表 2.7.6.17-32　重篤な有害事象の一覧表（20120231 試験）

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120229-22911001003	ATYPICAL NON-CARDIOGENIC CHEST PAIN [非心臓性胸痛]	20[redacted]-06-19	22	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-20	-
AMG 416	20120229-22911001003	LEFT ARM CELLULITIS [蜂巣炎]	20[redacted]-10-28 *	153	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-12 *	-
AMG 416	20120229-22911001003	RIGHT 1ST-3RD TOE NECROSIS [四肢壊死]	20[redacted]-04-07 *	314	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-06-05 *	-
AMG 416	20120229-22911001003	DRY GANGRENE [乾性壊疽]	20[redacted]-04-21	328	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-06-05	-
AMG 416	20120229-22911001006	BACTERAEMIA [菌血症]	20[redacted]-06-29	25	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-07-15	-
AMG 416	20120229-22911001010	INFECTED ARTERIO-VENOUS GRAFT [動静脈グラフト部位感染]	20[redacted]-10-31	156	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-11-18	-
AMG 416	20120229-22911001010	MSSA SEPSIS [ブドウ球菌性敗血症]	20[redacted]-10-31	156	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-11-04	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120229-22911001010	VASCULITIC RASH [血管炎性皮疹]	20[redacted]-12-05	191	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22911001010	CEPHAZOLIN ALLERGY [薬物過敏症]	20[redacted]-12-07	193	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-20	-
AMG 416	20120229-22911001010	VANCOMYCIN ALLERGY [薬物過敏症]	20[redacted]-12-16 *	202	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-20 *	-
AMG 416	20120229-22911001010	TACHYCARDIA [頻脈]	20[redacted]-01-11 *	228	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-16 *	-
AMG 416	20120229-22911001010	INFECTION OF CHRONIC LEFT LOWER LIMB ULCER [感染性皮膚潰瘍]	20[redacted]-06-16	384	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-22	-
AMG 416	20120229-22911003002	R LOWER LIMB CELLULITIS [蜂巣炎]	20[redacted]-09-16T09:00	153	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-11-21	-
AMG 416	20120229-22911003002	CARDIAC ARREST [心停止]	20[redacted]-11-21	219	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	EMERGENCY ROOM VISIT, OTHER	NOT RELATED	20[redacted]-11-21	-
AMG 416	20120229-22911003002	PULMONARY EMBOLISM [肺塞栓症]	20[redacted]-11-21	219	LIFE THREATENING	YES	Is Life Threatening	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-11-21	-
AMG 416	20120229-22911003003	RIGHT SURGICAL NECK OF HUMERUS FRACTURE [上腕骨骨折]	20[redacted]-05-11 *	53	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING *	-
AMG 416	20120229-22911003003	LABIAL ABSESS [性器膿瘍]	20[redacted]-01-06	293	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-29	-
AMG 416	20120229-22911003006	TERTIARY HYPER-PARATHYROIDISM [三次性副甲状腺機能亢進症]	20[redacted]-12-17	253	SEVERE	YES	-	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-12-22	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120229-22911013001	RIGHT SIDED CHEST PAIN [胸痛]	20[redacted]-05-28T12:10	85	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-05-29	-
AMG 416	20120229-22912001003	ATRIAL FIBRILLATION [心房細動]	20[redacted]-11-19 *	204	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22912001003	OPTICUSNEUROPATHY [視神経症]	20[redacted]-01	-	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22912001005	WORSENING OF PRE-EXISTING PERIPHERAL VASCULAR DISEASE [末梢血管障害]	20[redacted]-09-24 **	141	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-01 **	-
AMG 416	20120229-22912003001	PERIPHERAL ARTERIAL DISEASE SINCE 5/20[redacted]; * WORSENING SINCE 10/20[redacted]; SCHEDULED REINTERVENTION [末梢動脈閉塞性疾患]	20[redacted]-05-20 **	63	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-05-22 **	-
AMG 416	20120229-22912003001	PNEUMONIA [肺炎]	20[redacted]-10-06T12:00 **	202	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-10-18T15:00 **	-
AMG 416	20120229-22912003001	PNEUMONIA [肺炎]	20[redacted]-10-27T19:00 ***	223	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-11-07T15:00 ***	-
AMG 416	20120229-22912003001	WORSENING OF PERIPHERAL ARTERIAL DISEASE [末梢動脈閉塞性疾患]	20[redacted]-01-09T09:00 ***	297	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-02-06 ***	-
AMG 416	20120229-22912003001	CLOSTRIDIUM DIFFICILE COLITIS [クロストリジウム・ディフィシレ大腸炎]	20[redacted]-02-20T15:00	339	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-03-04T15:00	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time ***	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time ***	Outcome of Serious Adverse Event
AMG 416	20120229-22912003001	INFLUENZA B [インフルエンザ]	20[redacted]-03-11T21:50 ***	358	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-15 ***	-
AMG 416	20120229-22912003001	ACUTE CARDIAL EVENT [心障害]	20[redacted]-03-15T17:23	362	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	OTHER	NOT RELATED	20[redacted]-03-15	-
AMG 416	20120229-22913001001	HEMORROIDAL BLEEDING [痔出血]	20[redacted]-10-22T08:00	316	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-29T14:00	-
AMG 416	20120229-22913001004	ACUTE CHOLANGITIS [急性胆管炎]	20[redacted]-07-21T20:00	148	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-07-24T09:30	-
AMG 416	20120229-22913003006	CARDIAC BYPASS THROMBOSIS [冠動脈バイパス血栓症]	20[redacted]-01-21	254	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	ONGOING	-
AMG 416	20120229-22913005001	OCCLUSION OF ARTERY POPLITEA LEFT [末梢動脈閉塞性疾患]	20[redacted]-07-08	77	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-10	-
AMG 416	20120229-22913005001	PSEUDO-ANEURYSM OF ARTERIA POPLITEA LEFT [血管偽動脈瘤]	20[redacted]-07-08	77	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-10	-
AMG 416	20120229-22913005005	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-03-24	328	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22913007006	MESENTERIC ISCHEMIA [腸管虚血]	20[redacted]-01-25	2	SEVERE	YES	-	DOSE NOT CHANGED	DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-02-05	-
AMG 416	20120229-22913009002	RECURRENT FALLS [転倒]	20[redacted]-10-21	337	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-01	-

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AMG 416	20120229-22913009002	TREMOR [振戦]	20[redacted]-10-21	337	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22916001003	NON COMPLICATED DIVERTICULITIS [憩室炎]	20[redacted]-12-23T09:26	266	MODERATE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-12-24	-
AMG 416	20120229-22916001004	CONFUSION [錯乱状態]	20[redacted]-05-09	37	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22916001004	HYPOCALCEMIA [低カルシウム血症]	20[redacted]-05-09	37	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-05-15	-
AMG 416	20120229-22916001004	SEIZURE [痙攣発作]	20[redacted]-05-09	37	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-09	-
AMG 416	20120229-22916001004	SEVERE HYPOGLYCEMIA [低血糖症]	20[redacted]-05-09	37	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-09	-
AMG 416	20120229-22916001007	OSTEITIS LEFT FIRST TOE [骨炎]	20[redacted]-01-26	292	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-03-11	-
AMG 416	20120229-22921003001	PNEUMONIA [肺炎]	20[redacted]-01-14T16:00	344	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-02-13	-
AMG 416	20120229-22921003002	SCAPULA FRACTURE [肩甲骨骨折]	20[redacted]-03-27*	-6	MODERATE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-06-18*	-
AMG 416	20120229-22921003002	LEFT FEMUR FRACTURE [大腿骨骨折]	20[redacted]-01-18	292	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-01	-

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AMG 416	20120229-229210030 02	SEPSIS [敗血症]	20[redacted]-01-30	304	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-01T00:15	-
AMG 416	20120229-229210050 01	ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-11-05	302	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-05	-
AMG 416	20120229-229210050 03	UROSEPSIS [尿路性敗血症]	20[redacted]-01-26	19	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-27	-
AMG 416	20120229-229210050 03	RELAPS UROSEPSIS [尿路性敗血症]	20[redacted]-04-09	92	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-21	-
AMG 416	20120229-229210050 03	BLEEDING [出血]	20[redacted]-05-20	133	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-21	-
AMG 416	20120229-229210050 03	RELAPSE UROSEPSIS [尿路性敗血症]	20[redacted]-05-20	133	LIFE THREATENING	YES	Is Life Threatening	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-20	-
AMG 416	20120229-229210050 03	AC.HEART FAILURE [急性心不全]	20[redacted]-05-21	134	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-21T00:02	-
AMG 416	20120229-229250010 02	BONE PAIN [骨痛]	20[redacted]-04-15	97	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-04-19	-

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AMG 416	20120229-22925001002	DEPRESSION [うつ病]	20[redacted]-04-15	97	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-19	-
AMG 416	20120229-22925001003	BLOOD HYPER-FLUX OF ARTERIO-VENOUS FESTULA. [動静脈瘻部位合併症]	20[redacted]-10-10T13:30	269	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-03	-
AMG 416	20120229-22925001005	ANGINA PECTORIS [狭心症]	20[redacted]-05-24	18	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-19	-
AMG 416	20120229-22925007001	WORSENING OF UNSTABLE ANGINA [不安定狭心症]	20[redacted]-07-22	168	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-24	-
AMG 416	20120229-22925007001	CARDIOGENIC SHOCK [心原性ショック]	20[redacted]-07-24	170	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-07-24	-
AMG 416	20120229-22926003003	PATELLA FRACTURE LEFT [膝蓋骨骨折]	20[redacted]-06-07	87	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-08-05	-
AMG 416	20120229-22926003003	INFECTION SURGICAL WOUND AFTER PATELLA FRACTURE SURGERY [術後創感染]	20[redacted]-06-25	105	LIFE THREATENING	YES	Is Life Threatening	DRUG WITHDRAWN	MEDICATION TAKEN, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-08-05	-
AMG 416	20120229-22926003003	SEPSIS AFTER AMPUTATION WOUND LEFT LEG [膿創]	20[redacted]-08-05	146	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-08-05	-
AMG 416	20120229-22926005001	THROMBOSIS OF ATERIOVENOUS GRAFT [血管グラフト血栓症]	20[redacted]-06-13	39	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-18	-

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AMG 416	20120229-22926005001	THROMBOSIS OF ATERIOVENOUS GRAFT [血管グラフト血栓症]	20[redacted]-07-15T14:30	71	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-19	-
AMG 416	20120229-22926005001	THROMBOSIS OF ARTERIO-VENOUS GRAFT [血管グラフト血栓症]	20[redacted]-07-26	82	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-28	-
AMG 416	20120229-22926005001	THROMBOSIS OF ARTERIO VENOUS GRAFT [血管グラフト血栓症]	20[redacted]-08-07	94	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-10	-
AMG 416	20120229-22926005001	THROMBOSIS OF ARTERIO-VENOUS GRAFT [血管グラフト血栓症]	20[redacted]-08-14	101	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-20	-
AMG 416	20120229-22926005001	THROMBOSIS OF ARTERIO-VENOUS GRAFT [血管グラフト血栓症]	20[redacted]-11-29	208	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-04	-
AMG 416	20120229-22926005003	WORSENING OF ARTERIO-VENOUSIS SHUNT STENOSIS [シャント狭窄]	20[redacted]-01-07	260	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-08	-
AMG 416	20120229-22926005004	DIAGNOSTIC OF DIVERTICULOSIS ON COLON [腸憩室]	20[redacted]-02-11	288	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-02-14	-
AMG 416	20120229-22926005006	PARTIAL THROMBOSIS OF AV-FISTULA [動静脈瘻血栓症]	20[redacted]-03-25	309	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-30	-
AMG 416	20120229-22926005008	PERIPHERALARTERIALOCCLUSIVE DISEASE AGGRAVITED LEFT LEG [末梢動脈閉塞性疾患]	20[redacted]-02-05	-104	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-12	-
AMG 416	20120229-22926005008	WORSENING OF CORONARY HEART DISEASE [冠動脈疾患]	20[redacted]-07-30	72	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-01	-
AMG 416	20120229-22926005008	WORSENING OF RIVA STENOSIS [冠動脈狭窄]	20[redacted]-09-15	119	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-09-19	-

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AMG 416	20120229-22926005008	WORSENING OF PERIPHERAL VASCULAR DISEASE RIGHT LEG [末梢血管障害]	20[redacted]-09-20	124	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-10	-
AMG 416	20120229-22926005008	DECOMPENSATION OF AORTIC VALVE STENOSIS [大動脈弁狭窄]	20[redacted]-10-28	162	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-12	-
AMG 416	20120229-22929001003	WORSENING AV FISTULA FUNCTION [動静脈瘻部位合併症]	20[redacted]-09-02T08:00 *	225	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-09-04T08:00 *	-
AMG 416	20120229-22929001003	PROGRESSING CATARACT OF LEFT EYE [白内障]	20[redacted]-02-11T07:18	387	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE EXPLANTATION	NOT RELATED	20[redacted]-02-12T07:00	-
AMG 416	20120229-22929003006	CEREBRAL HAEMORRHAGIA [脳出血]	20[redacted]-07-13T07:49	137	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-19	-
AMG 416	20120229-22929007002	ANGINA PECTORIS [狭心症]	20[redacted]-10-28T12:00	29	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-29	-
AMG 416	20120229-22929007004	PROBLEMATIC PUNCTURE OF THE AV FISTULA [動静脈瘻部位合併症]	20[redacted]-04-15T11:13	100	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	ONGOING	-

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AMG 416	20120229-22929007004	GASTROENTERITIS [胃腸炎]	20[redacted]-08-14T15:00	221	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-18T10:00	-
AMG 416	20120229-22929007005	ACUTE GASTROENTERITIS [胃腸炎]	20[redacted]-02-21T08:00	33	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-26T16:00	-
AMG 416	20120229-22929007005	CIMINO'S FITULE STENOSIS [動静脈瘻部位合併症]	20[redacted]-03-11T22:32	51	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-13T14:07	-
AMG 416	20120229-22929007006	ILEUS [イレウス]	20[redacted]-08-12T16:12	183	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-08-14T01:05	-
AMG 416	20120229-22929007006	SEPSIS [敗血症]	20[redacted]-08-12T16:12	183	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-08-14T01:05	-
AMG 416	20120229-22929007006	WORSENING ANAEMIA [貧血]	20[redacted]-08-12T16:12	183	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-14T01:05	-
AMG 416	20120229-22929007008	THE WOUND OF THE LEFT FOURTH TOE ABLATION INFLAMMATION (SAME AS IN 229 SAE 003 [創傷]	20[redacted]-01-23T16:50	-54	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-01T11:14	-
AMG 416	20120229-22929007008	PERIFERAL ARTERY DISEASE [末梢血管障害]	20[redacted]-03-11T13:58	-7	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-18T09:58	-
AMG 416	20120229-22929007008	LEFT III. AND V. FINGER OSTEOMYELITIS [骨髄炎]	20[redacted]-05-01T16:48	45	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-17T08:00	-

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AMG 416	20120229-22929007008	LEFT HALLUX OSTEOMYELITIS [骨髄炎]	20[redacted]-09-02T11:26	169	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-11T08:26	-
AMG 416	20120229-22929007017	ERYTHROPOETIN RESISTANCE [薬剤耐性]	20[redacted]-06-10T10:03	86	SEVERE	YES	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-06-16T11:00	-
AMG 416	20120229-22929007017	TRANSPLANTED KIDNEY PAIN (COMPLICATION) [移植腎の合併症]	20[redacted]-06-10T10:03	86	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-16T11:00	-
AMG 416	20120229-22929007018	CIMINO FISTULE STENOSIS [動静脈瘻部位合併症]	20[redacted]-03-03	300	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-05	-
AMG 416	20120229-22932001008	MYOCARDIAL INFARCTION/NSTEMI [急性心筋梗塞]	20[redacted]-09-04T07:00 *	115	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-08T14:19 *	-
AMG 416	20120229-22932001008	ARRHYTHMIA: VF STORM [心室細動]	20[redacted]-05-06 *	359	LIFE THREATENING	YES	Is Life Threatening	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-05-06 *	-
AMG 416	20120229-22932001008	CARDIOPULMONARY ARREST [心肺停止]	20[redacted]-05-06	359	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-05-06	-
AMG 416	20120229-22932003004	SEPSIS [敗血症]	20[redacted]-06-03	20	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-06-29	-
AMG 416	20120229-22933001002	WORSENING OF RENAL FUNCTION [腎機能障害]	20[redacted]-01-03T10:30	31	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-23T17:30	-

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AMG 416	20120229-22933011008	CHOLELITIASIS [胆石症]	20[redacted]-05-29T09:00	114	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-31	-
AMG 416	20120229-22933011010	WORSENING OF PERIPHERAL ARTERY DISEASE [末梢血管障害]	20[redacted]-05-29T09:00	100	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-03	-
AMG 416	20120229-22933011011	SUSPECT CENTRAL VENOUS CATHETER RELATED SEPSIS [医療機器関連敗血症]	20[redacted]-05-19T17:00	76	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-05-30	-
AMG 416	20120229-22933011011	BLEEDING FROM THE ARTERIOVENOUS FISTULA [動静脈瘻部位出血]	20[redacted]-06-25T18:00	113	SEVERE	YES	-	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-06-25T19:51	-
AMG 416	20120229-22933011011	SUSPECT CENTRAL VENOUS CATHETER-RELATED SEPSIS [医療機器関連敗血症]	20[redacted]-07-02	120	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-09	-
AMG 416	20120229-22948001001	SEIZURES [痙攣発作]	20[redacted]-03-07T08:15	75	LIFE THREATENING	YES	Is Life Threatening	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, OTHER	RELATED	20[redacted]-03-07	-
AMG 416	20120229-22948001005	THROMBOSIS OF AV FISTULA [動静脈瘻血栓症]	20[redacted]-02-23	391	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-02-23	-
AMG 416	20120229-22948003001	SUDDEN DEATH - UNKNOWN REASON [突然死]	20[redacted]-09-22	207	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-22	-
AMG 416	20120229-22948003002	WORSENING SPINA PAIN [脊椎痛]	20[redacted]-04-17	52	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-05-24	-

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AMG 416	20120229-22948003002	AGGRAVATED HYPERTENSION [高血圧]	20[redacted]-05-17	82	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-24	-
AMG 416	20120229-22948003002	SPONDYLOSIS [変形性脊椎症]	20[redacted]-05-17T17:30	82	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-24T23:00	-
AMG 416	20120229-22948003002	BRONCHOPNEUMONIA [気管支肺炎]	20[redacted]-06-17 *	113	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-26 *	-
AMG 416	20120229-22948003002	WORSENING SPINAL PAIN [脊椎痛]	20[redacted]-02-05	346	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-02-19	-
AMG 416	20120229-22948003003	BONE AND MUSCLE PAIN [筋骨格痛]	20[redacted]-03-05T05:30	8	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-12T09:30	-
AMG 416	20120229-22948003003	BRONCHOPNEUMONIA [気管支肺炎]	20[redacted]-04-07	41	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-04-07	-
AMG 416	20120229-22948005006	BODY WEIGHT LOSS [体重減少]	20[redacted]-09-03T07:51	238	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-09-04T12:00	-
AMG 416	20120229-22948005006	UNCONTROLLED HYPERTENSION [高血圧]	20[redacted]-09-29	264	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22948005007	ATRIAL FIBRILLATION [心房細動]	20[redacted]-11-20	330	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22948005008	SEIZURE [痙攣発作]	20[redacted]-02-21T14:00	121	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-

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AMG 416	20120229-22948005009	INFLAMMATION OF A-V FISTULA REGION [動静脈瘻部位合併症]	20[redacted]-07-01	181	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-04	-
AMG 416	20120229-22948005009	DYSFUNCTION OF ARTERIO-VENOUS FISTULA [動静脈瘻部位合併症]	20[redacted]-09-17	259	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER, OTHER	NOT RELATED	20[redacted]-09-24	-
AMG 416	20120229-22948005010	NON-CARDIAC CHEST PAIN [非心臓性胸痛]	20[redacted]-04-12	101	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-13	-
AMG 416	20120229-22948005011	EXACERBATION OF CHRONIC HEART FAILURE [慢性心不全]	20[redacted]-01-07	6	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-13	-
AMG 416	20120229-22948005013	STAPHYLOCOCCUS AUREUS SEPSIS [ブドウ球菌性敗血症]	20[redacted]-06-09	61	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN	NOT RELATED	ONGOING	-
AMG 416	20120229-22951001004	ACUTE CORPOREAL GASTRIC EROSION [びらん性胃炎]	20[redacted]-01-08T01:00	347	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, OTHER	NOT RELATED	20[redacted]-01-19	-
AMG 416	20120229-22951003004	METASTATIC LESIONS OF VERTEBREA [脊椎転移]	20[redacted]-05-25	89	SEVERE	YES	-	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	ONGOING	-
AMG 416	20120229-22951003004	INCREASING AST [アスパラギン酸アミノトランスフェラーゼ増加]	20[redacted]-06-23	118	SEVERE	YES	-	DOSE NOT CHANGED	NO ACTION TAKEN	RELATED	20[redacted]-07-24	-
AMG 416	20120229-22951003004	VERTEBROGENIC PAIN WORSERING [脊椎痛]	20[redacted]-07-06	131	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22951003004	WEAKNESS [無力症]	20[redacted]-07-06	131	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120229-22951003005	OD INITIAL CATARACT LENS SUBLUXATION IMPAIRMENT [水晶体脱臼]	20[redacted]-05-14	78	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-19	-
AMG 416	20120229-22951007003	OCCLUSION LOWER EXTREMITY ARTERIES [末梢動脈再閉塞]	20[redacted]-04-14	62	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-04-30	-
AMG 416	20120229-22951007003	OCCLUSION OF THE RADIAL AND ULNAR ARTERIES OF THE LEFT HAND [動脈閉塞性疾患]	20[redacted]-05-08	86	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN, NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-06-05	-
AMG 416	20120229-22951007003	FISTULA THROMBOSIS ON THE RIGHT FOREARM [動静脈瘻血栓症]	20[redacted]-09-15 *	216	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-09-29 *	-
AMG 416	20120229-22951007003	PERMANENT CATHETER THROMBOSIS [医療機器関連の血栓症]	20[redacted]-01-19 *	342	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-02-09 *	-
AMG 416	20120229-22951007003	ACUTE CARDIOVASCULAR INSUFFICIENCY [心血管不全]	20[redacted]-02-10T20:30	364	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-02-11T04:00	-

