
	YES	6/23 (26.1%)	2/7 (28.6%)	2/7 (28.6%)
Creatinine Clearance Group 2	<50 mL/min	1/4 (25.0%)		
	50 - <80 mL/min	4/15 (26.7%)	1/3 (33.3%)	1/4 (25.0%)
	>=80 mL/min	2/7 (28.6%)	4/9 (44.4%)	2/5 (40.0%)
Creatinine Clearance Group 3	30 - <50 mL/min	1/4 (25.0%)		
	50 - <80 mL/min	4/15 (26.7%)	1/3 (33.3%)	1/4 (25.0%)
	>=80 mL/min	2/7 (28.6%)	4/9 (44.4%)	2/5 (40.0%)

表 2.7.4.7- 63 部分集団別及び予定投与期間別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Sex	Male	2/11 (18.2%)	1/7 (14.3%)	2/6 (33.3%)
	Female	5/15 (33.3%)	4/5 (80.0%)	1/3 (33.3%)
Weight Group 2	<90 kg	6/24 (25.0%)	4/11 (36.4%)	3/9 (33.3%)
	>=90 kg	1/2 (50.0%)	1/1 (100.0%)	
Weight Group 1	<=70 kg	6/22 (27.3%)	4/8 (50.0%)	3/9 (33.3%)
	>70 - <=90 kg	0/2 (0.0%)	0/3 (0.0%)	
	>90 kg	1/2 (50.0%)	1/1 (100.0%)	
Weight Group 3	<=50 kg	0/7 (0.0%)	1/2 (50.0%)	
	50 - <=70 kg	6/15 (40.0%)	3/6 (50.0%)	3/9 (33.3%)
	70 - <=90 kg	0/2 (0.0%)	0/3 (0.0%)	
	>90 kg	1/2 (50.0%)	1/1 (100.0%)	
Weight (supp)	<50 kg	0/7 (0.0%)	1/2 (50.0%)	
	>=50 kg	7/19 (36.8%)	4/10 (40.0%)	3/9 (33.3%)
Location of index DVT	.	5/10 (50.0%)		1/2 (50.0%)
	Femoral or more proximal	2/13 (15.4%)	3/9 (33.3%)	2/7 (28.6%)
	Popliteal or more distal	0/3 (0.0%)	2/3 (66.7%)	
Index DVT/PE	Spontaneous DVT/PE	6/20 (30.0%)	3/6 (50.0%)	3/6 (50.0%)
	Secondary DVT/PE	1/6 (16.7%)	2/6 (33.3%)	0/3 (0.0%)
Previous episode(s) of DVT/PE	NO	7/25 (28.0%)	5/12 (41.7%)	3/9 (33.3%)
	YES	0/1 (0.0%)		
Idiopathic VTE	NO	4/11 (36.4%)	3/8 (37.5%)	0/3 (0.0%)
	YES	3/15 (20.0%)	2/4 (50.0%)	3/6 (50.0%)

表 2.7.4.7- 63 部分集団別及び予定投与期間別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Recent surgery or trauma	NO	6/21 (28.6%)	4/9 (44.4%)	3/8 (37.5%)
	YES	1/5 (20.0%)	1/3 (33.3%)	0/1 (0.0%)
Prolonged immobilization	NO	7/25 (28.0%)	5/10 (50.0%)	3/7 (42.9%)
	YES	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)
Use of estrogen containing drugs	NO	7/26 (26.9%)	5/12 (41.7%)	3/9 (33.3%)
Puerperium	NO	7/26 (26.9%)	5/12 (41.7%)	3/9 (33.3%)
Active cancer	NO	7/26 (26.9%)	4/11 (36.4%)	3/9 (33.3%)
	YES		1/1 (100.0%)	
Antithrombin deficiency	NO	7/26 (26.9%)	4/11 (36.4%)	3/9 (33.3%)
	YES		1/1 (100.0%)	
Factor V Leiden gene mutation	NO	7/26 (26.9%)	5/12 (41.7%)	3/9 (33.3%)
Hyperhomocysteinaemia	NO	7/26 (26.9%)	5/12 (41.7%)	3/9 (33.3%)
Antiphospholipid antibodies	NO	7/26 (26.9%)	5/12 (41.7%)	3/9 (33.3%)
Protein C deficiency	NO	7/25 (28.0%)	4/11 (36.4%)	3/8 (37.5%)
	YES	0/1 (0.0%)	1/1 (100.0%)	0/1 (0.0%)
Protein S deficiency	NO	7/26 (26.9%)	5/12 (41.7%)	2/8 (25.0%)
	YES			1/1 (100.0%)
Prothrombin gene mutation	NO	7/26 (26.9%)	5/12 (41.7%)	3/9 (33.3%)