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AMG 416	20120229-22951009004	FRACTURE OF THE RIGHT RADIUS [橈骨骨折]	20[redacted]-04-22T12:00	63	SEVERE	YES	-	DOSE NOT CHANGED	SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION, EMERGENCY ROOM VISIT	RELATED	20[redacted]-06-30T12:00	-
AMG 416	20120229-22958003008	FRACTURE OF RADIUS [橈骨骨折]	20[redacted]-12-22	11	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-25	-
AMG 416	20120229-22958009002	LITHIASIC CHOLECISTITIS [胆嚢炎]	20[redacted]-05-06	139	LIFE THREATENING	YES	Is Life Threatening	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	NOT RELATED	20[redacted]-05-21	-
AMG 416	20120229-22958009002	HEPATIC COLIC [胆道仙痛]	20[redacted]-06-10	174	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-30	-
AMG 416	20120229-22958009006	INFECTION OF SACRAL ULCER [感染性皮膚潰瘍]	20[redacted]-11-18	327	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-11-25	-
AMG 416	20120229-22958009006	SEPTIC SHOCK [敗血症性ショック]	20[redacted]-11-18	327	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-11-25	-
AMG 416	20120229-22958009009	STENT OCCLUSION OF THE LEFT SUPERFICIAL FEMORAL ARTERY [医療機器閉塞]	20[redacted]-03-17	13	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-04-16	-
AMG 416	20120229-22958009009	DEEP VEIN THROMBOSIS (RIGHT LOWER EXTREMITY [深部静脈血栓症]	20[redacted]-03-31	27	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN, OTHER	NOT RELATED	20[redacted]-04-09	-
AMG 416	20120229-22958009009	GASTROENTERITIS [胃腸炎]	20[redacted]-04-18*	45	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	NOT RELATED	20[redacted]-04-23*	-
AMG 416	20120229-22958009009	ORTOSTATIC HYPOTENSION [起立性低血圧]	20[redacted]-02-15*	348	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN, OTHER	NOT RELATED	20[redacted]-02-16*	-
AMG 416	20120229-22958009009	TOXIC HYPERKALEMIA [高カリウム血症]	20[redacted]-02-15	348	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-16	-

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AMG 416	20120229-22958009018	ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-04-06	56	LIFE THREATENING	YES	Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-04-07	-
AMG 416	20120229-22958009018	ISCHEMIC DELATED CARDIOMIOPATHY WITH SEVERAL DEPRESS LEFT VENTRICULAR DISFUNCTION [心筋虚血]	20[redacted]-04-06	56	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-07	-
AMG 416	20120229-22958009018	VENTRICULAR FIBRILATION [心室細動]	20[redacted]-04-06	56	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-07	-
AMG 416	20120229-22965003004	SUPRA VENTRICULAR TACCHYCARDIA [上室性頻脈]	20[redacted]-08-19T16:00	83	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-19	-
AMG 416	20120229-22965003006	DIARRHOEA [下痢]	20[redacted]-04-27	355	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-28	-
AMG 416	20120229-22965003006	LOW ABDOMINAL PAIN [下腹部痛]	20[redacted]-04-27T05:00	355	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-28	-
AMG 416	20120229-22965005002	DIARRHOEA [下痢]	20[redacted]-06-30T05:00	69	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-01T05:00	-
AMG 416	20120229-22965005002	INFECTED FOOT LESION [皮膚感染]	20[redacted]-06-30T05:00	69	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22965005002	NUMB RIGHT LEG [感覚鈍麻]	20[redacted]-06-30T05:00	69	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-07T05:00	-

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AMG 416	20120229-22965005002	PURPURIC ERUPTIONS ON UPPER AND LOWER EXTREMITIES AND TO LOWER ABDOMEN, BUTTOCKS AND BACK [紫斑]	20[redacted]-02-24	308	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-06-05	-
AMG 416	20120229-22965007003	SOFT TISSUE INJURY TO RIGHT THIGH [軟部組織損傷]	20[redacted]-03-26T07:00	332	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22965007003	BILATERAL LEG ULCERS [皮膚潰瘍]	20[redacted]-04-14T07:00	351	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966001002	ATRIAL FIB W RVR [心房細動]	20[redacted]-06-09	85	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-11	-
AMG 416	20120229-22966001002	DIABETIC FOOT ULCER RIGHT 2ND TOE [糖尿病性足病変]	20[redacted]-07-29	135	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-01	-
AMG 416	20120229-22966003023	SUPRAVENTRICULAR TACHYCARDIA [上室性頻脈]	20[redacted]-09-02	106	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966005002	EROSIVE GASTRITIS [びらん性胃炎]	20[redacted]-09-01	230	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-03	-
AMG 416	20120229-22966005002	LEFT LOWER LEG CELLULITIS [蜂巣炎]	20[redacted]-09-01	230	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-03	-
AMG 416	20120229-22966005004	WORSENING ANXIETY [不安]	20[redacted]-03-25	-6	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-26	-
AMG 416	20120229-22966005004	NON CARDIAC ATYPICAL CHEST PAIN [非心臓性胸痛]	20[redacted]-08-26	149	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-27	-

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AMG 416	20120229-22966009003	EXASCERBATION OF BILATERAL KIDNEY STONES [腎結石症]	20[redacted]-04-09	162	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-16	-
AMG 416	20120229-22966009003	PNEUMONIA [肺炎]	20[redacted]-06-02	216	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-14	-
AMG 416	20120229-22966009003	ATRIAL FIBRILLATION, TRANSIENT [心房細動]	20[redacted]-06-04	218	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-06-05	-
AMG 416	20120229-22966009003	EXACERBATION OF CORONARY ARTERY DISEASE [冠動脈疾患]	20[redacted]-10-24	360	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-29	-
AMG 416	20120229-22966009003	KIDNEY STONE EXACERBATION [腎結石症]	20[redacted]-10-24	360	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-10-29	-
AMG 416	20120229-22966009003	EXACERBATION OF LEFT FLANK PAIN [側腹部痛]	20[redacted]-11-03	370	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-04	-
AMG 416	20120229-22966009003	HYPERKALEMIA [高カリウム血症]	20[redacted]-11-03	370	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-04	-
AMG 416	20120229-22966009004	PNEUMONIA [肺炎]	20[redacted]-06-14	235	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-17	-
AMG 416	20120229-22966009004	CAVITARY LESSION OF LUNG [肺空洞形成]	20[redacted]-07-18	269	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966009004	LYMPHADENOPATHY [リンパ節症]	20[redacted]-07-18	269	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966009008	EPISTAXIS [鼻出血]	20[redacted]-02-16	116	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-02-25	-

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AMG 416	20120229-22966009008	SEVERE HYPERKALEMIA [高カリウム血症]	20[redacted]-02-17	117	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-02-25	-
AMG 416	20120229-22966009008	ANEMIA [貧血]	20[redacted]-08-09	290	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-12	-
AMG 416	20120229-22966009008	EPISTAXIS [鼻出血]	20[redacted]-08-09	290	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-12	-
AMG 416	20120229-22966009009	FLUID OVERLOAD [水分過負荷]	20[redacted]-01-04	45	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-08	-
AMG 416	20120229-22966009009	SEVERE HYPERKALEMIA [高カリウム血症]	20[redacted]-01-04	45	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-08	-
AMG 416	20120229-22966009009	UREMIA [高窒素血症]	20[redacted]-01-04	45	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-08	-
AMG 416	20120229-22966009009	PULMONARY EDEMA [肺水腫]	20[redacted]-02-28	100	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-03-02	-
AMG 416	20120229-22966009009	FLUID OVERLOAD [水分過負荷]	20[redacted]-07-29	251	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-31	-
AMG 416	20120229-22966009010	HYPERKALEMIA [高カリウム血症]	20[redacted]-06-16	229	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-19	-
AMG 416	20120229-22966009010	INCREASED BLOOD PRESSURE [血圧上昇]	20[redacted]-06-16	229	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-19	-

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AMG 416	20120229-22966009010	A-V GRAFT STENOSIS [移植血管合併症]	20[redacted]-10-16	351	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-10-17	-
AMG 416	20120229-22966009010	PRESYNCOPE [失神寸前の状態]	20[redacted]-10-28	363	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-31	-
AMG 416	20120229-22966009010	BRADYCARDIA [徐脈]	20[redacted]-11-13	379	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-16	-
AMG 416	20120229-22966009011	EXACERBATION OF POST-MENOPAUSAL BLEEDING [閉経後出血]	20[redacted]-10-31	359	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-03	-
AMG 416	20120229-22966009011	HYPOTENSION [低血圧]	20[redacted]-10-31	359	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-03	-
AMG 416	20120229-22966009011	SEIZURE [痙攣発作]	20[redacted]-10-31	359	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-03	-
AMG 416	20120229-22966009014	ATRIAL FIBRILLATION [心房細動]	20[redacted]-11-02	18	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-12	-
AMG 416	20120229-22966009014	COMPLETE HEART BLOCK [完全房室ブロック]	20[redacted]-12-12	58	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-12-30	-
AMG 416	20120229-22966009014	A-V FISTULA BLEED [動静脈瘻部位出血]	20[redacted]-12-17 *	63	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-12-17 *	-
AMG 416	20120229-22966009014	CARDIAC ARREST [心停止]	20[redacted]-01-02 *	79	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, OTHER	NOT RELATED	20[redacted]-01-02 *	-
AMG 416	20120229-22966009014	VENTRICULAR FIBRILLATION [心室細動]	20[redacted]-01-03	80	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	NOT RELATED	20[redacted]-01-03	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120229-22966009015	GASTROINTESTINAL BLEED [胃腸出血]	20[redacted]-02-04	41	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-02-06	-
AMG 416	20120229-22966009015	MODERATE ANEMIA [貧血]	20[redacted]-02-25	62	MODERATE	YES	-	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-02-26	-
AMG 416	20120229-22966009015	RECURRENCE OF ATRIAL FIBRILLATION [心房細動]	20[redacted]-05-01	127	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-05-02	-
AMG 416	20120229-22966009015	RECURRENCE OF GASTROINTESTINAL BLEED [胃腸出血]	20[redacted]-05-03	129	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-05-09	-
AMG 416	20120229-22966009017	ACUTE OSTEOMYELITIS LEFT FOOT [急性骨髄炎]	20[redacted]-11-04	154	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-11-17	-
AMG 416	20120229-22966009017	STAPH AUREUS BACTEREMIA [ブドウ球菌性菌血症]	20[redacted]-11-04 *	154	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-17 *	-
AMG 416	20120229-22966009017	DEEP VEIN THROMBOSIS [深部静脈血栓症]	20[redacted]-01-11 *	222	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-16 *	-
AMG 416	20120229-22966009017	INFLUENZA [インフルエンザ]	20[redacted]-01-22 *	233	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-28 *	-
AMG 416	20120229-22966009017	VIRAL UPPER RESPIRATORY INFECTION [ウイルス性上気道感染]	20[redacted]-02-17	259	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-20	-
AMG 416	20120229-22966011004	ACUTE ON CHRONIC SYSTOLIC CHF [うっ血性心不全]	20[redacted]-03-03	75	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-03-07	-

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AMG 416	20120229-22966011010	CLOTTED AV GRAFT [血管グラフト血栓症]	20[redacted]-02-23	295	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-25	-
AMG 416	20120229-22966011018	ISCHEMIC COLITIS [虚血性大腸炎]	20[redacted]-09-14	110	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-01	-
AMG 416	20120229-22966011018	ACUTE RESPIRATORY FAILURE [急性呼吸不全]	20[redacted]-09-16	112	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-16	-
AMG 416	20120229-22966011018	CARDIAC ARREST [心停止]	20[redacted]-09-16	112	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-16	-
AMG 416	20120229-22966011018	ENTEROCUTANEOUS FISTULA [腸管皮膚瘻]	20[redacted]-09-16	112	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966011018	GENERALIZED WEAKNESS [無力症]	20[redacted]-10-02	128	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966013005	WORSENING PERIPHERAL VASCULAR DISEASE [末梢血管障害]	20[redacted]-04-03T13:51	16	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-10	-
AMG 416	20120229-22966013005	WORSENING CORONARY ARTERY DISEASE [冠動脈疾患]	20[redacted]-05-15	58	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-31	-
AMG 416	20120229-22966013005	CEREBRIAL VASCULAR ACCIDENT [脳血管発作]	20[redacted]-05-21	64	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-31	-
AMG 416	20120229-22966013005	CARDIOPULMONARY ARREST [心肺停止]	20[redacted]-05-30	73	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-31	-

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AMG 416	20120229-22966013007	WORSENING CORONARY ARTERY DISEASE [冠動脈疾患]	20[redacted]-04-28	34	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	NOT RELATED	20[redacted]-04-30	-
AMG 416	20120229-22966013007	CARDIOPULMONARY ARREST [心肺停止]	20[redacted]-04-30	36	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-04-30	-
AMG 416	20120229-22966019007	WORSENING OF INFECTED DIALYSIS CATHETER [医療機器関連感染]	20[redacted]-09-29	181	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-03	-
AMG 416	20120229-22966019007	INFECTED DIALYSIS CATHETER [医療機器関連感染]	20[redacted]-12-13	256	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-12-20	-
AMG 416	20120229-22966019007	WORSENING OF INFECTED DIALYSIS CATHETER [医療機器関連感染]	20[redacted]-12-27	270	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966019011	ATRIAL FIBRILLATION [心房細動]	20[redacted]-12-08T16:24	196	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-13	-
AMG 416	20120229-22966021003	EXCESS FLUID IN BLOOD DUE TO MISSING HEMODIALYSIS ON NOV-8-20[redacted] [水分過負荷]	20[redacted]-11-11T19:00	302	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-13	-
AMG 416	20120229-22966021003	HYPERKALEMIA [高カリウム血症]	20[redacted]-11-11T19:00	302	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-13	-
AMG 416	20120229-22966023004	HYPERKALEMIA [高カリウム血症]	20[redacted]-09-06	264	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-07	-
AMG 416	20120229-22966023004	SEVERE HEADACHE THIS TERM CHANGED TO WORSENING OF HYPERTENSION [高血圧]	20[redacted]-11-20	339	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-11-21	-
AMG 416	20120229-22966023005	AORTIC STENOSIS [大動脈狭窄]	20[redacted]-12-19	56	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-24	-

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AMG 416	20120229-22966023005	ISCHEMIC HEART DISEASE [心筋虚血]	20[redacted]-12-19	56	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-24	-
AMG 416	20120229-22966023005	URO SEPSIS [尿路性敗血症]	20[redacted]-12-19	56	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-24	-
AMG 416	20120229-22966023005	ATRIAL FIBRILLATION [心房細動]	20[redacted]-12-27T01:49	64	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-30T07:08	-
AMG 416	20120229-22966023005	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-12-27T01:49	64	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-30T07:08	-
AMG 416	20120229-22966023005	MITRAL VALVE REGURGITATION [僧帽弁閉鎖不全症]	20[redacted]-12-27T01:49 *	64	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-30T07:08 *	-
AMG 416	20120229-22966023005	HYPERVOLEMIC CONGESTIVE CARDIAC FAILURE. [うっ血性心不全]	20[redacted]-08-11T05:00 *	291	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-12T11:26 *	-
AMG 416	20120229-22966023005	ATRIAL FIBRILLATION [心房細動]	20[redacted]-09-04T16:06	315	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-09T11:44	-
AMG 416	20120229-22966023010	CONGESTIVE CARDIAC FAILURE [うっ血性心不全]	20[redacted]-05-06T10:31	113	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-10T12:51	-
AMG 416	20120229-22966023010	HYPERVOLEMIA [血液量増加症]	20[redacted]-05-06T10:31	113	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-10T12:51	-
AMG 416	20120229-22966023010	POST TRAUMATIC SUBDURAL HEMATOMA [硬膜下血腫]	20[redacted]-11-22	313	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-04 *	-
AMG 416	20120229-22966023010	HYPERVOLEMIA [血液量増加症]	20[redacted]-12-27	348	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-08	-

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AMG 416	20120229-22966027007	MITRAL VALVE PROLAPSE [僧帽弁逸脱]	20[redacted]-11-26 *	-50	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-02-04 *	-
AMG 416	20120229-22966027007	MITRAL/ TRICUSPID VALVE DISEASE [心臓弁膜疾患]	20[redacted]-02-04 *	21	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-17 *	-
AMG 416	20120229-22966027007	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-02-08 *	25	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-02-11 *	-
AMG 416	20120229-22966027007	TRACHEOBRONCHITIS [気管気管支炎]	20[redacted]-02-12 *	29	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-17 *	-
AMG 416	20120229-22966027007	INFECTED ABSCESS STERNAL WOUND [創傷感染]	20[redacted]-02-15 *	32	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-02-22 *	-
AMG 416	20120229-22966027007	CARDIAC ARREST [心停止]	20[redacted]-02-26 *	43	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-02-26 *	-
AMG 416	20120229-22966027007	TORSADES DE POINTES [トルサード　ド　ポアント]	20[redacted]-02-26 *	43	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-02-26 *	-
AMG 416	20120229-22966027007	PALPITATIONS [動悸]	20[redacted]-03-24 *	69	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-27 *	-
AMG 416	20120229-22966027007	SUBTHERAPEUTIC INR [抗凝固薬濃度治療量以下]	20[redacted]-03-24 *	69	SEVERE	YES	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-03-31 *	-
AMG 416	20120229-22966027007	INTERMITTENT CHEST PAIN [胸痛]	20[redacted]-06-16	153	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-19	-

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AMG 416	20120229-22966027007	LEFT SIDED MUSCULOSKELETAL CHEST PAIN [筋骨格系胸痛]	20[redacted]-12-15	335	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-18	-
AMG 416	20120229-22966029001	CHEST PAIN - CARDIAC NON MI [狭心症]	20[redacted]-08-18T16:58 *	-192	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-09-06 *	-
AMG 416	20120229-22966029001	GASTROENTERITIS [胃腸炎]	20[redacted]-02-17T05:33 *	-9	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-24T18:55 **	-
AMG 416	20120229-22966029001	OSTEOMYELITIS [骨髄炎]	20[redacted]-12-03T06:57	281	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-05	-
AMG 416	20120229-22966029005	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-09-29T15:12	155	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-05	-
AMG 416	20120229-22966029005	ENCEPHALOPATHY SECONDARY TO ANOXIC EVENT [低酸素性虚血性脳症]	20[redacted]-12-10	227	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-23	-
AMG 416	20120229-22966031004	FLUID OVERLOAD [水分過負荷]	20[redacted]-09-16T14:11	147	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-20T18:36 *	-
AMG 416	20120229-22966031004	CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION [慢性閉塞性肺疾患]	20[redacted]-12-26	248	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-06 *	-
AMG 416	20120229-22966031004	PNEUMONIA [肺炎]	20[redacted]-12-26	248	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-09	-

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AMG 416	20120229-22966031004	PNEUMONIA [肺炎]	20[redacted]-05-01	374	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-04	-
AMG 416	20120229-22966031006	FLUID OVERLOAD [水分過負荷]	20[redacted]-05-18T19:42 *	54	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-19T12:30 *	-
AMG 416	20120229-22966031006	INFECTIOUS MONONUCLEOSIS [伝染性単核症]	20[redacted]-03-01	341	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-06	-
AMG 416	20120229-22966033003	NON CARDIAC CHEST PAIN [非心臓性胸痛]	20[redacted]-03-30	75	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-31	-
AMG 416	20120229-22966033003	HYPOGLYCEMIA [低血糖症]	20[redacted]-04-17	93	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	NOT RELATED	20[redacted]-04-19	-
AMG 416	20120229-22966035004	INFECTED SKIN ULCER [感染性皮膚潰瘍]	20[redacted]-01-07	28	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-02-07	-
AMG 416	20120229-22966035004	MALIGNANT HTN [悪性高血圧]	20[redacted]-12-01	356	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966035005	ANGINA PECTORIS [狭心症]	20[redacted]-05-01T23:00	95	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	ONGOING	-
AMG 416	20120229-22966035005	HYPERKALEMIA [高カリウム血症]	20[redacted]-05-14	108	MODERATE	YES	-	DOSE ALTERED OR WITHHELD	OTHER	NOT RELATED	20[redacted]-05-29	-
AMG 416	20120229-22966035005	MALIGNANT HYPERTENSION [悪性高血圧]	20[redacted]-05-14	108	MODERATE	YES	-	DOSE ALTERED OR WITHHELD	OTHER	NOT RELATED	20[redacted]-05-29	-
AMG 416	20120229-22966035005	RIGHT FOOT CELLULITIS [蜂巣炎]	20[redacted]-05-14	108	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-29	-
AMG 416	20120229-22966035005	RIGHT FOOT ULCER [皮膚潰瘍]	20[redacted]-05-14	108	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-29	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120229-22966035005	ACUTE PULMONARY EDEMA [急性肺水腫]	20[redacted]-08-31	217	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-01	-
AMG 416	20120229-22966035005	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-11-30	308	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-02	-
AMG 416	20120229-22966035005	VOLUME OVERLOAD [水分過負荷]	20[redacted]-11-30	308	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-02	-
AMG 416	20120229-22966035005	LEFT TOE OSTEOMYELITIS [骨髄炎]	20[redacted]-12-18	326	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-23	-
AMG 416	20120229-22966035005	LEFT FOOT PAIIN [四肢痛]	20[redacted]-12-19*	327	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-23	-
AMG 416	20120229-22966035005	LIVER TOXICITY [肝毒性]	20[redacted]-01-02*	341	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966035005	CELLULITIS OF BOTH LEGS [蜂巣炎]	20[redacted]-01-21*	360	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966035005	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-02-15*	385	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966035005	ULCER OF FOOT [皮膚潰瘍]	20[redacted]-02-25	395	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966035010	CHEST PAIN(NON CARDIAC ORIGIN) [非心臓性胸痛]	20[redacted]-03-26	13	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-01	-
AMG 416	20120229-22966037001	PANCREATITIS [膵炎]	20[redacted]-07-23T10:00*	55	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-27T12:00	-
AMG 416	20120229-22966037001	HYPOGLYCEMIA [低血糖症]	20[redacted]-01-24*	240	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING*	-
AMG 416	20120229-22966037001	DIARRHOEA [下痢]	20[redacted]-01-25	241	MODERATE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	NOT RELATED	20[redacted]-01-26	-

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AMG 416	20120229-22966037001	ARTERIO-VENOUS FISTULA SITE BLEEDING. [動静脈瘻部位出血]	20[redacted]-03-03	278	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-04	-
AMG 416	20120229-22966041005	BILATERAL PLEURAL EFFUSION [胸水]	20[redacted]-08-25	92	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-18	-
AMG 416	20120229-22966041005	IATROGENIC SPLENIC INJURY [脾臓損傷]	20[redacted]-08-25	92	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-05	-
AMG 416	20120229-22966041005	POST-OP RESPIRATORY FAILURE [術後呼吸不全]	20[redacted]-08-25	92	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-18	-
AMG 416	20120229-22966041005	SYNCOPE [失神]	20[redacted]-08-25	92	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-08-25	-
AMG 416	20120229-22966041005	CELLULITIS OF LEFT FOOT [蜂巣炎]	20[redacted]-10-17	145	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-23	-
AMG 416	20120229-22966041005	WORSENING PERIPHERAL ARTERY DISEASE [末梢動脈閉塞性疾患]	20[redacted]-10-17	145	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-23	-
AMG 416	20120229-22966041005	CARDIAC ARREST [心停止]	20[redacted]-10-23T00:45	151	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-23T00:45	-
AMG 416	20120229-22966045001	NSTEMI [急性心筋梗塞]	20[redacted]-06-09	69	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-17	-
AMG 416	20120229-22966045001	HYPOTENSION [低血圧]	20[redacted]-06-30	90	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-07-02	-

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AMG 416	20120229-22966047002	OCCLUDED FISTULA [動静脈瘻閉塞]	20[redacted]-03-21	17	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-22	-
AMG 416	20120229-22966049004	CELLULITIS - BLLATERAL LEGS [蜂巣炎]	20[redacted]-05-16	8	MODERATE	YES	-	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	ONGOING	-
AMG 416	20120229-22966049006	ACUTE BILIARY PANCREATITIS [急性膵炎]	20[redacted]-05-17	23	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-21	-
AMG 416	20120229-22966049006	CHOLECYSTITIS [胆嚢炎]	20[redacted]-05-17	23	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-21	-
AMG 416	20120229-22966051009	COLON CANCER STAGE II [結腸癌第２期]	20[redacted]-03-31T11:00	102	SEVERE	YES	-	DRUG WITHDRAWN	SURGICAL INTERVENTION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966051016	FEVER [発熱]	20[redacted]-02-19	284	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-21	-
AMG 416	20120229-22966053002	CHEST PAIN [胸痛]	20[redacted]-08-18	242	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-21	-
AMG 416	20120229-22966053002	ANTRAL EROSIONS [びらん性胃炎]	20[redacted]-09-07	262	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-10	-
AMG 416	20120229-22966053002	RESPIRATORY INSUFFICENCEY [呼吸不全]	20[redacted]-09-22	277	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-25	-
AMG 416	20120229-22966053002	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-10-05	290	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-22	-

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AMG 416	20120229-22966053002	WORSENING HEART FAILURE [心不全]	20[redacted]-10-06	291	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-22	-
AMG 416	20120229-22966055002	NONCARDIAC CHEST PAIN [非心臓性胸痛]	20[redacted]-01-25T00:12	20	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-26T00:12	-
AMG 416	20120229-22966055002	GI BLEED SECONDARY TO GASTRITIS [出血性胃炎]	20[redacted]-10-02	270	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	RELATED	20[redacted]-10-06	-
AMG 416	20120229-22966055002	ABDOMINAL PAIN, SECONDARY TO ENTERITIS [小腸炎]	20[redacted]-12-15	344	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-19	-
AMG 416	20120229-22966057002	CELLULITIS [蜂巣炎]	20[redacted]-11-28T11:00	390	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-12-08	-
AMG 416	20120229-22966057002	HEMATOMA [血腫]	20[redacted]-11-28T11:00	390	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-12-08	-
AMG 416	20120229-22966057002	LEFT LEG PAIN [四肢痛]	20[redacted]-11-28T11:00	390	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-12-08	-

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AMG 416	20120229-22966057007	LOW BLOOD PRESSURE [低血圧]	20[redacted]-10-27T11:25	251	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-10-28T09:00	-
AMG 416	20120229-22966059001	ACCESS SITE BLEEDING (AV FISTULA) [動静脈瘻部位出血]	20[redacted]-03-02	110	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-03	-
AMG 416	20120229-22966059001	ISCHEMIC BOWEL [腸管虚血]	20[redacted]-03-04	112	LIFE THREATENING	YES	Is Life Threatening	DRUG WITHDRAWN	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-05	-
AMG 416	20120229-22966059001	SEPTIC SHOCK [敗血症性ショック]	20[redacted]-03-04	112	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-03-05	-
AMG 416	20120229-22966059001	BILATERAL CEREBRAL STROKE [脳血管発作]	20[redacted]-03-05	113	LIFE THREATENING	YES	Is Life Threatening	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-03-05	-
AMG 416	20120229-22966061004	ALLERGY [過敏症]	20[redacted]-02-03	376	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-05	-
AMG 416	20120229-22966061004	ANGIOEDEMA [血管浮腫]	20[redacted]-02-03	376	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-05	-
AMG 416	20120229-22966061004	BACK OF THROAT WAS CLOSING OUT [咽喉絞扼感]	20[redacted]-02-03	376	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-05	-
AMG 416	20120229-22966061004	STRIDOR [上気道性喘鳴]	20[redacted]-02-03	376	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-05	-
AMG 416	20120229-22966061008	HYPOTENSION [低血圧]	20[redacted]-06-14T17:19	11	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-18T19:40	-
AMG 416	20120229-22966061008	WEAKNESS [無力症]	20[redacted]-06-14T17:19	11	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-18T19:40	-

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AMG 416	20120229-22966079005	ARTERIOVENOUS GRAFT THROMBOSIS [血管グラフト血栓症]	20[redacted]-08-11	197	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-08-13	-
AMG 416	20120229-22966081002	DEPRESSION WITH SUICIDAL IDEATION [希死念慮を有するうつ病]	20[redacted]-02-05	17	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-06	-
AMG 416	20120229-22966081002	MAXILLARY SINUS FRACTURE [顎の骨折]	20[redacted]-06-04	136	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-13	-
AMG 416	20120229-22966081002	SYNCOPAL EPISODE [失神]	20[redacted]-06-04	136	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-13	-
AMG 416	20120229-22966081002	DEPRESSION [うつ病]	20[redacted]-09-05	229	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-17	-
AMG 416	20120229-22966081002	HELICOBACTER PYLORI GASTRITIS WITH EROSION [ヘリコバクター性胃炎]	20[redacted]-09-09	233	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-09-17	-
AMG 416	20120229-22966081006	HYPERKALEMIA [高カリウム血症]	20[redacted]-05-27	51	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-07	-
AMG 416	20120229-22966081006	HYPOCALCEMIA [低カルシウム血症]	20[redacted]-05-27	51	MODERATE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	RELATED	20[redacted]-06-09	-
AMG 416	20120229-22966081006	HYPOTENSION [低血圧]	20[redacted]-05-27	51	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-07	-
AMG 416	20120229-22966081006	SYNCOPE [失神]	20[redacted]-08-25	141	SEVERE	YES	-	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-08-25	-
AMG 416	20120229-22966081006	COUGH [咳嗽]	20[redacted]-09-29	176	MODERATE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	ONGOING	-
AMG 416	20120229-22966081006	GASTROESOPHAGEAL REFLUX DISEASE [胃食道逆流性疾患]	20[redacted]-11-20	228	MODERATE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	ONGOING	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120229-22966081006	SEASONAL ALLERGIES [季節性アレルギー]	20[redacted]-11-21	229	MODERATE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	ONGOING	-
AMG 416	20120229-22966087005	COMPRESSION FRACTURE [圧迫骨折]	20[redacted]-03-17T17:00	34	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-04-10T18:00	-
AMG 416	20120229-22966087005	BACTEREMIA [菌血症]	20[redacted]-03-17T18:00	34	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, CULTURE TAKEN, IV ANTIMICROBIAL TAKEN	NOT RELATED	ONGOING	-
AMG 416	20120229-22966087005	BACTEREMIA [菌血症]	20[redacted]-05-06T09:00	84	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-05-09T15:00	-
AMG 416	20120229-22966087005	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-05-06T12:30	84	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	ONGOING	-
AMG 416	20120229-22966087005	LEFT FOOT FRACTURE [足骨折]	20[redacted]-08-06T09:00	176	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-08-11T12:20	-
AMG 416	20120229-22966087006	CHEST PAIN (NON-CARDIAC) [非心臓性胸痛]	20[redacted]-10-22T21:14	204	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-10-23T19:57	-
AMG 416	20120229-22966089001	CELLULITIS LEFT SECOND TOE [蜂巣炎]	20[redacted]-05-19	102	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-20	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120229-22966089001	LEFT ANKLE SWELLING [関節腫脹]	20[redacted]-12-08	305	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-10	-
AMG 416	20120229-22966089001	BRONCHOSPASM [気管支痙攣]	20[redacted]-12-26	323	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-27	-
AMG 416	20120229-22966089006	CHEST PAIN [胸痛]	20[redacted]-11-11	223	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-13	-
AMG 416	20120229-22966089006	EXERTIONAL DYSPNEA [労作性呼吸困難]	20[redacted]-11-11	223	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-13	-
AMG 416	20120229-22966089006	HYPERKALEMIA [高カリウム血症]	20[redacted]-11-11	223	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-15	-
AMG 416	20120229-22966113006	DIALYSIS ACCESS HEMORRHAGE [動静脈瘻部位出血]	20[redacted]-05-13*	14	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-15*	-
AMG 416	20120229-22966113006	DIALYSIS ACCESS HEMORRHAGE [動静脈瘻部位出血]	20[redacted]-03-31T23:00*	336	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-01T08:00*	-
AMG 416	20120229-22966113006	HYPERKALEMIA [高カリウム血症]	20[redacted]-04-21	357	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-04-22	-
AMG 416	20120229-22966117001	LEFT HAND STEAL SYNDROME [スチール症候群]	20[redacted]-05-07	41	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-10	-
AMG 416	20120229-22966117001	ASPIRATION [誤嚥]	20[redacted]-05-11	45	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE ALTERED OR WITHHELD	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-05-11	-

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AMG 416	20120229-22966121002	CORNARY ARTERY DISEASE [冠動脈疾患]	20[redacted]-06-26	24	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966121002	LARGE NONHEMORRHAGIC RIGHT MCA DISTRIBUTION INFARCTION WITHOUT HEMORRHAGE OR MIDLINE SHIFT [脳梗塞]	20[redacted]-06-27	25	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966121007	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-03-28T15:30	-6	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-01	-
AMG 416	20120229-22966121007	FALSE POSITIVE ELEVATION OF TROPONIN (NO FURTHER INFORMATION AVAILABLE) [トロポニン増加]	20[redacted]-05-27	55	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-28	-
AMG 416	20120229-22966121007	ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE [心房細動]	20[redacted]-12-06 *	248	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-09	-
AMG 416	20120229-22966121007	FALL [転倒]	20[redacted]-01-23	296	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966133004	RUPTURED DIALYSIS ACCESS [血管確保合併症]	20[redacted]-09-29	252	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-10-01	-
AMG 416	20120229-22966133009	ABDOMINAL WALL CELLULITIS [蜂巣炎]	20[redacted]-03-02	6	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-03-24	-
AMG 416	20120229-22966133009	CHEST PAIN [胸痛]	20[redacted]-12-23T18:00	302	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-12-28	-

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AMG 416	20120229-22966133014	PNEUMONIA [肺炎]	20[redacted]-05-14	-2	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-19	-
AMG 416	20120229-22966133014	FLUID OVERLOAD [水分過負荷]	20[redacted]-08-18T12:00	95	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-08-21	-
AMG 416	20120229-22966133014	FLUID OVERLOAD [水分過負荷]	20[redacted]-09-06 *	114	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-09 *	-
AMG 416	20120229-22966133014	RIGHT GLUTEAL ABCESS [皮下組織膿瘍]	20[redacted]-03-02	291	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-06 *	-
AMG 416	20120229-22966167001	ALK ELEVATION (WORSENING) [血中アルカリホスファターゼ増加]	20[redacted]-12-17	330	MODERATE	YES	-	DOSE NOT CHANGED	OTHER, OTHER	NOT RELATED	20[redacted]-02-17 *	-
AMG 416	20120229-22966167001	ALT ELEVATION (WORSENING NO FURTHER INFORMATION AVAILABLE) [アラニンアミノトランスフェラーゼ増加]	20[redacted]-12-17	330	MODERATE	YES	-	DOSE NOT CHANGED	OTHER, OTHER	NOT RELATED	20[redacted]-02-17 *	-
AMG 416	20120229-22966167001	AST ELEVATION (WORSENING NO FURTHER INFORMATION AVAILABLE) [アスパラギン酸アミノトランスフェラーゼ増加]	20[redacted]-12-17	330	MODERATE	YES	-	DOSE NOT CHANGED	OTHER, OTHER	NOT RELATED	20[redacted]-02-17 *	-
AMG 416	20120229-22966167001	DIRECT BILIRUBIN ELEVATION [抱合ビリルビン増加]	20[redacted]-12-17	330	SEVERE	YES	-	DOSE NOT CHANGED	OTHER, OTHER	NOT RELATED	20[redacted]-02-17 *	-
AMG 416	20120229-22966167001	TOTAL BILIRUBIN ELEVATION [血中ビリルビン増加]	20[redacted]-12-17 *	330	SEVERE	YES	-	DOSE NOT CHANGED	OTHER, OTHER	NOT RELATED	20[redacted]-02-17 *	-
AMG 416	20120229-22966167001	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-02-09	384	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-02-17	-

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AMG 416	20120229-22966167001	HYPOGLYCEMIA [低血糖症]	20[redacted]-02-09 *	384	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-02-17 *	-
AMG 416	20120229-22966167001	HYPOTHERMIA [低体温]	20[redacted]-02-09 *	384	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-02-17 *	-
AMG 416	20120229-22966167001	PANCREATIC CARCINOMA [膵癌]	20[redacted]-02-10 *	385	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-17 *	-
AMG 416	20120229-22966167001	PANCREATIC DUCT OBSTRUCTION [膵管閉塞]	20[redacted]-02-10 *	385	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-17 *	-
AMG 416	20120229-22966167001	SEVERE SEPSIS [敗血症]	20[redacted]-02-11 *	386	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, IV ANTIBIOTICS TAKEN, OTHER	NOT RELATED	20[redacted]-02-17 *	-
AMG 416	20120229-22966167001	ACUTE RESPIRATORY FAILURE [急性呼吸不全]	20[redacted]-02-15 *	390	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, OTHER	NOT RELATED	20[redacted]-02-17 *	-
AMG 416	20120229-22966167001	ACINETOBACTER BACTEREMIA [アシネトバクター性菌血症]	20[redacted]-02-16	391	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, IV ANTIBIOTICS TAKEN, OTHER	NOT RELATED	20[redacted]-02-17	-

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AMG 416	20120229-22966167005	WORSENING OF ELEVATED INTERNATIONAL NORMALIZED RATIO (INR) [国際標準比増加]	20[redacted]-08-06T17:08	169	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-08-10T04:15	-
AMG 416	20120229-22966171004	LEFT SIDED WEAKNESS, CAUSE UNCERTAIN [不全片麻痺]	20[redacted]-04-01 *	41	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-02 *	-
AMG 416	20120229-22966171004	MINI STROKE [一過性脳虚血発作]	20[redacted]-02-12	358	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-03-06	-
AMG 416	20120229-22966193002	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-09-11T15:37	183	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-17T12:55	-
AMG 416	20120229-22966193002	ASPIRATION PNEUMONIA [誤嚥性肺炎]	20[redacted]-09-11T15:37	183	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-17T12:55	-
AMG 416	20120229-22966193002	GASTROENTERITIS [胃腸炎]	20[redacted]-09-11T15:37	183	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-17T12:55	-
AMG 416	20120229-22966193002	NAUSEA [悪心]	20[redacted]-09-11T15:37	183	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-17T12:55	-
AMG 416	20120229-22966193002	VOMITING [嘔吐]	20[redacted]-09-11T15:37	183	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-17T12:55	-
AMG 416	20120229-22966193002	TUBULAR ADENOMACARCINOMA OF THE COLON [結腸腺癌]	20[redacted]-09-29T07:00 *	201	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	OTHER	NOT RELATED	20[redacted]-10-09 *	-
AMG 416	20120229-22966193002	ACUTE GASTROENTERITIS [胃腸炎]	20[redacted]-01-10T08:00	304	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-14T08:00	-

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AMG 416	20120229-22966193004	C. DIFFICILE INFECTION [クロストリジウム・ディフィシレ感染]	20[redacted]-12-26T08:00	288	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-04T08:00 *	-
AMG 416	20120229-22966193004	LOWER GI BLEED [胃腸出血]	20[redacted]-12-26T08:00	288	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-04T08:00 *	-
AMG 416	20120229-22966193004	PRESUMPTIVE LIVER CIRRHOSIS [肝硬変]	20[redacted]-12-26T08:00 *	288	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-04T08:00 *	-
AMG 416	20120229-22966193004	FRACTURED ANKLE [足関節部骨折]	20[redacted]-01-18T07:00 *	311	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-22T07:00 *	-
AMG 416	20120229-22966193004	LOWER GI BLEED [胃腸出血]	20[redacted]-03-09T07:00	361	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-12T07:00	-
AMG 416	20120229-22966193009	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-05-31T07:00	19	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	ONGOING	-
AMG 416	20120229-22966193009	VOMITTING [嘔吐]	20[redacted]-05-31T07:00	19	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	ONGOING	-
AMG 416	20120229-22966215001	FRACTURES, MULTIPLE [多発骨折]	20[redacted]-01-27	274	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966215001	INTRACRANIAL HEMORRHAGE [頭蓋内出血]	20[redacted]-01-27	274	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966233001	BRADYCARDIA [徐脈]	20[redacted]-07-14	76	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-16	-
AMG 416	20120229-22966233001	HYPERKALEMIA [高カリウム血症]	20[redacted]-07-14	76	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-16	-

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AMG 416	20120229-22966233001	PRESYNCOPE LIKELY SECONDARY TO BRADYCARDIA [失神寸前の状態]	20[redacted]-07-14	76	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-16	-
AMG 416	20120230-23011006002	RIGHT RECTUS SHEATH HAEMATOMA [腹壁血腫]	20[redacted]-09-04	161	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-21	-
AMG 416	20120230-23011006003	HEADACHE [頭痛]	20[redacted]-06-18	64	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-19	-
AMG 416	20120230-23011006003	UNCONSCIOUS COLLAPSE [失神]	20[redacted]-06-18T14:45	64	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-18T14:54	-
AMG 416	20120230-23011006003	LOWER RESPIRATORY TRACT INFECTION [下気道感染]	20[redacted]-06-23	69	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-26	-
AMG 416	20120230-23011006003	ACUTE PULMONARY OEDEMA [急性肺水腫]	20[redacted]-06-23T10:09	69	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-23T20:45	-
AMG 416	20120230-23011008002	THROMBOSED RIGHT PTFE GRAFT (DIALYSIS ACCESS) [血管グラフト血栓症]	20[redacted]-06-09T10:00	48	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-06-18T15:21	-
AMG 416	20120230-23011008002	MULTINODULAR GOITRE [甲状腺腫]	20[redacted]-11-28T08:30	220	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-12-02T15:00	-

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AMG 416	20120230-23011008002	THYROID FOLLICULAR LESION [甲状腺新生物]	20[redacted]-11-28T08:30	220	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-12-02T15:00	-
AMG 416	20120230-23011008002	LOW SERUM CALCIUM [血中カルシウム減少]	20[redacted]-11-28T17:32	220	MODERATE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN, OTHER	NOT RELATED	20[redacted]-11-29T07:53	-
AMG 416	20120230-23011008007	BRITTLE TEETH AND BONE DUE TO TEETH DECAY [齲歯]	20[redacted]-02-13T10:46	311	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-02-15T10:29	-
AMG 416	20120230-23011010001	WORSENING BILATERAL HIP PAIN [関節痛]	20[redacted]-04-14	20	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	RELATED	20[redacted]-05-14	-
AMG 416	20120230-23011010001	WORSENING HYPOPHOSPHATAEMIA [低リン酸血症]	20[redacted]-04-14	20	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	RELATED	20[redacted]-04-23	-
AMG 416	20120230-23011010001	FLUID OVERLOAD [水分過負荷]	20[redacted]-04-28	34	SEVERE	YES	-	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-04-29	-
AMG 416	20120230-23011010001	HYPERKALAEMIA [高カリウム血症]	20[redacted]-04-28	34	SEVERE	YES	-	DOSE NOT CHANGED	DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-04-29	-
AMG 416	20120230-23011010001	EXACERBATION OF CONGESTIVE CARDIAC FAILURE (CCF) [うっ血性心不全]	20[redacted]-05-05	41	SEVERE	YES	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-05-05	-
AMG 416	20120230-23011010001	INFECTED RIGHT INDEX FINGER [限局性感染]	20[redacted]-10-25	214	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-10-27	-

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AMG 416	20120230-23011010001	OBSTRUCTED LEFT RV AVF OUTFLOW [動静脈瘻閉塞]	20[redacted]-12-01	251	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-04	-
AMG 416	20120230-23011012003	DIARRHOEA [下痢]	20[redacted]-03-28T12:00	45	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-04-21T12:00	-
AMG 416	20120230-23011012003	CLOTTED FISTULA [動静脈瘻血栓症]	20[redacted]-04-11T08:00	59	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-14	-
AMG 416	20120230-23011012003	LOWER RESPIRATORY TRACT INFECTION [下気道感染]	20[redacted]-04-15T00:05	63	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-03T12:00	-
AMG 416	20120230-23011012003	POST OPERATIVE HAEMATOMA OF LEFT AVF [処置後血腫]	20[redacted]-07-28T16:00	167	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-28T23:00	-
AMG 416	20120230-23011012003	HYPERKALEAMIA [高カリウム血症]	20[redacted]-07-30T07:00	169	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-07-30T13:25 **	-
AMG 416	20120230-23011012005	SPLIT SKIN GRAFT TO ULCER ON LEFT LOWER LEG POSTERIA ASPECT [植皮感染]	20[redacted]-10-21T12:00	-200	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-08	-
AMG 416	20120230-23011012005	ATRIAL FIBRILATION [心房細動]	20[redacted]-12-20T08:50 *	-140	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-12-24T23:59 **	-
AMG 416	20120230-23011012005	NECROTIC ULCER IN THE LATERAL LOWER LEFT LEG [皮膚潰瘍]	20[redacted]-08-28T12:00	112	MODERATE	YES	-	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-29	-