表 2.7.4.7- 63　部分集団別及び予定投与期間別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 6 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Pulmonary disease	No pulmonary disease	6/23 (26.1%)	5/10 (50.0%)	3/8 (37.5%)
	Pulmonary disease	1/3 (33.3%)	0/2 (0.0%)	0/1 (0.0%)
Cardiac disease	No cardiac disease	3/19 (15.8%)	5/11 (45.5%)	3/9 (33.3%)
	Cardiac disease	4/7 (57.1%)	0/1 (0.0%)	
Baseline ALT	<= upper limit of normal range	5/22 (22.7%)	4/11 (36.4%)	3/8 (37.5%)
	> upper limit of normal range	2/4 (50.0%)	1/1 (100.0%)	0/1 (0.0%)

Incidence = # of events / # at risk, where:
# of events = # of subjects reporting the event after randomization up to end of intended treatment time.
# at risk = # of subjects in reference population.
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表 2.7.4.7- 63 部分集団別及び予定投与期間別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Age Group 2	<60 years	1/7 (14.3%)	1/2 (50.0%)	1/1 (100.0%)
	>=60 years	6/12 (50.0%)	1/5 (20.0%)	3/5 (60.0%)
Age Group 3	<65 years	3/9 (33.3%)	2/5 (40.0%)	1/1 (100.0%)
	65 - 75 years	3/8 (37.5%)	0/2 (0.0%)	2/3 (66.7%)
	>75 years	1/2 (50.0%)		1/2 (50.0%)
Age (supp)	<75 years	6/17 (35.3%)	2/7 (28.6%)	3/4 (75.0%)
	>=75 years	1/2 (50.0%)		1/2 (50.0%)
Baseline Body Mass Index Group 2	<30 kg/m2	7/17 (41.2%)	2/7 (28.6%)	2/3 (66.7%)
	>=30 kg/m2	0/2 (0.0%)		2/3 (66.7%)
Baseline Body Mass Index Group 3	<=18.5 kg/m2		1/1 (100.0%)	
	18.5 - <=25 kg/m2	5/9 (55.6%)	1/6 (16.7%)	2/3 (66.7%)
	25 - <=30 kg/m2	2/8 (25.0%)		
	30 - <=35 kg/m2	0/1 (0.0%)		2/3 (66.7%)
	>35 kg/m2	0/1 (0.0%)		
Unfractioned heparin/fondaparinux or warfarin treatment before randomization	NO	0/4 (0.0%)	0/2 (0.0%)	1/2 (50.0%)
	YES	7/15 (46.7%)	2/5 (40.0%)	3/4 (75.0%)
Creatinine Clearance Group 2	<50 mL/min	0/1 (0.0%)		
	50 - <80 mL/min	6/9 (66.7%)	2/4 (50.0%)	3/4 (75.0%)
	>=80 mL/min	1/9 (11.1%)	0/3 (0.0%)	1/2 (50.0%)
Creatinine Clearance Group 3	30 - <50 mL/min	0/1 (0.0%)		
	50 - <80 mL/min	6/9 (66.7%)	2/4 (50.0%)	3/4 (75.0%)
	>=80 mL/min	1/9 (11.1%)	0/3 (0.0%)	1/2 (50.0%)