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AMG 416	20120230-23011012005	PERIPHERAL VASCULAR DISEASE- LEFT LEG ULCER [末梢血管障害]	20[redacted]-08-28T12:00 *	112	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-29 **	-
AMG 416	20120230-23011012005	WORSENING OF NECROTIC ARTERIAL ULCER OF LEFT LOWER LEG [皮膚潰瘍]	20[redacted]-12-04T12:00	210	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-08	-
AMG 416	20120230-23013002001	SYNCOPE [失神]	20[redacted]-04-14T18:22	6	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-15T12:00	-
AMG 416	20120230-23013002003	PNEUMONIA [肺炎]	20[redacted]-12-15T06:47	237	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-12-27	-
AMG 416	20120230-23013004001	ABDOMINAL ABCESS WALL [腹壁膿瘍]	20[redacted]-06-04	87	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23013004004	NODULE LEFT LUNG [肺腫瘤]	20[redacted]-06-17	65	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-17	-
AMG 416	20120230-23013004004	AV FISTULA HEMORRAGY ON LEFT ARM [動静脈瘻部位出血]	20[redacted]-07-31T18:00	109	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-31	-
AMG 416	20120230-23013006002	PULMONARY CONGESTION [肺うっ血]	20[redacted]-02-06	28	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	ONGOING	-

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AMG 416	20120230-23013006002	WORSENING AORTIC VALVA INSUFFICIENCY [大動脈弁閉鎖不全症]	20[redacted]-02-14	36	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-09	-
AMG 416	20120230-23013006002	WORSENING CORONARY STENOSIS [冠動脈狭窄]	20[redacted]-02-14	36	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-09	-
AMG 416	20120230-23013006002	KLEBSIELLA SEPSIS ON DIALYSIS CATHETER [医療機器関連敗血症]	20[redacted]-09-24	258	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-11	-
AMG 416	20120230-23013008002	CHILL [悪寒]	20[redacted]-03-17T10:00	1	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-03-17	-
AMG 416	20120230-23013008002	PNEUMONIA [肺炎]	20[redacted]-03-17T10:00	1	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-04-07	-
AMG 416	20120230-23013008002	VOMITING [嘔吐]	20[redacted]-03-17T10:00	1	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, OTHER	NOT RELATED	20[redacted]-03-17	-
AMG 416	20120230-23013008003	DISABLING PAIN IN RIGHT SIDE OF ABDOMEN (PARIETAL APPEARANCE) [腹痛]	20[redacted]-10-26*	196	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-10-29	-
AMG 416	20120230-23013008003	FEMORAL NECK FRACTURE (RIGHT SIDE) [大腿骨頚部骨折]	20[redacted]-01-30T13:00	292	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	ONGOING	-
AMG 416	20120230-23013012001	ABSCESS IN THE AMPUTATION ZONE [術後膿瘍]	20[redacted]-07-11	-146	SEVERE	YES	-	DOSE NOT CHANGED	CULTURE TAKEN, OTHER	NOT RELATED	20[redacted]-12-19	-

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AMG 416	20120230-23013012001	HYPERVOLEMIA [血液量増加症]	20[redacted]-02-09 *	68	SEVERE	YES	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-02-10 *	-
AMG 416	20120230-23013012001	HYPERTHERMIA [高熱]	20[redacted]-02-18 *	77	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-28 *	-
AMG 416	20120230-23013012001	ACUTE PANCREATITIS [急性膵炎]	20[redacted]-03-08 *	95	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-22 *	-
AMG 416	20120230-23013012001	INFECTIOUS ENTERITIS [感染性腸炎]	20[redacted]-08-22	262	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-30	-
AMG 416	20120230-23013012003	SQUAMOUS CELL CARCINOMA EYEBROW [皮膚有棘細胞癌]	20[redacted]-02-05	56	SEVERE	YES	-	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-02-05	-
AMG 416	20120230-23016001004	CORONARY DISEASE OF 3 VESSELS [冠動脈疾患]	20[redacted]-02-17	308	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-02-26	-
AMG 416	20120230-23016001004	UPPER RESPIRATORY TRACT INFECTION [上気道感染]	20[redacted]-03-30T11:07	349	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-03-31T11:48	-
AMG 416	20120230-23016005003	DIABETIC KETOACIDOSIS [糖尿病性ケトアシドーシス]	20[redacted]-06-23	62	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23016005003	DIABETIC KETOACIDOSIS [糖尿病性ケトアシドーシス]	20[redacted]-10-27	188	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-29	-
AMG 416	20120230-23016005003	CONFUSION [錯乱状態]	20[redacted]-11-22	214	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-28	-
AMG 416	20120230-23016005003	SYNCOPE [失神]	20[redacted]-12-01	223	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-

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AMG 416	20120230-23016005003	FRACTURED BONE(RIGHT TALAR NECK) [足骨折]	20[redacted]-12-08	230	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23016005003	TONIC-CLONIC SEIZURE [全身性強直性間代性発作]	20[redacted]-12-22*	244	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23016005003	DELIRIUM [譫妄]	20[redacted]-03-25	337	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23021002001	DUODENAL ULCUS FORREST IB, ENDOSCOPIC HEMOSTASIS [十二指腸潰瘍]	20[redacted]-11-30T11:41	4	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN, TRANSFUSION PERFORMED, OTHER	NOT RELATED	20[redacted]-12-06	-
AMG 416	20120230-23021002001	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-12-07T03:09	11	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-12-08T11:55	-
AMG 416	20120230-23021002004	DIABETES GANGRENE/NECROSIS OF 3RD,4TH,5TH TOE OF LEFT LEG [糖尿病性壊疽]	20[redacted]-05-14	125	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-05	-
AMG 416	20120230-23021002005	EPISTAXIS [鼻出血]	20[redacted]-07-13*	159	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-13*	-
AMG 416	20120230-23021002005	HEMODIALYSIS INDUCED HYPOTENSION [処置による低血圧]	20[redacted]-01-24	354	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-27	-
AMG 416	20120230-23021010007	WORSENING OF BENIGN PROSTATIC HYPERTROPHY. [良性前立腺肥大症]	20[redacted]-09-10T13:40	141	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-10T14:04	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time *	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time *	Outcome of Serious Adverse Event
AMG 416	20120230-23021010007	WORSENING OF BENIGN PROSTATIC HYPERTROPHY [良性前立腺肥大症]	20[redacted]-01-23T07:54 *	276	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-23T08:24	-
AMG 416	20120230-23021010007	UROSEPSIS [尿路性敗血症]	20[redacted]-02-02T09:30	286	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	ONGOING	-
AMG 416	20120230-23021012001	DILOCATION OF FRACTURE FRAGMENTS OF LEFT CLAVICULA BONE [鎖骨骨折]	20[redacted]-06-11	134	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-14	-
AMG 416	20120230-23021012001	STENOSIS OF AV PHISTULA [動静脈瘻部位合併症]	20[redacted]-09-11	226	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-09-12	-
AMG 416	20120230-23021012003	TROMBOSIS OF AV PHISTULA [動静脈瘻血栓症]	20[redacted]-02-27T07:00	8	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-28T12:00	-
AMG 416	20120230-23021012003	RETROMBOSIS OF AV PHISTULA [動静脈瘻血栓症]	20[redacted]-03-04T07:00	13	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-05T12:00	-
AMG 416	20120230-23021012003	ABSENCE OF AV PHISTULA [動静脈瘻部位合併症]	20[redacted]-07-09	140	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-10	-
AMG 416	20120230-23021012003	USELESS HEMODIALYSIS ACCESS [血管確保合併症]	20[redacted]-09-10	203	SEVERE	YES	-	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-11	-
AMG 416	20120230-23021012003	TROMBOSIS OF AV PHISTULA [動静脈瘻血栓症]	20[redacted]-09-18	211	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-09-20	-

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AMG 416	20120230-23021012004	ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-08-11	152	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-08-18	-
AMG 416	20120230-23021012005	STENOSIS OF AV PHISTULA [動静脈瘻部位合併症]	20[redacted]-06-16	96	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-06-28	-
AMG 416	20120230-23021012005	TROMBOSIS OF AV PHISTULA [動静脈瘻血栓症]	20[redacted]-08-07	148	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-08-12	-
AMG 416	20120230-23021012005	STENOSIS OF VENOUS PART OF AV PHISTULA [動静脈瘻部位合併症]	20[redacted]-10-27	229	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-10-28	-
AMG 416	20120230-23021012005	TROMBOSIS OF AV PHISTULA [動静脈瘻血栓症]	20[redacted]-11-15	248	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-11-16	-
AMG 416	20120230-23021012006	CARDIAC INSUFICENCE [心不全]	20[redacted]-08-11	118	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-04T05:10	-
AMG 416	20120230-23025004001	ARTERIOVENOUS FISTULA STENOSIS [動静脈瘻部位合併症]	20[redacted]-05-30T18:30	129	SEVERE	YES	-	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-01	-
AMG 416	20120230-23025004002	FISTULA THROMBOSIS [動静脈瘻血栓症]	20[redacted]-03-27T17:00	64	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-28T18:00	-

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AMG 416	20120230-23025004002	FISTULA THROMBOSIS [動静脈瘻血栓症]	20[redacted]-06-24T14:00	153	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-25T07:00	-
AMG 416	20120230-23025004002	ACUTE CORONARY SYNDROME [急性冠動脈症候群]	20[redacted]-06-26T08:00	155	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-06-26T20:00	-
AMG 416	20120230-23025004002	HYPOGLYCEMIA [低血糖症]	20[redacted]-09-04T13:00	225	SEVERE	YES	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-15	-
AMG 416	20120230-23025004004	ARTERIOVENOUS FISTULA STENOSIS [動静脈瘻部位合併症]	20[redacted]-02-12	323	SEVERE	YES	-	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-02-12T20:00	-
AMG 416	20120230-23025012002	SEPSIS [敗血症]	20[redacted]-08-25	132	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-01	-
AMG 416	20120230-23025012005	SIGMOITIDIS [大腸炎]	20[redacted]-01-26	286	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-02-05	-
AMG 416	20120230-23029004001	CARDIATIC FAILURE [心不全]	20[redacted]-08-03	236	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-06	-
AMG 416	20120230-23029004003	OSTEOMYELITIS PEDIS LATERIS SINISTRI [骨髄炎]	20[redacted]-07-08	216	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, IV ANTIBIOTICS TAKEN, OTHER	NOT RELATED	20[redacted]-08-15	-

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AMG 416	20120230-23029004003	SEPSIS [敗血症]	20[redacted]-08-23	262	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-09-05	-
AMG 416	20120230-23029004003	DECUBITUS OF LEFT LEG [褥瘡性潰瘍]	20[redacted]-09-05	275	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-15	-
AMG 416	20120230-23029004003	SEPSIS [敗血症]	20[redacted]-10-15	315	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-18	-
AMG 416	20120230-23029006004	LEG NUMBNESS [感覚鈍麻]	20[redacted]-04-14T11:30	370	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-21	-
AMG 416	20120230-23029008002	INCREASING OF AORTAL ANEURYSM [大動脈瘤]	20[redacted]-04-28	131	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-10	-
AMG 416	20120230-23029008005	HEARTH FAILURE [心不全]	20[redacted]-11-19	332	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-25	-
AMG 416	20120230-23029008011	SPONDYLARTHROSIS [変形性脊椎症]	20[redacted]-03-20T14:29	30	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-31	-
AMG 416	20120230-23029008013	PNEUMONIA [肺炎]	20[redacted]-02-16	321	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-02	-
AMG 416	20120230-23029010002	RIGHT KIDNEY CLEAR CELL CARCINOMA [腎明細胞癌]	20[redacted]-06-16T11:00	152	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-23T17:04	-

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AMG 416	20120230-23032002006	LT BRACHIO-AXILLAR ARTERIO-VENOUS FISTULOGRAPHY AND THROMBECTOMY ATEMPT OF PREVIOUSLY TROMBOSED AV GRAFT -FAILURE OF THROMBECTOMY (SITE REFUSED TO SPLIT) [処置後合併症]	20[redacted]-05-27T10:34	27	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-05-28T12:29	-
AMG 416	20120230-23032002006	ELECTIVE HOSPITALIZATION FOR CONSTRUCTION OF ARTERIO-VENOUS GRAFT FOR HEMODIALYSIS [動静脈グラフト]	20[redacted]-06-30T10:32	61	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-01T10:00	-
AMG 416	20120230-23032002006	UREMIC SYNDROME [高窒素血症]	20[redacted]-12-07T13:00	221	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-12-16T14:47	-
AMG 416	20120230-23032002009	ACUTE MYOCARDIAL INFRACTION [急性心筋梗塞]	20[redacted]-02-02T12:30	279	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-02-06T12:07	-
AMG 416	20120230-23032004002	RIGHT CAROTID STENOSIS [頚動脈狭窄]	20[redacted]-03-31	335	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-03	-
AMG 416	20120230-23033002003	COMPLICATION OF FISTULA(ARTERIOVENOUS GRAFT FISTULA) [動静脈瘻部位合併症]	20[redacted]-06-13	65	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-06-20	-
AMG 416	20120230-23033002003	COMPLICATION OF FISTULA (STENOSIS OF FISTULA) [動静脈瘻部位合併症]	20[redacted]-07-03	85	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-07-05	-

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AMG 416	20120230-23033002003	STENOSIS OF FISTULA [動静脈瘻部位合併症]	20[redacted]-09-09	153	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-09-13	-
AMG 416	20120230-23033008004	CHOLECISTITIS ALITIASICA [胆嚢炎]	20[redacted]-08-28	234	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-09-07	-
AMG 416	20120230-23033008004	SEPSIS [敗血症]	20[redacted]-08-28	234	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-07	-
AMG 416	20120230-23042004001	SHUNT CLOSE BY THROMBUS [シャント血栓症]	20[redacted]-03-20T08:00	17	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-23T08:00	-
AMG 416	20120230-23042004001	BLADDER WITH PUS [膀胱炎]	20[redacted]-03-23T08:00	20	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-29T08:00 *	-
AMG 416	20120230-23042004001	PNEUMONIA [肺炎]	20[redacted]-12-30T08:00 *	302	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-06T08:00 *	-
AMG 416	20120230-23042004001	RECURRENCE RESPIRATORY INFECTION [気道感染]	20[redacted]-01-15T08:00 *	318	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-23 *	-
AMG 416	20120230-23042004001	RECCURRENCE RESPIRATOR INFECTION [気道感染]	20[redacted]-01-31T08:00	334	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-04T08:00	-

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AMG 416	20120230-23042004001	PERI-ANAL ABSCESS [直腸周囲膿瘍]	20[redacted]-02-18T20:00	352	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-02	-
AMG 416	20120230-23042006002	ACUTE CORONARY SYNDROME [急性冠動脈症候群]	20[redacted]-06-30T19:02	127	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-07-04	-
AMG 416	20120230-23042006003	HERNIA INGUINALIS [鼠径ヘルニア]	20[redacted]-10-20T08:00	182	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-21 *	-
AMG 416	20120230-23042010001	HOSPITALISATION DUE TO SHUNT INFECTION [シャント感染]	20[redacted]-12-30	288	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN, NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-01-06	-
AMG 416	20120230-23048002003	CHRONIC CORONARY HEART DISEASE [冠動脈疾患]	20[redacted]-05-28	45	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-05-30	-
AMG 416	20120230-23048002003	AGGRAVATED ARTERIAL HYPERTENSION [高血圧]	20[redacted]-07-03	81	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-24	-
AMG 416	20120230-23048002003	SUBARACHNOID HEMORRHAGE [くも膜下出血]	20[redacted]-07-03	81	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-24	-
AMG 416	20120230-23048002003	ATRIO-VENTRICULAR BLOCK 3 DEGREE [完全房室ブロック]	20[redacted]-08-19	128	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-09-22	-

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AMG 416	20120230-23048002003	AGGRAVATED DIABETIC FOOT [糖尿病性足病変]	20[redacted]-10-20	190	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	ONGOING	-
AMG 416	20120230-23048002004	AGGRAVATED ARTERIAL HYPERTENSION [高血圧]	20[redacted]-07-14	78	SEVERE	YES	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-07-18	-
AMG 416	20120230-23048002004	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-07-15	79	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-07-18	-
AMG 416	20120230-23048002004	CORONARY HEART DISEASE [冠動脈疾患]	20[redacted]-08-18	113	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23048002004	URINARY TRACT INFECTION [尿路感染]	20[redacted]-08-27	122	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-08-29	-
AMG 416	20120230-23048002004	HEMORRHAGE TO PELVIC [骨盤内出血]	20[redacted]-08-29	124	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-09-12	-
AMG 416	20120230-23048002004	HEART FAILURE [心不全]	20[redacted]-12-10	227	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-22 *	-
AMG 416	20120230-23048002004	PNEUMONIA [肺炎]	20[redacted]-12-31 *	248	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-01-15	-
AMG 416	20120230-23048002004	AGGRAVATED ARTERIAL HYPERTENSION [高血圧]	20[redacted]-01-26 *	274	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING *	-
AMG 416	20120230-23048002004	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-05-11	379	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-15	-
AMG 416	20120230-23048002005	HAEMORRHAGIC STROKE [出血性卒中]	20[redacted]-02-27	411	LIFE THREATENING	YES	Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-02-27	-

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AMG 416	20120230-23048002009	MECHANICAL SUBILEUS [亜イレウス]	20[redacted]-05-24	33	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-10	-
AMG 416	20120230-23048002009	PARAPARESIS BECOUSE OF METASTASES TO THE SPINE [脊椎転移]	20[redacted]-08-28	129	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-17	-
AMG 416	20120230-23048002009	BREAST CANCER [乳癌]	20[redacted]-09-12	144	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-17T21:25	-
AMG 416	20120230-23048004009	PNEUMONIA [肺炎]	20[redacted]-09-25	295	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-10-14	-
AMG 416	20120230-23048004016	POSITIVE HCV ANTIBODIES TEST [C型肝炎抗体陽性]	20[redacted]-04-30	122	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	ONGOING	-
AMG 416	20120230-23048004020	SUDDEN DEATH [突然死]	20[redacted]-11-24	266	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-11-24	-
AMG 416	20120230-23048008001	PARONYCHIA AND LEFT HAND SUBCUTANEOUS TISSUE INFLAMMATION. [皮膚感染]	20[redacted]-05-17	38	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-07-01	-
AMG 416	20120230-23048008001	ALLERGY (PURPURA ALLERGICA) [ヘノッホ・シェーンライン紫斑病]	20[redacted]-05-19	40	SEVERE	YES	-	DRUG WITHDRAWN	MEDICATION TAKEN, OTHER	RELATED	20[redacted]-07-01	-
AMG 416	20120230-23048010001	BLEEDING FROM GI TRACT [胃腸出血]	20[redacted]-05-17T09:30	68	SEVERE	YES	-	DOSE NOT CHANGED	TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-06-10	-
AMG 416	20120230-23048010003	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-01-07T17:00	296	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-12T15:00	-

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AMG 416	20120230-23048010006	BLEEDING ANORECTAL VARICES [肛門直腸静脈瘤出血]	20[redacted]-04-13T14:53	34	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-16T11:00	-
AMG 416	20120230-23048014001	VENTRICULAR FIBRILLATION [心室細動]	20[redacted]-04-08	21	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-04-09T22:00	-
AMG 416	20120230-23048014002	PROSTATE ADENOCARCINOMA [前立腺癌]	20[redacted]-12-23*	322	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	ONGOING	-
AMG 416	20120230-23048014002	VOMITING [嘔吐]	20[redacted]-01-21*	351	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23048014002	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-01-30	360	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23051004002	HOSPITALISATION WITH SICK SINUS SYNDROME [洞結節機能不全]	20[redacted]-03-23	365	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	RELATED	ONGOING	-
AMG 416	20120230-23051006006	CHRONIC PANCREATITIS.ACUTE PHASE [急性膵炎]	20[redacted]-03-20	52	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	NOT RELATED	20[redacted]-03-26	-
AMG 416	20120230-23051006006	DIABETES MELLITUS, DECOMPENSATION [糖尿病]	20[redacted]-03-20	52	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-31	-
AMG 416	20120230-23051006008	ARTERIOVENOUS FISTULA THROMBOSIS [動静脈瘻血栓症]	20[redacted]-03-07	40	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-19	-
AMG 416	20120230-23051006008	ARTERIOVENOUS FISTULA THROMBOSIS [動静脈瘻血栓症]	20[redacted]-08-18	204	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-22	-
AMG 416	20120230-23051006009	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-02-08	5	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-11	-

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AMG 416	20120230-23051006009	PAROXYSM OF ATRIAL FIBRILLATION [心房細動]	20[redacted]-02-08	5	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-18	-
AMG 416	20120230-23051006009	PULMONARY ARTERY THROMBOEMBOLIA [肺塞栓症]	20[redacted]-02-13	10	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-17	-
AMG 416	20120230-23051006009	PULMONARY INFARCTION S 4,5 [肺梗塞]	20[redacted]-02-18	15	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-05	-
AMG 416	20120230-23051006012	RESIDUAL CHOLEDOCHOLITIASIS (PREVIOUSLY OBSTRUCTIVE JAUNDICE) [胆管結石]	20[redacted]-05-06	98	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-19	-
AMG 416	20120230-23058002004	HEMORRHOID [痔核]	20[redacted]-05-30	129	SEVERE	YES	-	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-01	-
AMG 416	20120230-23058002005	HYPERHIDRATATION [水分過負荷]	20[redacted]-03-07T11:59	45	MODERATE	YES	-	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-03-08T23:03	-
AMG 416	20120230-23058002005	ARTERIO-VENOUS FISTULA DYSFUNCTION [動静脈瘻部位合併症]	20[redacted]-05-04	103	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-05-13	-
AMG 416	20120230-23058002005	PHERIPHERAL VERTIGO [回転性めまい]	20[redacted]-05-04	103	MODERATE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	ONGOING	-
AMG 416	20120230-23058002006	BLADDER ADENOCARCINOMA [膀胱腺癌、病期不明]	20[redacted]-01-24	3	SEVERE	YES	-	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-27	-
AMG 416	20120230-23058004007	SEPSIC SHOCK [敗血症性ショック]	20[redacted]-09-12	164	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-12	-

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AMG 416	20120230-23058004014	RENAL CYST INFECTION [腎嚢胞感染]	20[redacted]-08-16	117	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-02	-
AMG 416	20120230-23058008002	STROKE [脳血管発作]	20[redacted]-01-17	54	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-22	-
AMG 416	20120230-23058008002	DEHYDRATION [脱水]	20[redacted]-06-20	208	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-22	-
AMG 416	20120230-23058008002	CARDIAC ARREST [心停止]	20[redacted]-11-22	363	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-11-22	-
AMG 416	20120230-23058008007	AVF THROMBOSIS [動静脈瘻血栓症]	20[redacted]-12-24	6	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-12-28	-
AMG 416	20120230-23058008010	AVF THROMBOSIS [動静脈瘻血栓症]	20[redacted]-03-03	83	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-04	-
AMG 416	20120230-23058008010	ABDOMINAL PAIN [腹痛]	20[redacted]-11-14	339	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-21	-
AMG 416	20120230-23058008011	DIABETIC ULCER IN RIGHT FOOT [糖尿病性足病変]	20[redacted]-05-08	16	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-13	-
AMG 416	20120230-23058010004	CAMPYLOBACTER JEJUNI ACUTE GASTROENTERITIS. DIARRHEA [カンピロバクター胃腸炎]	20[redacted]-08-03T08:00	216	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-11	-
AMG 416	20120230-23058010004	CAMPYLOBACTER JEJUNI ACUTE GASTROENTERITIS. FEVER [カンピロバクター胃腸炎]	20[redacted]-08-03T08:00	216	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-11	-

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AMG 416	20120230-23059002001	DIPLOPIA [複視]	20[redacted]-08-27T02:39	113	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-28T17:30	-
AMG 416	20120230-23059002001	HEADACHE [頭痛]	20[redacted]-08-27T02:39	113	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-28T17:30	-
AMG 416	20120230-23059002001	VERTIGO [回転性めまい]	20[redacted]-08-27T02:39	113	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-28T17:30	-
AMG 416	20120230-23059006001	NON-STEMI [急性心筋梗塞]	20[redacted]-05-04T07:30	11	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-05-04	-
AMG 416	20120230-23059006001	FEVER [発熱]	20[redacted]-05-08 *	15	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-12 *	-
AMG 416	20120230-23059006001	FRACTURE OS NASALE [顔面骨骨折]	20[redacted]-01-11 *	263	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-12 *	-
AMG 416	20120230-23059006001	SYNCOPE [失神]	20[redacted]-01-11	263	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-12	-
AMG 416	20120230-23066004003	UNSTABLE ANGINA [不安定狭心症]	20[redacted]-02-24	120	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-05	-
AMG 416	20120230-23066004003	STUMP BURSITIS [滑液包炎]	20[redacted]-07-07	253	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-10	-
AMG 416	20120230-23066004003	ACUTE HEPATITIS [急性肝炎]	20[redacted]-07-12	258	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-17	-

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AMG 416	20120230-23066004003	ENCEPHALOPATHY [脳症]	20[redacted]-07-12	258	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-17	-
AMG 416	20120230-23066004003	ENCEPHALOPATHY [脳症]	20[redacted]-07-24	270	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-30	-
AMG 416	20120230-23066004007	HYPOGLYCEMIA [低血糖症]	20[redacted]-09-06	335	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-09-07	-
AMG 416	20120230-23066004013	HYPERKALEMIA [高カリウム血症]	20[redacted]-12-10	58	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-11	-
AMG 416	20120230-23066004017	INFLUENZA [インフルエンザ]	20[redacted]-01-05	69	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-08	-
AMG 416	20120230-23066004017	SMALL BOWEL OBSTRUCTION [小腸閉塞]	20[redacted]-01-05	69	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-01-08	-
AMG 416	20120230-23066004017	HYPERKALEMIA [高カリウム血症]	20[redacted]-01-27	91	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-28	-
AMG 416	20120230-23066004017	HYPOGLYCEMIA [低血糖症]	20[redacted]-01-27	91	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-28	-
AMG 416	20120230-23066004017	HYPERKALEMIA [高カリウム血症]	20[redacted]-11-04	372	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-05	-
AMG 416	20120230-23066004017	UREMIA [高窒素血症]	20[redacted]-11-11	379	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-11-13	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120230-23066004022	ISCHEMIC BOWEL [腸管虚血]	20[redacted]-12-24	92	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-12-31	-
AMG 416	20120230-23066004022	SEPSIS [敗血症]	20[redacted]-12-24	92	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-31	-
AMG 416	20120230-23066004024	OSTEOMYELITIS LEFT FIFTH DIGIT [骨髄炎]	20[redacted]-12-12 *	31	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	SURGICAL INTERVENTION, CULTURE TAKEN	NOT RELATED	20[redacted]-12-16 *	-
AMG 416	20120230-23066004024	OSTEOMYELITIS 4TH FINGER [骨髄炎]	20[redacted]-01-03 *	53	SEVERE	YES	-	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-08 *	-
AMG 416	20120230-23066004024	ABSCESS LEFT HAND [四肢膿瘍]	20[redacted]-02-04 *	85	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-02-12 *	-
AMG 416	20120230-23066004024	SEPSIS [敗血症]	20[redacted]-02-04 *	85	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-02-12 *	-
AMG 416	20120230-23066004024	ABDOMINAL WOUND [創傷]	20[redacted]-06-27 *	228	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-07-03 *	-
AMG 416	20120230-23066004024	CELLULITUS - WORSENED [蜂巣炎]	20[redacted]-06-27 *	228	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-03 *	-
AMG 416	20120230-23066004024	PERFORATED CECUM [大腸穿孔]	20[redacted]-08-18 *	280	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-09 *	-
AMG 416	20120230-23066004024	PERITONITIS [腹膜炎]	20[redacted]-08-18	280	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-09	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time *	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time *	Outcome of Serious Adverse Event
AMG 416	20120230-23066004024	SEPSIS [敗血症]	20[redacted]-08-24 *	286	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-09 *	-
AMG 416	20120230-23066004024	ABDOMINAL WOUND BLEEDING [創傷出血]	20[redacted]-11-25 *	379	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-26 *	-
AMG 416	20120230-23066004024	ABDOMINAL WOUND INFECTION [創傷感染]	20[redacted]-11-25	379	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-12-17	-
AMG 416	20120230-23066004028	VIRAL GASTROENTERITIS [ウイルス性胃腸炎]	20[redacted]-06-17	191	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-23	-
AMG 416	20120230-23066006001	EXACERBATION OF CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-03-31	154	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-01	-
AMG 416	20120230-23066006005	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-02-24	127	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-26	-
AMG 416	20120230-23066006005	WORSENING OF HYPERTENSION [高血圧]	20[redacted]-02-24	127	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-26	-
AMG 416	20120230-23066006006	SENSORINEURAL HEARING LOSS [感音性難聴]	20[redacted]-12-17	388	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23066006006	SINUS NODE DISFUNCTION [洞結節機能不全]	20[redacted]-12-17	388	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, OTHER	NOT RELATED	20[redacted]-12-24	-
AMG 416	20120230-23066006008	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-05-19	196	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-20	-
AMG 416	20120230-23066006010	HYPOTENSION [低血圧]	20[redacted]-04-09	163	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-04-18	-

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AMG 416	20120230-23066006018	GASTROINTESTINAL BLEEDING [胃腸出血]	20[redacted]-03-03	15	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-05	-
AMG 416	20120230-23066006018	ASTHMA EXACERBATION [喘息]	20[redacted]-05-12	85	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-18	-
AMG 416	20120230-23066006018	CHRONIC OBSTRUCTIVE PULMONARY DISEASE [慢性閉塞性肺疾患]	20[redacted]-05-12	85	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-18	-
AMG 416	20120230-23066006018	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-05-12	85	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-18	-
AMG 416	20120230-23066006018	ATRIAL FIBRILLATION [心房細動]	20[redacted]-08-05	170	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-10	-
AMG 416	20120230-23066006018	ACUTE GASTROINTESTINAL BLEED [胃腸出血]	20[redacted]-08-12	177	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-08-14	-
AMG 416	20120230-23066006018	ATRIAL FIBRILLATION [心房細動]	20[redacted]-08-12	177	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-16	-
AMG 416	20120230-23066006018	HYPERKALEMIA [高カリウム血症]	20[redacted]-08-12	177	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-16	-
AMG 416	20120230-23066006018	KNEE OSTEOARTHRITIS [変形性関節症]	20[redacted]-10-30*	256	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-11-04*	-
AMG 416	20120230-23066006018	ATRIAL FIBRILLATION [心房細動]	20[redacted]-02-05	354	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-02-06	-
AMG 416	20120230-23066006021	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-05-05	43	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-07	-
AMG 416	20120230-23066006021	CONSTIPATION [便秘]	20[redacted]-05-05	43	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	NOT RELATED	20[redacted]-05-07	-

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AMG 416	20120230-23066006021	HYPERTENSION [高血圧]	20[redacted]-05-05	43	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-07	-
AMG 416	20120230-23066006021	EXACERBATION OF CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-09-07	168	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-09	-
AMG 416	20120230-23066006021	SMALL BOWEL OBSTRUCTION [小腸閉塞]	20[redacted]-10-13 *	204	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-31 *	-
AMG 416	20120230-23066006021	EXACERBATION OF CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-03-09	351	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-13	-
AMG 416	20120230-23066006026	FLUID OVERLOAD [水分過負荷]	20[redacted]-07-09 *	94	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-14 *	-
AMG 416	20120230-23066006026	BACTERIEMIA [菌血症]	20[redacted]-01-05 *	274	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-09 *	-
AMG 416	20120230-23066006026	ENCEPHALOPATHIA [脳症]	20[redacted]-01-05	274	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-09	-
AMG 416	20120230-23066006028	CLOTTED LEFT UPPER ARM GRAFT [血管グラフト血栓症]	20[redacted]-02-05	318	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-02-09	-
AMG 416	20120230-23066006029	UNSPECIFIED CHEST PAIN [胸痛]	20[redacted]-12-25	276	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-27	-
AMG 416	20120230-23066008001	CHEST PAIN [胸痛]	20[redacted]-03-03	125	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-05	-
AMG 416	20120230-23066010007	GASTROINTESTINAL BLEED [胃腸出血]	20[redacted]-09-30	167	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-10-02	-

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AMG 416	20120230-23066010007	HEMORRHAGIC SHOCK [出血性ショック]	20[redacted]-09-30	167	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-10-02	-
AMG 416	20120230-23066010011	CARDIOGENIC SHOCK [心原性ショック]	20[redacted]-05-09	10	MODERATE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	NOT RELATED	20[redacted]-06-18	-
AMG 416	20120230-23066010011	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-05-09	10	SEVERE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-05-09	-
AMG 416	20120230-23066012006	ACUTE CORONARY SYNDROME [急性冠動脈症候群]	20[redacted]-08-28 *	162	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-08-30 *	-
AMG 416	20120230-23066012006	INFLUENZA A [インフルエンザ]	20[redacted]-01-16 *	303	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-19 *	-
AMG 416	20120230-23066012006	FRACTURED TIBIA AND FIBULA RIGHT LEG [下肢骨折]	20[redacted]-02-28 *	346	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-02 *	-
AMG 416	20120230-23066012006	HYPOGLYCEMIA [低血糖症]	20[redacted]-03-07 *	353	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-07 *	-
AMG 416	20120230-23066012006	PERIPHERAL VASCULAR DISEASE [末梢血管障害]	20[redacted]-03-13	359	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-27	-
AMG 416	20120230-23066014018	RESPIRATORY FAILURE [呼吸不全]	20[redacted]-01-31	293	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-02-18	-
AMG 416	20120230-23066014018	SEPSIS [敗血症]	20[redacted]-01-31	293	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-02-18	-
AMG 416	20120230-23066014018	VOLUME OVERLOAD [水分過負荷]	20[redacted]-01-31	293	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-02-18	-

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AMG 416	20120230-23066016005	MYOCARDIAL INFARTION [心筋梗塞]	20[redacted]-11-20	240	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-11-22	-
AMG 416	20120230-23066016007	HEMORRHAGIC RENAL CYST IN LEFT KIDNEY [腎嚢胞出血]	20[redacted]-06-27	171	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-09-25	-
AMG 416	20120230-23066016014	DISKITIS [椎間板炎]	20[redacted]-06-12	44	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-01	-
AMG 416	20120230-23066016014	CELLULITIS RIGHT LEG [蜂巣炎]	20[redacted]-07-07	69	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-10	-
AMG 416	20120230-23066016014	HEMATOMA RIGHT LEG [血腫]	20[redacted]-07-07	69	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-10	-
AMG 416	20120230-23066020001	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-04-28	55	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-30	-
AMG 416	20120230-23066020001	HYPERKALEMIA [高カリウム血症]	20[redacted]-04-28	55	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23066020001	RESPIRATORY ARREST [呼吸停止]	20[redacted]-04-28	55	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-29	-
AMG 416	20120230-23066020001	BLEEDING FROM AV FISTULA [動静脈瘻部位出血]	20[redacted]-10-09	219	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-09	-

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AMG 416	20120230-23066020001	BLEEDING FROM AV FISTULA [動静脈瘻部位出血]	20[redacted]-11-06	247	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-07	-
AMG 416	20120230-23066020001	BLEEDING FROM AV FISTULA [動静脈瘻部位出血]	20[redacted]-11-08	249	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-21	-
AMG 416	20120230-23066020003	UREMIA [高窒素血症]	20[redacted]-11-07	220	MILD	YES	-	DOSE ALTERED OR WITHHELD	OTHER	NOT RELATED	20[redacted]-11-13	-
AMG 416	20120230-23066020003	ABDOMINAL PAIN [腹痛]	20[redacted]-11-09	222	MILD	YES	-	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	NOT RELATED	20[redacted]-11-13	-
AMG 416	20120230-23066020003	CHEST PAIN (UNKNOWN) [胸痛]	20[redacted]-11-09	222	MILD	YES	-	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	NOT RELATED	20[redacted]-11-13	-
AMG 416	20120230-23066020003	HYPERKALEMIA [高カリウム血症]	20[redacted]-11-09	222	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-13	-
AMG 416	20120230-23066022014	SEPTIC SHOCK [敗血症性ショック]	20[redacted]-04-09	382	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-12	-
AMG 416	20120230-23066022014	SEPTICEMIA [敗血症]	20[redacted]-04-09	382	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-12	-
AMG 416	20120230-23066022014	SIGMOID PERFORATION DIVERTICULOSIS [憩室穿孔]	20[redacted]-04-11	384	MODERATE	YES	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-04-15	-
AMG 416	20120230-23066022014	ACUTE MULTIFACTORIAL ENCEPHALOPATHY [脳症]	20[redacted]-04-23	396	MODERATE	YES	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-04-23	-
AMG 416	20120230-23066022014	POSTOPERATIVE PANCREATITIS [膵炎]	20[redacted]-04-23	396	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-12	-
AMG 416	20120230-23066022019	CLOTTED AV GRAFT [血管グラフト血栓症]	20[redacted]-03-28	38	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-07	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120230-23066024005	CHEST PAIN OF NON-CARDIAC ORIGIN [非心臓性胸痛]	20[redacted]-02-09	349	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-10	-
AMG 416	20120230-23066024005	HYPERKALEMIA [高カリウム血症]	20[redacted]-02-09	349	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-10	-
AMG 416	20120230-23066028005	CORONARY ARTERY DISEASE [冠動脈疾患]	20[redacted]-05-23T12:00	31	SEVERE	YES	-	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-26T12:00	-
AMG 416	20120230-23066028006	ACUTE RESPIRATORY FAILURE [急性呼吸不全]	20[redacted]-12-15T12:00	237	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-29T12:00	-
AMG 416	20120230-23066032001	ACUTE FRACTURE RIGHT INFERIOR CALCANEOUS [足骨折]	20[redacted]-02-25	100	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER	NOT RELATED	ONGOING	-
AMG 416	20120230-23066032001	WORSENING AORTIC VALVULAR DISEASE [大動脈弁疾患]	20[redacted]-08-19	275	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-08-21	-
AMG 416	20120230-23066032001	HYPERKALEMIA [高カリウム血症]	20[redacted]-11-19	367	SEVERE	YES	-	DOSE NOT CHANGED	DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-11-20	-
AMG 416	20120230-23066032001	SUPRAVENTRICULAR TACHYCARDIA [上室性頻脈]	20[redacted]-11-19	367	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-19	-
AMG 416	20120230-23066032004	WORSENED ENDSTAGE RENAL DISEASE [慢性腎臓病]	20[redacted]-05-28	164	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, OTHER	NOT RELATED	20[redacted]-06-13	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120230-23066032004	LARGE PERIRENAL HEMATOMA [腎周囲血腫]	20[redacted]-05-29T11:57	165	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-30T00:20	-
AMG 416	20120230-23066032005	CARDIOPULMONARY ARREST [心肺停止]	20[redacted]-03-18	79	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-18	-
AMG 416	20120230-23066032005	HYPERKALEMIA [高カリウム血症]	20[redacted]-03-18	79	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-18	-
AMG 416	20120230-23066032005	CARDIAC ARREST [心停止]	20[redacted]-03-22	83	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	20[redacted]-03-22	-
AMG 416	20120230-23066032006	CEREBROVASCULAR ACCIDENT [脳血管発作]	20[redacted]-12-04*	-40	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING*	-
AMG 416	20120230-23066032006	PNEUMONIA [肺炎]	20[redacted]-02-12*	31	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-14*	-
AMG 416	20120230-23066032006	UPPER RESPIRATORY INFECTION [上気道感染]	20[redacted]-12-08	330	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-15	-
AMG 416	20120230-23066034002	TIA [一過性脳虚血発作]	20[redacted]-11-06T08:00	198	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-12T12:00	-
AMG 416	20120230-23066034009	HYPOTENSION [低血圧]	20[redacted]-11-01T14:00	188	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-06T12:00	-
AMG 416	20120230-23066034009	TRANSIENT ALTERATION IN CONSCIOUSNESS [意識変容状態]	20[redacted]-11-01T14:00	188	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-06T12:00	-

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AMG 416	20120230-23066034010	CARDIAC ARREST [心停止]	20[redacted]-11-03T13:06	190	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-11-03T14:30	-
AMG 416	20120230-23066036002	PSEUDOANEURYSOM OF THE A-V GRAFT [移植血管合併症]	20[redacted]-11-15 *	9	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, OTHER	NOT RELATED	20[redacted]-11-17	-
AMG 416	20120230-23066036002	INFECTION OF THE LEFT A-V GRAFT [動静脈グラフト部位感染]	20[redacted]-04-03 *	148	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-04-14 *	-
AMG 416	20120230-23066036002	LEFT A-V GRAFT INFECTION S/P REVISION [動静脈グラフト部位感染]	20[redacted]-05-01 *	176	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-14 *	-
AMG 416	20120230-23066036002	LEFT ARM A-V GRAFT INFECTION (WOUND EXPLORATION & EXCISION OF THE REMNANTS OF TEH A-V GRAFT) [動静脈グラフト部位感染]	20[redacted]-07-08	244	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-07-11	-
AMG 416	20120230-23066036004	TRACHEITIS [気管炎]	20[redacted]-03-31	106	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-04	-
AMG 416	20120230-23066036004	TRACHEOSTOMY SITE PAIN [ストーマ部疼痛]	20[redacted]-05-07	143	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-17	-
AMG 416	20120230-23066036004	PNEUMONIA TRACHEITIS [細菌性気管炎]	20[redacted]-07-30	227	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-07	-
AMG 416	20120230-23066036004	HERPES ZOSTER [帯状疱疹]	20[redacted]-08-15	243	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-18	-

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AMG 416	20120230-23066036016	MEDICATION REACTION [医薬品副作用]	20[redacted]-03-08	87	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-03-09	-
AMG 416	20120230-23066036019	DIVERTICULITIS [憩室炎]	20[redacted]-09-22	230	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-28	-
AMG 416	20120230-23066042001	ACUTE TRACHEOBRONCHITIS [気管気管支炎]	20[redacted]-01-12	336	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-17	-
AMG 416	20120230-23066042001	ATRIAL FIBRILLATION [心房細動]	20[redacted]-01-12	336	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-17	-
AMG 416	20120230-23066042001	THROMBOCYTOPENIA [血小板減少症]	20[redacted]-01-12	336	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-17	-
AMG 416	20120230-23066042002	HYPOGLYCEMIA [低血糖症]	20[redacted]-01-28	37	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-02-02	-
AMG 416	20120230-23066042002	HYPOGLYCEMIA [低血糖症]	20[redacted]-02-09	49	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-14	-
AMG 416	20120230-23066042002	HEMATEMESIS [吐血]	20[redacted]-03-31	99	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-02 *	-
AMG 416	20120230-23066042002	NSTEMI [急性心筋梗塞]	20[redacted]-12-29	372	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-02 *	-
AMG 416	20120230-23066042002	URINARY TRACT INFECTION [尿路感染]	20[redacted]-12-29	372	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-02	-
AMG 416	20120230-23066042006	GI HEMORRHAGE [胃腸出血]	20[redacted]-04-18	81	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-04-20	-

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AMG 416	20120230-23066042006	GI HEMORRHAGE [胃腸出血]	20[redacted]-09-12	228	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-14	-
AMG 416	20120230-23066046007	GASTRITIS [胃炎]	20[redacted]-06-21	176	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-23	-
AMG 416	20120230-23066046008	SUSPECTED METASTATIC LUNG CANCER [遠隔転移を伴う肺癌]	20[redacted]-01-16	20	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-29	-
AMG 416	20120230-23066046008	WORSENING ABDOMINAL PAIN [腹痛]	20[redacted]-01-16	20	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-29	-
AMG 416	20120230-23066052003	CARDIOMYOPATHY [心筋症]	20[redacted]-01-10	18	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-12	-
AMG 416	20120230-23066052008	CORONARY ARTERY STENOSIS [冠動脈狭窄]	20[redacted]-11-11*	308	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-22*	-
AMG 416	20120230-23066052008	GASTROENTERITIS [胃腸炎]	20[redacted]-01-19	377	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-21	-
AMG 416	20120230-23066056001	FEVER OF UNKNOWN ORIGIN [発熱]	20[redacted]-07-06	147	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-10	-
AMG 416	20120230-23066056002	RESPIRATORY FAILURE [呼吸不全]	20[redacted]-08-03	175	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-10	-
AMG 416	20120230-23066056003	ATYPICAL CHEST PAIN [胸痛]	20[redacted]-12-20	320	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-21	-