表 2.7.4.7- 63 部分集団別及び予定投与期間別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Sex	Male	3/10 (30.0%)	2/6 (33.3%)	1/3 (33.3%)
	Female	4/9 (44.4%)	0/1 (0.0%)	3/3 (100.0%)
Weight Group 2	<90 kg	7/17 (41.2%)	2/7 (28.6%)	3/5 (60.0%)
	>=90 kg	0/2 (0.0%)		1/1 (100.0%)
Weight Group 1	<=70 kg	5/9 (55.6%)	1/5 (20.0%)	2/3 (66.7%)
	>70 - <=90 kg	2/8 (25.0%)	1/2 (50.0%)	1/2 (50.0%)
	>90 kg	0/2 (0.0%)		1/1 (100.0%)
Weight Group 3	<=50 kg	0/2 (0.0%)		1/1 (100.0%)
	50 - <=70 kg	5/7 (71.4%)	1/5 (20.0%)	1/2 (50.0%)
	70 - <=90 kg	2/8 (25.0%)	1/2 (50.0%)	1/2 (50.0%)
	>90 kg	0/2 (0.0%)		1/1 (100.0%)
Weight (supp)	<50 kg	0/2 (0.0%)		1/1 (100.0%)
	>=50 kg	7/17 (41.2%)	2/7 (28.6%)	3/5 (60.0%)
Location of index DVT	.	4/6 (66.7%)		1/2 (50.0%)
	Femoral or more proximal	3/10 (30.0%)	2/6 (33.3%)	0/1 (0.0%)
	Popliteal or more distal	0/3 (0.0%)	0/1 (0.0%)	3/3 (100.0%)
Index DVT/PE	Spontaneous DVT/PE	6/15 (40.0%)	2/5 (40.0%)	2/4 (50.0%)
	Secondary DVT/PE	1/4 (25.0%)	0/2 (0.0%)	2/2 (100.0%)
Previous episode(s) of DVT/PE	NO	6/13 (46.2%)	2/7 (28.6%)	3/5 (60.0%)
	YES	1/6 (16.7%)		1/1 (100.0%)
Idiopathic VTE	NO	1/8 (12.5%)	1/3 (33.3%)	4/5 (80.0%)
	YES	6/11 (54.5%)	1/4 (25.0%)	0/1 (0.0%)

表 2.7.4.7- 63 部分集団別及び予定投与期間別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Recent surgery or trauma	NO	6/15 (40.0%)	2/6 (33.3%)	4/6 (66.7%)
	YES	1/4 (25.0%)	0/1 (0.0%)	
Prolonged immobilization	NO	6/16 (37.5%)	2/7 (28.6%)	3/5 (60.0%)
	YES	1/3 (33.3%)		1/1 (100.0%)
Use of estrogen containing drugs	NO	7/19 (36.8%)	2/7 (28.6%)	3/5 (60.0%)
	YES			1/1 (100.0%)
Puerperium	NO	7/19 (36.8%)	2/7 (28.6%)	4/6 (66.7%)
Active cancer	NO	7/19 (36.8%)	2/6 (33.3%)	3/5 (60.0%)
	YES		0/1 (0.0%)	1/1 (100.0%)
Antithrombin deficiency	NO	7/19 (36.8%)	2/7 (28.6%)	4/6 (66.7%)
Factor V Leiden gene mutation	NO	7/19 (36.8%)	2/7 (28.6%)	4/6 (66.7%)
Hyperhomocysteinaemia	NO	7/19 (36.8%)	2/7 (28.6%)	4/6 (66.7%)
Antiphospholipid antibodies	NO	7/19 (36.8%)	2/7 (28.6%)	4/6 (66.7%)
Protein C deficiency	NO	7/19 (36.8%)	2/7 (28.6%)	3/5 (60.0%)
	YES			1/1 (100.0%)
Protein S deficiency	NO	7/19 (36.8%)	2/7 (28.6%)	4/6 (66.7%)
Prothrombin gene mutation	NO	7/19 (36.8%)	2/7 (28.6%)	4/6 (66.7%)

表 2.7.4.7- 63　部分集団別及び予定投与期間別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Intended treatment duration: 12 MONTHS

Covariate	Category	Rivaroxaban 15 mg BID/OD n/N(%)	Rivaroxaban 10 mg BID/15 mg OD n/N(%)	UFH / Warfarin n/N(%)
Pulmonary disease	No pulmonary disease	5/14 (35.7%)	2/6 (33.3%)	4/5 (80.0%)
	Pulmonary disease	2/5 (40.0%)	0/1 (0.0%)	0/1 (0.0%)
Cardiac disease	No cardiac disease	7/18 (38.9%)	2/7 (28.6%)	4/6 (66.7%)
	Cardiac disease	0/1 (0.0%)		
Baseline ALT	<= upper limit of normal range	7/14 (50.0%)	2/7 (28.6%)	4/5 (80.0%)
	> upper limit of normal range	0/5 (0.0%)		0/1 (0.0%)

Incidence = # of events / # at risk, where:
# of events = # of subjects reporting the event after randomization up to end of intended treatment time.
# at risk = # of subjects in reference population.
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表 2.7.4.7- 64　性別及び出血部位別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）

Sex: Male

Bleeding events Characteristic of events Location of events	Rivaroxaban 10 mg BID/15 mg OD N=15 (100%)	Rivaroxaban 15 mg BID/OD N=25 (100%)	UFH / Warfarin N=10 (100%)	Total N=50 (100%)
Any confirmed bleeding	3 (20.0%)	6 (24.0%)	3 (30.0%)	12 (24.0%)
Clinically relevant non-major bleeding	0	1 (4.0%)	0	1 (2.0%)
CLINICALLY OVERT	0	1 (4.0%)	0	1 (2.0%)
GASTROINTESTINAL - LOWER	0	1 (4.0%)	0	1 (2.0%)
Trivial bleeding	3 (20.0%)	6 (24.0%)	3 (30.0%)	12 (24.0%)
CLINICALLY OVERT	3 (20.0%)	6 (24.0%)	3 (30.0%)	12 (24.0%)
NASAL	3 (20.0%)	1 (4.0%)	0	4 (8.0%)
GASTROINTESTINAL TRACT - GINGIVAL	0	1 (4.0%)	0	1 (2.0%)
INJECTION / BLOOD SAMPLING SITE	1 (6.7%)	1 (4.0%)	0	2 (4.0%)
GASTROINTESTINAL TRACT - PHARYNX	0	1 (4.0%)	0	1 (2.0%)
SKIN (OTHER THAN INJECTION SITE)	1 (6.7%)	4 (16.0%)	3 (30.0%)	8 (16.0%)
EYE - CONJUNCTIVAL	0	1 (4.0%)	0	1 (2.0%)

Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more events, the subject is counted only once in a category. The same subject may appear in different categories.
Percentages calculated with the number of subjects in each group as denominator.
Treatment-emergent is defined as the event occurred after randomization and up to 2 days after the last dose of study drug.
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表 2.7.4.7- 64　性別及び出血部位別の治験薬投与下で発現した出血（CIAC 判定）（試験 14568 と試験 15960 の統合解析、安全性解析対象集団）（続き）

Sex: Female

Bleeding events Characteristic of events Location of events	Rivaroxaban 10 mg BID/15 mg OD N=7 (100%)	Rivaroxaban 15 mg BID/OD N=30 (100%)	UFH / Warfarin N=9 (100%)	Total N=46 (100%)
Any confirmed bleeding	5 (71.4%)	11 (36.7%)	5 (55.6%)	21 (45.7%)
Clinically relevant non-major bleeding	3 (42.9%)	2 (6.7%)	1 (11.1%)	6 (13.0%)
CLINICALLY OVERT	3 (42.9%)	2 (6.7%)	1 (11.1%)	6 (13.0%)
GASTROINTESTINAL - UPPER	1 (14.3%)	0	0	1 (2.2%)
GASTROINTESTINAL - LOWER	1 (14.3%)	0	0	1 (2.2%)
MACROSCOPIC HEMATURIA	0	1 (3.3%)	1 (11.1%)	2 (4.3%)
SKIN (OTHER THAN INJECTION SITE)	1 (14.3%)	1 (3.3%)	0	2 (4.3%)
Trivial bleeding	4 (57.1%)	11 (36.7%)	4 (44.4%)	19 (41.3%)
CLINICALLY OVERT	4 (57.1%)	11 (36.7%)	4 (44.4%)	19 (41.3%)
NASAL	0	3 (10.0%)	1 (11.1%)	4 (8.7%)
GASTROINTESTINAL - LOWER	0	3 (10.0%)	0	3 (6.5%)
GASTROINTESTINAL TRACT - GINGIVAL	2 (28.6%)	1 (3.3%)	1 (11.1%)	4 (8.7%)
SKIN (OTHER THAN INJECTION SITE)	1 (14.3%)	8 (26.7%)	3 (33.3%)	12 (26.1%)
EYE - CONJUNCTIVAL	1 (14.3%)	0	0	1 (2.2%)

Incidences are based on the number of subjects, not the number of events. Although a subject may have had 2 or more events, the subject is counted only once in a category. The same subject may appear in different categories.
Percentages calculated with the number of subjects in each group as denominator.
Treatment-emergent is defined as the event occurred after randomization and up to 2 days after the last dose of study drug.
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2.7.5　参考文献

2.7 臨床概要における参考文献の掲載先を以下に示す。

2.7.2 臨床薬理試験；「参考文献」の項

2.7.3 臨床的有効性；「参考文献」の項

2.7.4 臨床的安全性；「参考文献」の項

2.7.6.2 ；　「2.7.6.2.4　参考文献」の項