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AMG 416	20120230-23066056003	CHEST PAIN [胸痛]	20[redacted]-12-22	322	MILD	YES	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-12-23 *	-
AMG 416	20120230-23066056003	PSUEDOANEURYSM OFF THE LEFT FEMORAL ARTERY [血管偽動脈瘤]	20[redacted]-12-30 *	330	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-01 *	-
AMG 416	20120230-23066056003	CHOLELITHIASIS [胆石症]	20[redacted]-01-19	350	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-22	-
AMG 416	20120230-23066056005	WORSENING HYPERKALEMIA [高カリウム血症]	20[redacted]-02-10	7	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-02-25	-
AMG 416	20120230-23066056005	HYPOTESION [低血圧]	20[redacted]-04-01	57	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-11	-
AMG 416	20120230-23066056005	BRADYCARDIC [徐脈]	20[redacted]-04-01T15:15	57	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-11	-
AMG 416	20120230-23066056005	CLOTTED FEMORAL GRAFT [移植片血栓症]	20[redacted]-04-12	68	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-16	-
AMG 416	20120230-23066056005	RESPIRATORY FAILURE [呼吸不全]	20[redacted]-04-16	72	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-25	-
AMG 416	20120230-23066056008	ALTERED LEVEL OF CONSCIOUSNESS [意識変容状態]	20[redacted]-03-13	59	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-16	-
AMG 416	20120230-23066056008	METABOLIC ENCEPHALOPATHY [代謝性脳症]	20[redacted]-05-19	126	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-22	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120230-23066056011	VERTIGO [回転性めまい]	20[redacted]-09-16 *	212	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-21 *	-
AMG 416	20120230-23066056011	WORSENING HIP ARTHRITIS [関節炎]	20[redacted]-02-11	360	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-12	-
AMG 416	20120230-23066056015	PARTIAL SMALL BOWEL OBSTRUCTION [小腸閉塞]	20[redacted]-03-21 *	26	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-27 *	-
AMG 416	20120230-23066056015	RIGHT CHRONIC TIBIAL PLATEAU FRACTURE [脛骨骨折]	20[redacted]-02-16	358	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-24	-
AMG 416	20120230-23066078001	GASTROENTERITIS [胃腸炎]	20[redacted]-04-02T07:46	36	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-04-03T14:35	-
AMG 416	20120230-23066078001	FEVER OF UNKNOWN ORIGIN [発熱]	20[redacted]-09-12	199	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-09-15	-
AMG 416	20120230-23066078001	LARGE LEFT PLEURAL EFFUSION [胸水]	20[redacted]-11-18 *	266	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	ONGOING *	-
AMG 416	20120230-23066078001	BRONCHITIS [気管支炎]	20[redacted]-01-28	337	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-31	-
AMG 416	20120230-23066078012	UNCONTROLLED HYPERTENSION [高血圧]	20[redacted]-04-23	17	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-26	-

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AMG 416	20120230-23066078012	CEREBRAL VASCULAR ACCIDENT [脳血管発作]	20[redacted]-03-07 *	335	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-03-13 *	-
AMG 416	20120230-23066078012	ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-03-12 *	340	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-13 *	-
AMG 416	20120230-23066078014	ERYSIPELAS NOSE [丹毒]	20[redacted]-04-26T15:51 *	20	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-04-29T11:30 *	-
AMG 416	20120230-23066078014	PULMONARY EDEMA [肺水腫]	20[redacted]-03-01T21:43	329	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-03T14:35	-
AMG 416	20120230-23066080003	ABDOMINAL PAIN [腹痛]	20[redacted]-09-05	169	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-10	-
AMG 416	20120230-23066080003	NON-CARDIAC CHEST PAIN [非心臓性胸痛]	20[redacted]-09-05	169	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-10	-
AMG 416	20120230-23066084004	BILATERAL PLEURAL EFFUSION [胸水]	20[redacted]-09-08	209	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-23	-
AMG 416	20120230-23066084004	CONSTIPATION [便秘]	20[redacted]-09-08	209	MODERATE	YES	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-23	-
AMG 416	20120230-23066084004	POORLY DIFFERENTIATED CARCINOMA; UNKNOWN PRIMARY [悪性新生物]	20[redacted]-09-08	209	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-23	-

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AMG 416	20120230-23066084004	RIGHT LOWER LOBE PULMONARY EMBOLUS [肺塞栓症]	20[redacted]-09-23	224	LIFE THREATENING	YES	Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-23	-
AMG 416	20120230-23066102005	HYPOXIA [低酸素症]	20[redacted]-05-10	25	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-13	-
AMG 416	20120230-23066102005	GENERALIZED WEAKNESS [無力症]	20[redacted]-05-10T15:42	25	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-13	-
AMG 416	20120230-23066102005	ATRIAL FLUTTER [心房粗動]	20[redacted]-05-28	43	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-31	-
AMG 416	20120230-23066104004	ARTERIAL VENOUS MALFORMATION DUODENUM [胃腸血管奇形]	20[redacted]-04-16	59	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-04-20	-
AMG 416	20120230-23066104004	GASTRIC ANTRAL VASCULAR ECTASIA [胃前庭部毛細血管拡張症]	20[redacted]-04-16	59	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-04-20	-
AMG 416	20120230-23066104004	WORSENED CHRONIC ANEMIA [貧血]	20[redacted]-07-17	151	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-07-18	-
AMG 416	20120230-23066104004	BLEEDING GASTRIC ANTRAL VASCULAR ECTASIA [胃出血]	20[redacted]-08-14	179	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-08-16	-

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AMG 416	20120230-23066104004	ANEMIA [貧血]	20[redacted]-09-20	216	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-09-23	-
AMG 416	20120230-23066104004	GASTRIC ANTRAL VASCULAR ECTASIA [胃前庭部毛細血管拡張症]	20[redacted]-09-20	216	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-09-23	-
AMG 416	20120230-23066104004	SYMPTOMATIC ANEMIA [貧血]	20[redacted]-01-14 *	332	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-01-15 *	-
AMG 416	20120230-23066104006	NON HEALING ULCER OF LEFT FOOT [治癒不良]	20[redacted]-04-23	63	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-25	-
AMG 416	20120230-23066104006	UNHEALING ULCER OF LEFT FOOT [皮膚潰瘍]	20[redacted]-04-23	63	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-25	-
AMG 416	20120230-23066104006	OSTEOMYELITIS OF LEFT LEG [骨髄炎]	20[redacted]-05-15	85	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-20	-
AMG 416	20120230-23066104011	LEFT HALLUX ULCER [皮膚潰瘍]	20[redacted]-10-22	177	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-10-31	-

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AMG 416	20120230-23066104012	CHOLELITHIASIS [胆石症]	20[redacted]-02-24	-77	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-03	-
AMG 416	20120230-23066104012	COMPLICATIONS WITH WOUNDS OF BILATERAL FOOT BURNS [熱傷]	20[redacted]-06-24	44	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23066104012	COMPLICATIONS WITH FEET WOUNDS [創合併症]	20[redacted]-09-19	131	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23066104012	INFECTION OF RIGHT FOOT CHRONIC NON-HEALING ULCERATION [感染性皮膚潰瘍]	20[redacted]-12-02	205	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-12-05	-
AMG 416	20120230-23066104012	OSTEOMYELITIS OF RIGHT CALCANEOUS [骨髄炎]	20[redacted]-12-02	205	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-12-05	-
AMG 416	20120230-23066130008	HYPERTENSIVE EMERGENCY [高血圧緊急症]	20[redacted]-08-26	134	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-08-29	-
AMG 416	20120230-23066130008	PULMONARY EDEMA [肺水腫]	20[redacted]-08-26	134	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-08-29	-
AMG 416	20120230-23066130008	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-08-26	134	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-08-29	-
AMG 416	20120230-23066132002	HYPERTENSION [高血圧]	20[redacted]-07-07	106	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-10	-
AMG 416	20120230-23066132002	DIZZINESS [浮動性めまい]	20[redacted]-08-01	131	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-08-03	-

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AMG 416	20120230-23066132002	ACINETOBACTER BAUMANNI [アシネトバクター感染]	20[redacted]-02-08 *	322	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-13 *	-
AMG 416	20120230-23066132002	ACUTE ENCEPHALOPATHY [脳症]	20[redacted]-02-08 *	322	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-13 *	-
AMG 416	20120230-23066132002	CHOLECYSTITIS [胆嚢炎]	20[redacted]-02-08	322	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-13	-
AMG 416	20120230-23066132003	URINARY TRACT INFECTION [尿路感染]	20[redacted]-01-21	288	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-28	-
AMG 416	20120230-23066132005	GASTROPATHY [胃障害]	20[redacted]-05-07	22	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-05-13	-
AMG 416	20120230-23066132005	ENDOCARDITIS [心内膜炎]	20[redacted]-08-25	132	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-21	-
AMG 416	20120230-23066132005	ATRIAL FIBRILLATION [心房細動]	20[redacted]-09-08	146	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-09	-
AMG 416	20120230-23066132005	DISKITIS [椎間板炎]	20[redacted]-09-08	146	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-07	-
AMG 416	20120230-23066132005	TRICUSPID REGURGITATION [三尖弁閉鎖不全症]	20[redacted]-09-08	146	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23066132005	ATRIAL FLUTTER [心房粗動]	20[redacted]-11-04	203	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-09	-
AMG 416	20120230-23066150001	ULCER RIGHT FOOT [皮膚潰瘍]	20[redacted]-11-21	-90	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-

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AMG 416	20120230-23066150001	RIGHT FOOT ULCER [皮膚潰瘍]	20[redacted]-06-06 **	108	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-13 **	-
AMG 416	20120230-23066150001	SYNCOPE [失神]	20[redacted]-01-07	323	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-08	-
AMG 416	20120230-23066150003	ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-12-12	234	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-23	-
AMG 416	20120230-23066150003	SHINGLES [帯状疱疹]	20[redacted]-12-16 *	238	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-23 *	-
AMG 416	20120230-23066150003	SEPSIS [敗血症]	20[redacted]-01-12	265	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-17	-
AMG 416	20120230-23066150005	BELL'S PALSY [第７脳神経麻痺]	20[redacted]-01-21	-92	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-30	-
AMG 416	20120230-23066150008	BACTERIMIA [菌血症]	20[redacted]-06-09	111	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-16	-
AMG 416	20120230-23066150008	LEFT PLEURAL EFFUSION [胸水]	20[redacted]-06-27	129	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-30	-
AMG 416	20120230-23066150008	PNEUMONIA [肺炎]	20[redacted]-06-27	129	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-30	-
AMG 416	20120230-23066150008	BACTERIAL PNEUMONIA [細菌性肺炎]	20[redacted]-12-08	293	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-12	-
AMG 416	20120230-23066152004	CHEST PAIN, NON-CARDIAC [非心臓性胸痛]	20[redacted]-05-21	99	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-24	-
AMG 416	20120230-23066152011	ESOPHAGITIS, ACUTE [食道炎]	20[redacted]-06-27	107	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-04	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120230-23066152011	UPPER GI BLEED [上部消化管出血]	20[redacted]-06-27	107	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-04	-
AMG 416	20120230-23066152011	VISUAL HALLUCINATIONS SECONDARY TO BACLOFEN USAGE [幻視]	20[redacted]-06-27	107	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-04	-
AMG 416	20120230-23066152011	COMPRESSION FRACTURE OF L2 [腰椎骨折]	20[redacted]-07-02 *	112	MODERATE	YES	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-07-02	-
AMG 416	20120230-23066152011	LEFT HIP FRACTURE [股関節部骨折]	20[redacted]-01-17	311	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23066152012	NON ST ELEVATION MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-03-29 *	24	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-16 *	-
AMG 416	20120230-23066152012	FLUID OVERLOAD [水分過負荷]	20[redacted]-01-05 *	306	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-06 *	-
AMG 416	20120230-23066152012	PULMONARY EDEMA [肺水腫]	20[redacted]-01-05 *	306	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-06 *	-
AMG 416	20120230-23066152012	NON-ST ELEVATED MYOCARDIAL INFAARCTION [急性心筋梗塞]	20[redacted]-01-16 *	317	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-01-20 *	-
AMG 416	20120230-23066152012	CHEST PAIN-CARDIAC [狭心症]	20[redacted]-01-26	327	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-28	-
AMG 416	20120230-23066152013	CHEST PAIN [胸痛]	20[redacted]-03-11T07:00	27	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-12	-
AMG 416	20120230-23066152013	ACUTE BLOOD LOSS ANEMIA [出血性貧血]	20[redacted]-05-24	101	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-05-27	-

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AMG 416	20120230-23066152013	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-10-19	249	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-22	-
AMG 416	20120230-23066152013	HYPERTENSIVE CRISIS [高血圧クリーゼ]	20[redacted]-10-19	249	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-22	-
AMG 416	20120230-23066152018	EXASCERBATION OF CHRONIC VASCULITIS [血管炎]	20[redacted]-10-07	202	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-09	-
AMG 416	20120230-23066152018	WORSENED MUSCULOSKELETAL PAIN [筋骨格痛]	20[redacted]-10-07	202	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-09	-
AMG 416	20120230-23066152022	SEVERE HYPERKALEMIA [高カリウム血症]	20[redacted]-04-15	5	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-04-16	-
AMG 416	20120230-23066152022	WORSENED VIRAL SYNDROME (UNSPECIFIED) [ウイルス感染]	20[redacted]-08-25	137	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-08-26	-
AMG 416	20120230-23066152022	ACUTE APPENDICITIS [虫垂炎]	20[redacted]-10-28	201	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23066152022	RECTAL BLEEDING [直腸出血]	20[redacted]-12-04	238	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-06	-
AMG 416	20120230-23066166005	CONTUSION WITH INTACT SKIN- SCALP LEFT [挫傷]	20[redacted]-02-04T11:30	16	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER	NOT RELATED	20[redacted]-02-07T10:00	-
AMG 416	20120230-23066166005	SUBDURAL HEMATOMA [硬膜下血腫]	20[redacted]-02-04T11:30	16	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-02-07T10:00	-

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AMG 416	20120230-23066166005	ELEVATED INR WITH COUMADIN [国際標準比増加]	20[redacted]-02-04T12:59	16	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-02-05T04:32	-
AMG 416	20120230-23066166005	RHABDOMYOLYSIS [横紋筋融解症]	20[redacted]-05-22	123	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-06-12T02:20	-
AMG 416	20120230-23066166005	ACUTE HYPOXIC RESPIRATORY FAILURE RELATED TO UNRESPONSIVE EPISODE REQUIRING INTUBATION TO FOR AIRWAY PROTECTION [呼吸不全]	20[redacted]-05-25	126	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-05-27	-
AMG 416	20120230-23066166005	BRADYCARDIA [徐脈]	20[redacted]-05-25	126	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-27	-
AMG 416	20120230-23066166005	HYPOTENSION [低血圧]	20[redacted]-05-25	126	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-27	-
AMG 416	20120230-23066166005	UNRESPONSIVE EPISODE [意識消失]	20[redacted]-05-25	126	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-27	-
AMG 416	20120230-23066166005	CHEST PAIN-CARDIAC (ANGINA) [狭心症]	20[redacted]-06-11T14:12	143	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-11T17:53	-
AMG 416	20120230-23066166005	COLON POLYPS [大腸ポリープ]	20[redacted]-08-09	202	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER	NOT RELATED	20[redacted]-12-17	-

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AMG 416	20120230-23066166005	GASTRITIS [胃炎]	20[redacted]-08-15	208	MILD	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-08-20	-
AMG 416	20120230-23066166005	HEMATURIA [血尿]	20[redacted]-08-16	209	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER	NOT RELATED	20[redacted]-08-20	-
AMG 416	20120230-23066166005	FAILURE TO THRIVE [成長障害]	20[redacted]-12-11	326	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-12-17	-
AMG 416	20120230-23066166005	MALNUTRITION RELATED TO FAILURE TO THRIVE [栄養障害]	20[redacted]-12-11	326	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-12-17	-
AMG 416	20120230-23066202003	METOMENNORHAGIA WITH PAIN [月経過多]	20[redacted]-05-07	56	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23066202003	BILATERAL LOWER ABDOMINAL PAIN [下腹部痛]	20[redacted]-05-29	78	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23066202003	NAUSEA WITH EMESIS [嘔吐]	20[redacted]-05-30T22:27	79	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120230-23066202003	ACUTE ABDOMINAL PAIN [腹痛]	20[redacted]-06-20T07:30	100	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-06-21T07:44	-

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AMG 416	20120230-23066202003	METABOLIC ACIDOSIS [代謝性アシドーシス]	20[redacted]-06-20T18:15	100	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-26T10:45	-
AMG 416	20120230-23066202003	RIGHT-SIDED PARATUBAL HEMORRHAGIC CYST [出血性嚢胞]	20[redacted]-06-20T21:34	100	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-21T07:44	-
AMG 416	20120230-23066202003	TORSED ROUX LIMB SECONDARY TO SINGLE ADHESION [腹部癒着]	20[redacted]-06-20T21:34	100	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-21T07:44	-
AMG 416	20120230-23066202003	CELLULITIS OF RT LEG [蜂巣炎]	20[redacted]-12-11T20:38 *	274	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	ONGOING *	-
AMG 416	20120230-23066202003	CHOLECYSTITIS [胆嚢炎]	20[redacted]-03-11 *	364	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-13 *	-
AMG 416	20120230-23066202003	CALCULUS OF GALLBLADDER [胆石症]	20[redacted]-03-11T19:40 *	364	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-13 *	-
AMG 416	20120230-23066202003	CHEST PAIN(NON CARDIAC) [非心臓性胸痛]	20[redacted]-03-11T19:40	364	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-13	-
AMG 416	20120230-23066232007	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-08-23T15:57	124	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-26T10:30	-
AMG 416	20120359-35966002004	ISCHEMIC COLITIS [虚血性大腸炎]	20[redacted]-01-10	3	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-26	-

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AMG 416	20120359-35966002004	HEMATEMESIS [吐血]	20[redacted]-03-27	79	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-28	-
AMG 416	20120359-35966002004	HEMORRHAGIC GASTRITIS [出血性胃炎]	20[redacted]-03-27	79	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-31T15:04	-
AMG 416	20120359-35966002004	ACUTE PULMONARY EMBOLUS [肺塞栓症]	20[redacted]-03-31T14:40	83	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-03-31T15:04	-
AMG 416	20120359-35966002007	BILATERAL DIABETIC FOOT ULCERS [糖尿病性足病変]	20[redacted]-10-06	272	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, OTHER	NOT RELATED	ONGOING	-
AMG 416	20120359-35966002007	SEPSIS [敗血症]	20[redacted]-10-08	274	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-10-16	-
AMG 416	20120359-35966004001	RIGHT ANKLE FRACTURE BIMALLEOLAR [足関節部骨折]	20[redacted]-06-20	127	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-25	-
AMG 416	20120359-35966004001	FEVER [発熱]	20[redacted]-07-10	147	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	NOT RELATED	20[redacted]-07-21	-
AMG 416	20120359-35966004001	RIGHT ANKLE DEHISCENE [創離開]	20[redacted]-07-10	147	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-07-21	-

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AMG 416	20120359-35966004001	RIGHT ANKLE PAIN [関節痛]	20[redacted]-07-10	147	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-07-21	-
AMG 416	20120359-35966004001	SEPSIS [敗血症]	20[redacted]-07-10	147	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-07-21	-
AMG 416	20120359-35966004001	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-07-31	168	MODERATE	YES	-	DOSE NOT CHANGED	UNKNOWN	NOT RELATED	20[redacted]-08-05	-
AMG 416	20120359-35966004001	PNEUMONIA [肺炎]	20[redacted]-07-31	168	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-08-05	-
AMG 416	20120359-35966004001	SEPSIS [敗血症]	20[redacted]-07-31	168	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-08-05	-
AMG 416	20120359-35966004001	URINARY TRACT INFECTION [尿路感染]	20[redacted]-07-31	168	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-08-05	-
AMG 416	20120359-35966004001	ORTHOSTATIC HYPOTENSION [起立性低血圧]	20[redacted]-10-29	258	MODERATE	YES	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-31	-
AMG 416	20120359-35966004001	SYNCOPE [失神]	20[redacted]-10-29	258	MODERATE	YES	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-31	-
AMG 416	20120359-35966004003	BLEEDING FISTULA [動静脈瘻部位出血]	20[redacted]-05-05	77	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-07	-
AMG 416	20120359-35966004003	CHRONIC ANEMIA [貧血]	20[redacted]-05-05*	77	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-07	-
AMG 416	20120359-35966004003	GI BLEED [胃腸出血]	20[redacted]-01-06	323	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120359-35966006001	NEPHROSCLEROSIS [腎硬化症]	20[redacted]-10-07	266	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-13	-
AMG 416	20120359-35966006003	ATAXIA [運動失調]	20[redacted]-02-10T07:30	22	MILD	YES	-	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	NOT RELATED	20[redacted]-02-14	-
AMG 416	20120359-35966010004	GASTRITIS WTIH HEMATEMESIS [出血性胃炎]	20[redacted]-03-06T22:00	37	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-11	-
AMG 416	20120359-35966010004	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-03-30	61	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-04	-
AMG 416	20120359-35966010004	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-08-20	204	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-08-26	-
AMG 416	20120359-35966010004	NON CARDIAC CHEST PAIN [非心臓性胸痛]	20[redacted]-09-08	223	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-13	-
AMG 416	20120359-35966010004	CERVICAL FRACTURE [頚椎骨折]	20[redacted]-10-03	248	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	ONGOING	-
AMG 416	20120359-35966010004	NON-CARDIAC CHEST PAIN [非心臓性胸痛]	20[redacted]-11-09T13:50	285	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-14	-
AMG 416	20120359-35966010004	ACUTE ON CHRONIC DIASTOLIC CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-11-30	306	SEVERE	YES	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-12-02	-
AMG 416	20120359-35966010006	TORN ROTATOR CUFF RIGHT SHOULDER [肩回旋筋腱板症候群]	20[redacted]-07-24	177	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-26	-

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AMG 416	20120359-35966015006	BILATERAL RENAL STONES [腎結石症]	20[redacted]-03-06	31	SEVERE	YES	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	ONGOING	-
AMG 416	20120359-35966015006	LEUKOCYTOSIS [白血球増加症]	20[redacted]-03-06	31	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-10	-
AMG 416	20120359-35966015006	RENAL COLIC [腎仙痛]	20[redacted]-03-06	31	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-10	-
AMG 416	20120359-35966015006	HYPERKALEMIA [高カリウム血症]	20[redacted]-04-12T09:00	68	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-16T10:00	-
AMG 416	20120359-35966018003	ABDOMINAL PAIN EPIGASTRIC [上腹部痛]	20[redacted]-04-24T20:03	80	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-28T13:37	-
AMG 416	20120359-35966018003	ANGINA PECTORIS [狭心症]	20[redacted]-04-24T20:03	80	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-28T13:37	-
AMG 416	20120359-35966018003	SHORTNESS OF BREATH-SUBJECT ADMITTED FOR FURTHER OBSERVATION ON SAE DATE, NO MI OCCURRED OR UNDERLYING CAUSE KNOWN. [呼吸困難]	20[redacted]-04-24T20:03	80	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-28T13:37	-
AMG 416	20120359-35966018003	GASTRO INTESTINAL BLEED [胃腸出血]	20[redacted]-08-21T13:56	199	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-28	-
AMG 416	20120359-35966018003	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-08-21T13:56	199	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-28	-

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AMG 416	20120359-35966018003	CARDIAC CHEST PAIN [狭心症]	20[redacted]-09-28	237	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-30	-
AMG 416	20120359-35966018003	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-10-16	255	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-22	-
AMG 416	20120359-35966018003	GENERALIZED WEAKNESS [無力症]	20[redacted]-10-16	255	MILD	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-22	-
AMG 416	20120359-35966018004	THROMBOSIS OF RIGHT FEMORAL CATHETER [医療機器関連の血栓症]	20[redacted]-09-30	240	MILD	YES	-	DOSE ALTERED OR WITHHELD	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-01	-
AMG 416	20120359-35966018004	SUBTHERAPEUTIC INR [抗凝固薬濃度治療量以下]	20[redacted]-10-30*	270	MILD	YES	-	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	NOT RELATED	20[redacted]-11-04*	-
AMG 416	20120359-35966018004	ANEMIA (ESRD) [腎性貧血]	20[redacted]-01-28	360	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, UNKNOWN	NOT RELATED	20[redacted]-01-30	-
AMG 416	20120359-35966019006	SARCOMA [肉腫]	20[redacted]-06-11	141	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	RELATED	ONGOING	-
AMG 416	20120359-35966019007	UPPER RESPIRATORY INFECTION [上気道感染]	20[redacted]-05-18	117	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-18	-
AMG 416	20120359-35966019007	WORSENING CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-05-18	117	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-21	-
AMG 416	20120359-35966019009	WORSENING OF VOMITING ON DIALYSIS [血液透析誘発症状]	20[redacted]-04-01T13:44	62	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-04-06	-

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AMG 416	20120359-35966025002	INFECTED AV GRAFT [動静脈グラフト部位感染]	20[redacted]-02-19	38	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-03-05	-
AMG 416	20120359-35966025002	MRSA BACTEREMIA [ブドウ球菌性菌血症]	20[redacted]-02-19	38	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-05	-
AMG 416	20120359-35966025002	ANEMIA [貧血]	20[redacted]-02-19T14:53	38	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-05T21:51	-
AMG 416	20120359-35966025002	SMALL BOWEL OBSTRUCTION [小腸閉塞]	20[redacted]-04-27	105	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120359-35966025002	INFECTED LEFT GROIN MASS [限局性感染]	20[redacted]-04-27T17:38	105	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-09T13:20	-
AMG 416	20120359-35966025002	SEPTIC SHOCK [敗血症性ショック]	20[redacted]-04-27T17:38	105	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-09T13:20	-
AMG 416	20120359-35966025002	SMALL BOWEL OBSTRUCTION [小腸閉塞]	20[redacted]-08-29T09:17	229	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-09	-
AMG 416	20120359-35966025002	CATHETER RELATED SEPSIS [医療機器関連敗血症]	20[redacted]-09-22	253	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-17	-
AMG 416	20120359-35966025002	FAILED LEFT THIGH ARTERIOVENOUS GRAFT THROMBECTOMY [血管グラフト血栓症]	20[redacted]-09-22	253	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-10-17	-
AMG 416	20120359-35966025002	SMALL BOWEL OBSTRUCTION [小腸閉塞]	20[redacted]-09-22	253	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-17 *	-
AMG 416	20120359-35966025002	CLOTTED RENAL ARTERIOVENOUS GRAFT [血管グラフト血栓症]	20[redacted]-10-22	283	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-09	-

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AMG 416	20120359-35966025002	CARDIAC CHEST PAIN [狭心症]	20[redacted]-11-10	302	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-12	-
AMG 416	20120359-35966025002	HYPERKALEMIA [高カリウム血症]	20[redacted]-11-10	302	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-12 *	-
AMG 416	20120359-35966025002	SMALL BOWEL OBSTRUCTION [小腸閉塞]	20[redacted]-11-27	319	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-09	-
AMG 416	20120359-35966025002	ANEMIA [貧血]	20[redacted]-12-14	336	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-12-22	-
AMG 416	20120359-35966025002	HYPERTENSIVE URGENCY [高血圧クリーゼ]	20[redacted]-12-14	336	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-22	-
AMG 416	20120359-35966025002	SEVERE EPISTAXIS [鼻出血]	20[redacted]-12-14	336	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-22	-
AMG 416	20120359-35966025004	CARDIAC ARREST [心停止]	20[redacted]-01-24T04:15	12	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-01-24T06:00	-
AMG 416	20120359-35966025006	COMPLETE HEART BLOCK [完全房室ブロック]	20[redacted]-05-19T09:31	112	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-05-20	-
AMG 416	20120359-35966025007	ARTERIOVENOUS GRAFT STENOSIS [移植血管合併症]	20[redacted]-02-14	17	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-16	-
AMG 416	20120359-35966025007	PSEUDOANEURYSM RIGHT ARM DIALYSIS [移植血管合併症]	20[redacted]-11-13	289	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-11-15	-

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AMG 416	20120359-35966028002	DIABETIC GASTROPARESIS [糖尿病性胃不全麻痺]	20[redacted]-02-10	22	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-13	-
AMG 416	20120359-35966028002	UNCONTROLLED HYPERTENSION [高血圧]	20[redacted]-02-10	22	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-13	-
AMG 416	20120359-35966028002	DIABETIC GASTROPARESIS [糖尿病性胃不全麻痺]	20[redacted]-04-06	77	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-09	-
AMG 416	20120359-35966028002	ABDOMINAL PAIN [腹痛]	20[redacted]-04-22	93	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-23	-
AMG 416	20120359-35966028003	CLOTTED ARTERIOVENOUS GRAFT [血管グラフト血栓症]	20[redacted]-10-04	258	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-10-07T13:55	-
AMG 416	20120359-35966028006	GANGRENE OF THE RIGHT GREAT TOE [壊疽]	20[redacted]-05-05	103	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-06	-
AMG 416	20120359-35966028006	WORSENING GANGRENE OF THE RIGHT FOOT [壊疽]	20[redacted]-05-12	110	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-24	-
AMG 416	20120359-35966028007	ACUTE CORONARY SYNDROME [急性冠動脈症候群]	20[redacted]-08-25	215	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-29	-
AMG 416	20120359-35966028007	CARDIAC ARREST [心停止]	20[redacted]-08-29	219	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE ALTERED OR WITHHELD	UNKNOWN	NOT RELATED	20[redacted]-08-29	-

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AMG 416	20120359-35966028015	DIABETIC FOOT INFECTION WITH GANGRENE [糖尿病性壊疽]	20[redacted]-02-21T13:03	25	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-02-25T21:33	-
AMG 416	20120359-35966028015	GANGRENOUS LEFT LOWER EXTREMITY [壊疽]	20[redacted]-03-28	60	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-04	-
AMG 416	20120359-35966028015	BRADYCARDIA [徐脈]	20[redacted]-03-31	63	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	NOT RELATED	20[redacted]-04-04	-
AMG 416	20120359-35966028015	HYPOTENSION [低血圧]	20[redacted]-03-31	63	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	NOT RELATED	20[redacted]-04-04	-
AMG 416	20120359-35966028015	GANGRENE OF LEFT LOWER EXTREMITY [壊疽]	20[redacted]-04-01	64	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-01	-
AMG 416	20120359-35966028015	BRADYCARDIA [徐脈]	20[redacted]-09-24T19:42	240	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-28T12:50	-
AMG 416	20120359-35966028015	BRADYCARDIA [徐脈]	20[redacted]-09-29T18:13	245	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-10-02T20:52	-
AMG 416	20120359-35966031005	DYSRHYTHMIA [不整脈]	20[redacted]-06-08	137	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-06-12	-
AMG 416	20120359-35966031005	SYNCOPAL EPISODE [失神]	20[redacted]-06-08	137	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-06-12	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120359-35966031007	CLOTTED ACCESS (CATHETER) [医療機器関連の血栓症]	20[redacted]-07-03	153	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-07-06	-
AMG 416	20120359-35966031008	GASTROINTESTINAL BLEED [胃腸出血]	20[redacted]-03-02	19	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-10	-
AMG 416	20120359-35966031008	INADEQUATE DIALYSIS [透析関連合併症]	20[redacted]-07-24	163	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120359-35966031010	FEVER [発熱]	20[redacted]-01-25	3	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-30	-
AMG 416	20120359-35966031011	HYPOTENSION [低血圧]	20[redacted]-03-29	66	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-03	-
AMG 416	20120359-35966032001	LEFT FOOT CHARCOT DISLOCATION [神経障害性関節症]	20[redacted]-06-18T05:30	132	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-20T06:00	-
AMG 416	20120359-35966032002	WORSENING OF FLUID OVERLOAD [水分過負荷]	20[redacted]-02-24T16:00 *	18	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-02 *	-
AMG 416	20120359-35966032002	PERICARDIAL EFFUSION [心嚢液貯留]	20[redacted]-02-09T14:30	368	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-12T16:30	-
AMG 416	20120359-35966032004	SUDDEN DEATH [突然死]	20[redacted]-06-28T12:00	146	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-06-28T12:00	-
AMG 416	20120359-35966033001	NAUSEA [悪心]	20[redacted]-03-08	47	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-11	-
AMG 416	20120359-35966033001	VOMITING [嘔吐]	20[redacted]-03-08	47	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-11	-

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AMG 416	20120359-35966033003	GRAM NEGATIVE SEPSIS [細菌性敗血症]	20[redacted]-12-21	365	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-02	-
AMG 416	20120359-35966033006	ASCITES [腹水]	20[redacted]-06-23	169	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-06-26	-
AMG 416	20120359-35966033006	VOLUME OVERLOAD [水分過負荷]	20[redacted]-06-23	169	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-26	-
AMG 416	20120359-35966033006	PNEUMONIA [肺炎]	20[redacted]-12-15	344	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-24	-
AMG 416	20120359-35966035005	WORSENING SYMPTOMATIC ANEMIA OF CHRONIC DISEASE [慢性疾患の貧血]	20[redacted]-07-05	166	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-07	-
AMG 416	20120359-35966038002	UPPER GASTROINTESTINAL BLEED [上部消化管出血]	20[redacted]-06-29	196	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-07-03	-
AMG 416	20120359-35966038002	RECURRENT GASTROINTESTINAL BLEED [胃腸出血]	20[redacted]-07-04	201	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-07-07	-
AMG 416	20120359-35966038004	DIABETIC FOOT ULCER [糖尿病性足病変]	20[redacted]-09-03	241	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, CULTURE TAKEN, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-09-09	-

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AMG 416	20120359-35966038004	OCCLUSION OF ANTERIOR TIBIAL ARTERY AT LEVEL OF RIGHT ANKLE [末梢動脈閉塞性疾患]	20[redacted]-09-04	242	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-09-09	-
AMG 416	20120359-35966038004	OCCLUSION OF POSTERIOR TIBIAL ARTERY AT LEVEL OF RIGHT ANKLE [末梢動脈閉塞性疾患]	20[redacted]-09-04	242	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-09-09	-
AMG 416	20120359-35966038004	NON-HEALING DIABETIC FOOT ULCER, RIGHT FOOT [糖尿病性足病変]	20[redacted]-10-30	298	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-04 *	-
AMG 416	20120359-35966038004	NON-HEALING DIABETIC FOOT ULCER, RIGHT FOOT [糖尿病性足病変]	20[redacted]-12-29	358	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-05 *	-
AMG 416	20120359-35966038004	SEPSIS [敗血症]	20[redacted]-12-30 *	359	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-05 *	-
AMG 416	20120359-35966038004	ACUTE ENCEPHALOPATHY [脳症]	20[redacted]-01-02	362	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-05	-

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AMG 416	20120359-35966038004	VENTRICULAR FIBRILLATION [心室細動]	20[redacted]-01-05	365	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, OTHER	NOT RELATED	20[redacted]-01-05	-
AMG 416	20120359-35966038006	MERALGIA PARESTHETICA LEFT LEG [感覚異常性大腿神経痛]	20[redacted]-02-06	40	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-10	-
AMG 416	20120359-35966038006	HEMODIALYSIS CATHETER INFECTION [医療機器関連感染]	20[redacted]-06-19	173	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-06-21	-
AMG 416	20120359-35966040004	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-06-04	168	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-05	-
AMG 416	20120359-35966040006	CARDIAC ARREST [心停止]	20[redacted]-05-24	150	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-05-24	-
AMG 416	20120359-35966040006	HYPOGLYCEMIA [低血糖症]	20[redacted]-05-24	150	LIFE THREATENING	YES	Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-05-24	-
AMG 416	20120359-35966040006	VENTRICULAR FIBRILLATION [心室細動]	20[redacted]-05-24	150	LIFE THREATENING	YES	Is Life Threatening	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-05-24	-
AMG 416	20120359-35966040007	DEPRESSION [うつ病]	20[redacted]-05-25	136	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-01	-
AMG 416	20120359-35966040007	TYLENOL TOXICITY [各種物質毒性]	20[redacted]-05-25	136	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-26	-
AMG 416	20120359-35966040007	INTENTIONAL OVERDOSE (SUICIDE ATTEMPT) [企図的過量投与]	20[redacted]-05-25T15:00	136	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-05-25	-

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AMG 416	20120359-35966047003	FALL [転倒]	20[redacted]-07-20T17:00	161	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	ONGOING	-
AMG 416	20120359-35966047003	WITHDRAWL FROM DIALYSIS [治療中断]	20[redacted]-08-12	184	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-08-17	-
AMG 416	20120359-35966047004	VOLUME OVERLAOD [水分過負荷]	20[redacted]-03-13	35	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-17	-
AMG 416	20120359-35966047004	HYPERKALEMIA [高カリウム血症]	20[redacted]-03-13T08:00	35	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER, OTHER	NOT RELATED	20[redacted]-03-17	-
AMG 416	20120359-35966047004	BILATERAL INTERNAL JUGULAR VEIN THROMBOSIS [頚静脈血栓症]	20[redacted]-05-13	96	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT, OTHER	NOT RELATED	ONGOING	-
AMG 416	20120359-35966047004	HYPERKALEMIA [高カリウム血症]	20[redacted]-08-11T15:00	186	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-08-11	-
AMG 416	20120359-35966048001	MIGRAINE [片頭痛]	20[redacted]-05-03*	101	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-30	-
AMG 416	20120359-35966048001	PNEUMONIA [肺炎]	20[redacted]-01-12	355	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	ONGOING	-
AMG 416	20120359-35966050004	CELLULITIS OF THE RIGHT LOWER EXTREMITY [蜂巣炎]	20[redacted]-09-10T12:00	227	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-09-12T20:14	-

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AMG 416	20120359-35966050004	OSTEOMYLITIS OF THE RIGHT SECOND DIGIT [骨髄炎]	20[redacted]-09-25T12:00	242	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-09-29T12:00	-
AMG 416	20120359-35966051003	ATYPICAL CHEST PAIN [胸痛]	20[redacted]-06-26T10:02	176	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120359-35966051004	COMPLICATIONS AFTER AVG REMOVAL [移植血管合併症]	20[redacted]-12-19T20:00	355	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-24T20:00 *	-
AMG 416	20120359-35966051004	ARTERIOVENOUS GRAFT INFECTION [動静脈グラフト部位感染]	20[redacted]-12-19T20:36	355	MODERATE	YES	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-01-03T12:40	-
AMG 416	20120359-35966051004	MALIGNANT HYPERTHERMIA [悪性高熱]	20[redacted]-12-19T20:36	355	MODERATE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-24T08:00	-
AMG 416	20120359-35966054006	FEVER [発熱]	20[redacted]-04-13	89	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-17	-
AMG 416	20120359-35966054006	HYPERKALEMIA [高カリウム血症]	20[redacted]-04-13	89	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-17	-
AMG 416	20120359-35966054006	ACUTE VOLUME OVERLOAD [水分過負荷]	20[redacted]-07-21	188	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-22	-
AMG 416	20120359-35966054006	HYPERKALEMIA [高カリウム血症]	20[redacted]-07-21	188	SEVERE	YES	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	NOT RELATED	20[redacted]-07-22	-

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AMG 416	20120359-35966057002	LEFT LEG INFECTED GRAFT [移植片感染]	20[redacted]-08-18T12:00	188	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-09-14	-
AMG 416	20120359-35966057002	LEFT HIP FRACTURE [股関節部骨折]	20[redacted]-08-25T10:00	195	SEVERE	YES	-	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-14	-
AMG 416	20120359-35966057002	NECROTIC BOWEL [消化管壊死]	20[redacted]-09-12T12:00	213	LIFE THREATENING	YES	Is Life Threatening	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-14T08:00	-
AMG 416	20120359-35966057002	PERFORATED BOWEL [腸管穿孔]	20[redacted]-09-12T12:00	213	LIFE THREATENING	YES	Is Life Threatening	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-14T08:00	-
AMG 416	20120359-35966057002	CARDIAC ARREST [心停止]	20[redacted]-09-14T12:00	215	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-14T14:46	-
AMG 416	20120359-35966057002	MEGAN COLON TOXIC [巨大結腸]	20[redacted]-09-14T12:00	215	LIFE THREATENING	YES	Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-14T14:46	-
AMG 416	20120359-35966057002	SEPTIC SHOCK [敗血症性ショック]	20[redacted]-09-14T12:00	215	LIFE THREATENING	YES	Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-14T14:46	-
AMG 416	20120359-35966061007	HYPERKALEMIA [高カリウム血症]	20[redacted]-06-11T08:00	140	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-13	-
AMG 416	20120359-35966062001	INFLUENZA B [インフルエンザ]	20[redacted]-05-17	123	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-23	-

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120359-35966062002	E. COLI BACTEREMIA [大腸菌性菌血症]	20[redacted]-03-31	69	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN	NOT RELATED	20[redacted]-04-09	-
AMG 416	20120359-35966062002	INFLUENZA B [インフルエンザ]	20[redacted]-05-19	118	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-22	-
AMG 416	20120359-35966064019	SYNCOPE [失神]	20[redacted]-10-31	278	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-01	-
NOT TREATED	20120229-22966051003	GENERALIZED WEAKNESS [無力症]	20[redacted]-12-16T00:05	40	SEVERE	YES	-	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-12-18T16:33	-
NOT TREATED	20120229-22966051003	VOMITTING [嘔吐]	20[redacted]-12-16T00:05	40	SEVERE	YES	-	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-12-18T16:33	-
NOT TREATED	20120229-22966051003	DIABETIC KETO ACIDOSIS [糖尿病性ケトアシドーシス]	20[redacted]-12-16T01:30 *	40	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-18T14:33 *	-
NOT TREATED	20120229-22966051003	HYPOGLYCEMIA [低血糖症]	20[redacted]-01-02T10:38	57	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-05T17:58	-

*1:MedDRA Version 18.0J
AMG 416 = ONO-5163

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

表 2.7.6.17-33　投与中止に至った有害事象の SOC・PT 別発現頻度（20120231 試験）
解析対象集団：SAF

SOC / PT		有害事象							
		親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
		プラセボ		ONO-5163		ONO-5163		ONO-5163	
		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	383		384		123		890	
全体		22/359.7 (6.1)	5.7	11/368.6 (3.0)	2.9	8/109.4 (7.3)	6.5	41/837.6 (4.9)	4.6
血液およびリンパ系障害		0/363.1 (0.0)	0.0	1/369.6 (0.3)	0.3	0/109.8 (0.0)	0.0	1/842.6 (0.1)	0.1
汎血球減少症		0/363.1 (0.0)	0.0	1/369.6 (0.3)	0.3	0/109.8 (0.0)	0.0	1/842.6 (0.1)	0.1
心臓障害		5/363.1 (1.4)	1.3	3/370.1 (0.8)	0.8	1/109.8 (0.9)	0.8	9/843.1 (1.1)	1.0
心停止		2/363.1 (0.6)	0.5	1/370.4 (0.3)	0.3	1/109.8 (0.9)	0.8	4/843.3 (0.5)	0.4
急性心筋梗塞		1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
徐脈		0/363.1 (0.0)	0.0	1/370.2 (0.3)	0.3	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
心障害		1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた.
n = 有害事象発現例数.
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.
出典［総括報告書 5.3.5.2-4（20120231 試験）Table 14-6.6 改変］

表 2.7.6.17-33　投与中止に至った有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 1）
解析対象集団：SAF

	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
SOC	プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
心肺停止	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
心筋虚血	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
上室性頻脈	0/363.1 (0.0)	0.0	1/370.3 (0.3)	0.3	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
心室細動	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
内分泌障害	0/363.1 (0.0)	0.0	0/370.4 (0.0)	0.0	1/109.8 (0.9)	0.8	1/843.3 (0.1)	0.1
副甲状腺機能亢進症	0/363.1 (0.0)	0.0	0/370.4 (0.0)	0.0	1/109.8 (0.9)	0.8	1/843.3 (0.1)	0.1
胃腸障害	5/361.4 (1.4)	1.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	5/841.6 (0.6)	0.6
悪心	2/362.7 (0.6)	0.5	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	2/842.9 (0.2)	0.2

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.

表 2.7.6.17-33　投与中止に至った有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 2）
解析対象集団：SAF

SOC / PT	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
	プラセボ		ONO-5163		ONO-5163		ONO-5163	
	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
嘔吐	2/361.8 (0.6)	0.5	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	2/842.1 (0.2)	0.2
胃食道逆流性疾患	1/362.9 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.1 (0.1)	0.1
腸管虚血	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
一般・全身障害および投与部位の状態	1/362.8 (0.3)	0.3	0/370.4 (0.0)	0.0	1/109.8 (0.9)	0.8	2/843.0 (0.2)	0.2
無力症	1/362.8 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.0 (0.1)	0.1
突然死	0/363.1 (0.0)	0.0	0/370.4 (0.0)	0.0	1/109.8 (0.9)	0.8	1/843.3 (0.1)	0.1
肝胆道系障害	1/363.1 (0.3)	0.3	1/370.3 (0.3)	0.3	0/109.8 (0.0)	0.0	2/843.2 (0.2)	0.2
胆嚢炎	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%=有害事象発現率＝100*n/N.

表 2.7.6.17-33　投与中止に至った有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 3）
解析対象集団：SAF

	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
SOC	プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
急性肝炎	0/363.1 (0.0)	0.0	1/370.3 (0.3)	0.3	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
感染症および寄生虫症	4/362.8 (1.1)	1.0	2/370.2 (0.5)	0.5	1/109.8 (0.9)	0.8	7/842.8 (0.8)	0.8
蜂巣炎	1/362.9 (0.3)	0.3	1/370.4 (0.3)	0.3	0/109.8 (0.0)	0.0	2/843.1 (0.2)	0.2
移植片感染	0/363.1 (0.0)	0.0	0/370.4 (0.0)	0.0	1/109.8 (0.9)	0.8	1/843.3 (0.1)	0.1
肺炎	1/363.0 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
術後創感染	0/363.1 (0.0)	0.0	1/370.3 (0.3)	0.3	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
敗血症	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
敗血症性ショック	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%=有害事象発現率＝100*n/N.

表 2.7.6.17-33　投与中止に至った有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 4）
解析対象集団：SAF

	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
SOC	プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
膿瘡	0/363.1 (0.0)	0.0	1/370.4 (0.3)	0.3	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
傷害、中毒および処置合併症	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
動静脈瘻部位出血	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
臨床検査	2/362.8 (0.6)	0.5	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	2/843.0 (0.2)	0.2
血中アルカリホスファターゼ増加	1/362.9 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.1 (0.1)	0.1
血中カルシウム減少	1/363.0 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
代謝および栄養障害	1/363.0 (0.3)	0.3	1/370.2 (0.3)	0.3	0/109.8 (0.0)	0.0	2/843.1 (0.2)	0.2
低カルシウム血症	1/363.0 (0.3)	0.3	1/370.2 (0.3)	0.3	0/109.8 (0.0)	0.0	2/843.1 (0.2)	0.2

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.

表 2.7.6.17-33　投与中止に至った有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 5）
解析対象集団：SAF

	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
SOC	プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
低血糖症	1/363.0 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
筋骨格系および結合組織障害	0/363.1 (0.0)	0.0	1/370.3 (0.3)	0.3	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
筋力低下	0/363.1 (0.0)	0.0	1/370.3 (0.3)	0.3	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
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）	1/363.0 (0.3)	0.3	2/370.2 (0.5)	0.5	1/109.7 (0.9)	0.8	4/842.8 (0.5)	0.4
結腸癌第２期	0/363.1 (0.0)	0.0	1/370.2 (0.3)	0.3	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
脊椎転移	1/363.0 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
悪性新生物	0/363.1 (0.0)	0.0	1/370.3 (0.3)	0.3	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
肉腫	0/363.1 (0.0)	0.0	0/370.4 (0.0)	0.0	1/109.7 (0.9)	0.8	1/843.1 (0.1)	0.1

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%=有害事象発現率＝100*n/N.

表 2.7.6.17-33　投与中止に至った有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 6）
解析対象集団：SAF

SOC / PT	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
	プラセボ		ONO-5163		ONO-5163		ONO-5163	
	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
神経系障害	5/362.8 (1.4)	1.3	2/370.1 (0.5)	0.5	0/109.8 (0.0)	0.0	7/842.7 (0.8)	0.8
痙攣発作	2/362.9 (0.6)	0.5	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	2/843.1 (0.2)	0.2
脳血管発作	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
脳症	0/363.1 (0.0)	0.0	1/370.3 (0.3)	0.3	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
感覚鈍麻	1/363.0 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
低酸素性虚血性脳症	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
錯感覚	0/363.1 (0.0)	0.0	1/370.2 (0.3)	0.3	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
一過性脳虚血発作	1/363.0 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.

表 2.7.6.17-33　投与中止に至った有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 7）
解析対象集団：SAF

	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
SOC	プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
妊娠、産褥および周産期の状態	0/363.1 (0.0)	0.0	0/370.4 (0.0)	0.0	1/109.8 (0.9)	0.8	1/843.2 (0.1)	0.1
妊娠	0/363.1 (0.0)	0.0	0/370.4 (0.0)	0.0	1/109.8 (0.9)	0.8	1/843.2 (0.1)	0.1
精神障害	2/362.9 (0.6)	0.5	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	2/843.1 (0.2)	0.2
錯乱状態	1/363.0 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
譫妄	1/363.0 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
腎および尿路障害	0/363.1 (0.0)	0.0	0/370.4 (0.0)	0.0	1/109.8 (0.9)	0.8	1/843.2 (0.1)	0.1
腎硬化症	0/363.1 (0.0)	0.0	0/370.4 (0.0)	0.0	1/109.8 (0.9)	0.8	1/843.2 (0.1)	0.1
呼吸器、胸郭および縦隔障害	0/363.1 (0.0)	0.0	0/370.4 (0.0)	0.0	1/109.8 (0.9)	0.8	1/843.3 (0.1)	0.1

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.

表 2.7.6.17-33　投与中止に至った有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 8）
解析対象集団：SAF

SOC / PT	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
	プラセボ		ONO-5163		ONO-5163		ONO-5163	
	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
肺塞栓症	0/363.1 (0.0)	0.0	0/370.4 (0.0)	0.0	1/109.8 (0.9)	0.8	1/843.3 (0.1)	0.1
皮膚および皮下組織障害	1/363.0 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
ヘノッホ・シェーンライン紫斑病	1/363.0 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
血管障害	0/363.1 (0.0)	0.0	1/370.4 (0.3)	0.3	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
末梢動脈閉塞性疾患	0/363.1 (0.0)	0.0	1/370.4 (0.3)	0.3	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた.
n = 有害事象発現例数.
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.
出典［総括報告書 5.3.5.2-4（20120231 試験）Table 14-6.6 改変］

表 2.7.6.17-34　投与中止に至った有害事象の一覧表（20120231 試験）

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120229-22912003001	ACUTE CARDIAL EVENT [心障害]	20[redacted]-03-15T17:23	362	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	OTHER	NOT RELATED	20[redacted]-03-15	-
AMG 416	20120229-22916001004	CONFUSION [錯乱状態]	20[redacted]-05-09	37	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-
AMG 416	20120229-22916001004	HYPOCALCEMIA [低カルシウム血症]	20[redacted]-05-09	37	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-05-15	-
AMG 416	20120229-22916001004	SEIZURE [痙攣発作]	20[redacted]-05-09	37	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-09	-
AMG 416	20120229-22916001004	SEVERE HYPOGLYCEMIA [低血糖症]	20[redacted]-05-09	37	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-09	-
AMG 416	20120229-22926003003	INFECTION SURGICAL WOUND AFTER PATELLA FRACTURE SURGERY [術後創感染]	20[redacted]-06-25	105	LIFE THREATENING	YES	Is Life Threatening	DRUG WITHDRAWN	MEDICATION TAKEN, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-08-05	-
AMG 416	20120229-22926003003	SEPSIS AFTER AMPUTATION WOUND LEFT LEG [膿創]	20[redacted]-08-05	146	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-08-05	-
AMG 416	20120229-22951001003	LEG WEAKNESS MILD CASE [筋力低下]	20[redacted]-06-25T19:00	150	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-06-29	-
AMG 416	20120229-22951001011	HYPOCALCEMIA SYMPTOMATICS [低カルシウム血症]	20[redacted]-04-11	17	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-04-25	-
AMG 416	20120229-22951003004	METASTATIC LESIONS OF VERTEBREA [脊椎転移]	20[redacted]-05-25	89	SEVERE	YES	-	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	ONGOING	-

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120229-22958009018	ISCHEMIC DELATED CARDIOMIOPATHY WITH SEVERAL DEPRESS LEFT VENTRICULAR DISFUNCTION [心筋虚血]	20[redacted]-04-06	56	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-07	-
AMG 416	20120229-22958009018	VENTRICULAR FIBRILATION [心室細動]	20[redacted]-04-06	56	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-07	-
AMG 416	20120229-22965003004	SUPRA VENTRICULAR TACCHYCARDIA [上室性頻脈]	20[redacted]-08-19T16:00	83	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-19	-
AMG 416	20120229-22966019011	WORSENING OF GASTROESPHOGEAL REFLUX [胃食道逆流性疾患]	20[redacted]-12-08	196	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	ONGOING	-
AMG 416	20120229-22966029005	ENCEPHALOPATHY SECONDARY TO ANOXIC EVENT [低酸素性虚血性脳症]	20[redacted]-12-10	227	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-23	-
AMG 416	20120229-22966041005	CELLULITIS OF LEFT FOOT [蜂巣炎]	20[redacted]-10-17	145	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-23	-
AMG 416	20120229-22966041005	WORSENING PERIPHERAL ARTERY DISEASE [末梢動脈閉塞性疾患]	20[redacted]-10-17	145	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-23	-
AMG 416	20120229-22966041005	CARDIAC ARREST [心停止]	20[redacted]-10-23T00:45	151	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-23T00:45	-
AMG 416	20120229-22966049004	CELLULITIS - BLLATERAL LEGS [蜂巣炎]	20[redacted]-05-16	8	MODERATE	YES	-	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	ONGOING	-

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120229-22966051009	COLON CANCER STAGE II [結腸癌第２期]	20[redacted]-03-31T11:00	102	SEVERE	YES	-	DRUG WITHDRAWN	SURGICAL INTERVENTION	NOT RELATED	ONGOING	-
AMG 416	20120229-22966053012	HAND NUMBNESS [感覚鈍麻]	20[redacted]-07-30	127	MODERATE	NO	-	DRUG WITHDRAWN	OTHER	RELATED	20[redacted]-08-06	-
AMG 416	20120229-22966059001	ACCESS SITE BLEEDING (AV FISTULA) [動静脈瘻部位出血]	20[redacted]-03-02	110	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-03	-
AMG 416	20120229-22966059001	ISCHEMIC BOWEL [腸管虚血]	20[redacted]-03-04	112	LIFE THREATENING	YES	Is Life Threatening	DRUG WITHDRAWN	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-05	-
AMG 416	20120229-22966059001	SEPTIC SHOCK [敗血症性ショック]	20[redacted]-03-04	112	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-03-05	-
AMG 416	20120229-22966059001	BILATERAL CEREBRAL STROKE [脳血管発作]	20[redacted]-03-05	113	LIFE THREATENING	YES	Is Life Threatening	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-03-05	-
AMG 416	20120229-22966171004	MINI STROKE [一過性脳虚血発作]	20[redacted]-02-12	358	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-03-06	-
AMG 416	20120229-22966171004	PNEUMONIA [肺炎]	20[redacted]-02-12	358	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-03-06	-
AMG 416	20120229-22966171004	SEIZURE DISORDER [痙攣発作]	20[redacted]-02-12	358	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	ONGOING	-
AMG 416	20120229-22966193009	VOMITTING [嘔吐]	20[redacted]-05-31T07:00	19	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	ONGOING	-
AMG 416	20120230-23016005003	DELIRIUM [譫妄]	20[redacted]-03-25	337	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	-

年齢以外のマスキングにおいて，
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＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120230-23025004002	FRAILTY [無力症]	20[redacted]-06-27T08:00	156	MILD	NO	-	DRUG WITHDRAWN	OTHER	NOT RELATED	ONGOING	-
AMG 416	20120230-23033008004	CHOLECISTITIS ALITIASICA [胆嚢炎]	20[redacted]-08-28	234	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-09-07	-
AMG 416	20120230-23033008004	SEPSIS [敗血症]	20[redacted]-08-28	234	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-07	-
AMG 416	20120230-23033008005	PARAESTHESIA [錯感覚]	20[redacted]-04-03	87	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-05-06	-
AMG 416	20120230-23042002001	LOW CALCIUM [血中カルシウム減少]	20[redacted]-01-02	276	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-01-14	-
AMG 416	20120230-23042002006	NAUSEA [悪心]	20[redacted]-04-19	5	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-06-14	-
AMG 416	20120230-23042002006	VOMITING [嘔吐]	20[redacted]-05-13	29	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-06-14	-
AMG 416	20120230-23048008001	ALLERGY (PURPURA ALLERGICA) [ヘノッホ・シェーンライン紫斑病]	20[redacted]-05-19	40	SEVERE	YES	-	DRUG WITHDRAWN	MEDICATION TAKEN, OTHER	RELATED	20[redacted]-07-01	-
AMG 416	20120230-23066004003	ACUTE HEPATITIS [急性肝炎]	20[redacted]-07-12	258	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-17	-
AMG 416	20120230-23066004003	ENCEPHALOPATHY [脳症]	20[redacted]-07-12	258	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-17	-

年齢以外のマスキングにおいて，
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＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120230-23066032005	CARDIOPULMONARY ARREST [心肺停止]	20[redacted]-03-18	79	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-18	-
AMG 416	20120230-23066032005	CARDIAC ARREST [心停止]	20[redacted]-03-22	83	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	20[redacted]-03-22	-
AMG 416	20120230-23066034010	CARDIAC ARREST [心停止]	20[redacted]-11-03T13:06	190	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-11-03T14:30	-
AMG 416	20120230-23066052003	NAUSEA [悪心]	20[redacted]-05-16	144	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-06-06	-
AMG 416	20120230-23066078012	ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-03-12	340	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-13	-
AMG 416	20120230-23066084004	POORLY DIFFERENTIATED CARCINOMA; UNKNOWN PRIMARY [悪性新生物]	20[redacted]-09-08	209	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-23	-
AMG 416	20120230-23066102005	PANCYTOPENIA [汎血球減少症]	20[redacted]-08-06T06:25	113	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	ONGOING	-
AMG 416	20120230-23066150007	BRADYCARDIA [徐脈]	20[redacted]-01-19	335	MILD	NO	-	DRUG WITHDRAWN	OTHER	RELATED	ONGOING	-
AMG 416	20120230-23066152002	ELAVATED SERUM ALKALINE PHOSPHOTASE [血中アルカリホスファターゼ増加]	20[redacted]-05-14	106	MILD	NO	-	DRUG WITHDRAWN	OTHER	NOT RELATED	ONGOING	-

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120359-35966002004	ACUTE PULMONARY EMBOLUS [肺塞栓症]	20[redacted]-03-31T14:40	83	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-03-31T15:04	-
AMG 416	20120359-35966006001	NEPHROSCLEROSIS [腎硬化症]	20[redacted]-10-07	266	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-13	-
AMG 416	20120359-35966019006	SARCOMA [肉腫]	20[redacted]-06-11	141	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	RELATED	ONGOING	-
AMG 416	20120359-35966022003	WORSENING HYPERPARATHYROIDISM [副甲状腺機能亢進症]	20[redacted]-02-17	78	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	ONGOING	-
AMG 416	20120359-35966025004	CARDIAC ARREST [心停止]	20[redacted]-01-24T04:15	12	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-01-24T06:00	-
AMG 416	20120359-35966032004	SUDDEN DEATH [突然死]	20[redacted]-06-28T12:00	146	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-06-28T12:00	-
AMG 416	20120359-35966044001	PREGNANCY [妊娠]	20[redacted]-03-19	43	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-03-30	-
AMG 416	20120359-35966057002	LEFT LEG INFECTED GRAFT [移植片感染]	20[redacted]-08-18T12:00	188	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-09-14	-

*1:MedDRA Version 18.0J
AMG 416 = ONO-5163

年齢以外のマスキングにおいて,
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）
解析対象集団：SAF

EOI		有害事象							
		親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
		プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	383		384		123		890	
無形成骨		0/363.1 (0.0)	0.0	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	0/843.3 (0.0)	0.0
心不全		19/351.5 (5.4)	5.0	19/360.5 (5.3)	4.9	3/108.1 (2.8)	2.4	41/820.2 (5.0)	4.6
急性肺水腫		1/362.2 (0.3)	0.3	1/369.9 (0.3)	0.3	0/109.8 (0.0)	0.0	2/842.0 (0.2)	0.2
心不全		2/363.0 (0.6)	0.5	3/369.5 (0.8)	0.8	0/109.8 (0.0)	0.0	5/842.4 (0.6)	0.6
急性心不全		1/362.1 (0.3)	0.3	1/370.4 (0.3)	0.3	0/109.8 (0.0)	0.0	2/842.3 (0.2)	0.2
慢性心不全		2/361.4 (0.6)	0.5	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	2/841.6 (0.2)	0.2

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%=有害事象発現率＝100*n/N.
出典［総括報告書 5.3.5.2-4（20120231 試験）Table 14-6.10 改変］

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）（続き 1）
解析対象集団：SAF

EOI	有害事象									
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計			
	プラセボ		ONO-5163		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**		
N	383		384		123		890			
うっ血性心不全	10/356.7 (2.8)	2.6	9/364.4 (2.5)	2.3	3/108.1 (2.8)	2.4	22/829.2 (2.7)	2.5		
心原性ショック	1/363.1 (0.3)	0.3	1/369.6 (0.3)	0.3	0/109.8 (0.0)	0.0	2/842.6 (0.2)	0.2		
駆出率減少	1/362.6 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/842.8 (0.1)	0.1		
肺水腫	2/361.5 (0.6)	0.5	6/367.5 (1.6)	1.6	0/109.8 (0.0)	0.0	8/838.9 (1.0)	0.9		
痙攣	5/361.2 (1.4)	1.3	3/369.6 (0.8)	0.8	0/109.8 (0.0)	0.0	8/840.7 (1.0)	0.9		
全身性強直性間代性発作	1/362.7 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/842.9 (0.1)	0.1		

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）（続き 2）
解析対象集団：SAF

EOI		有害事象							
		親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
		プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	383		384		123		890	
痙攣発作		4/361.6 (1.1)	1.0	3/369.6 (0.8)	0.8	0/109.8 (0.0)	0.0	7/841.1 (0.8)	0.8
過敏症		25/347.9 (7.2)	6.5	15/362.3 (4.1)	3.9	6/104.8 (5.7)	4.9	46/815.0 (5.6)	5.2
アナフィラキシー反応		1/362.5 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/842.7 (0.1)	0.1
血管浮腫		1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
気管支痙攣		1/362.9 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.1 (0.1)	0.1
アレルギー性結膜炎		1/362.5 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/842.7 (0.1)	0.1

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%=有害事象発現率＝100*n/N.

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）（続き 3）
解析対象集団：SAF

EOI	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
	プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
皮膚炎	0/363.1 (0.0)	0.0	2/369.5 (0.5)	0.5	0/109.8 (0.0)	0.0	2/842.4 (0.2)	0.2
ざ瘡様皮膚炎	1/363.0 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
接触性皮膚炎	2/361.3 (0.6)	0.5	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	2/841.5 (0.2)	0.2
薬疹	1/362.2 (0.3)	0.3	1/370.4 (0.3)	0.3	0/109.8 (0.0)	0.0	2/842.3 (0.2)	0.2
薬物過敏症	3/361.9 (0.8)	0.8	1/369.3 (0.3)	0.3	1/109.4 (0.9)	0.8	5/840.6 (0.6)	0.6
湿疹	1/363.0 (0.3)	0.3	1/369.8 (0.3)	0.3	0/109.8 (0.0)	0.0	2/842.7 (0.2)	0.2

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）（続き 4）
解析対象集団：SAF

EOI	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
	プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
眼瞼浮腫	1/362.1 (0.3)	0.3	2/369.2 (0.5)	0.5	0/109.8 (0.0)	0.0	3/841.1 (0.4)	0.3
顔面浮腫	5/359.1 (1.4)	1.3	1/370.0 (0.3)	0.3	0/109.8 (0.0)	0.0	6/838.9 (0.7)	0.7
ヘノッホ・シェーンライン紫斑病	1/363.0 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
過敏症	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
過敏性血管炎	0/363.1 (0.0)	0.0	1/369.4 (0.3)	0.3	0/109.8 (0.0)	0.0	1/842.3 (0.1)	0.1
眼窩周囲浮腫	0/363.1 (0.0)	0.0	0/370.4 (0.0)	0.0	1/108.8 (0.9)	0.8	1/842.3 (0.1)	0.1

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）（続き 5）
解析対象集団：SAF

EOI	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
	プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
アレルギー性そう痒症	0/363.1 (0.0)	0.0	1/370.4 (0.3)	0.3	1/109.0 (0.9)	0.8	2/842.4 (0.2)	0.2
発疹	1/362.8 (0.3)	0.3	3/369.6 (0.8)	0.8	1/108.8 (0.9)	0.8	5/841.2 (0.6)	0.6
全身性皮疹	0/363.1 (0.0)	0.0	1/369.7 (0.3)	0.3	0/109.8 (0.0)	0.0	1/842.6 (0.1)	0.1
そう痒性皮疹	1/362.2 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/842.4 (0.1)	0.1
膿疱性皮疹	1/362.3 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/842.5 (0.1)	0.1
アレルギー性鼻炎	1/362.5 (0.3)	0.3	1/369.4 (0.3)	0.3	2/108.2 (1.8)	1.6	4/840.1 (0.5)	0.4

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）（続き 6）
解析対象集団：SAF

EOI	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
	プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
皮膚壊死	1/363.0 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
顔面腫脹	1/362.1 (0.3)	0.3	1/370.0 (0.3)	0.3	0/109.8 (0.0)	0.0	2/842.0 (0.2)	0.2
蕁麻疹	3/361.5 (0.8)	0.8	1/369.5 (0.3)	0.3	0/109.8 (0.0)	0.0	4/840.9 (0.5)	0.4
血管炎性皮疹	1/362.6 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/842.8 (0.1)	0.1
低カルシウム血症	232/182.9 (126.8)	60.6	134/275.5 (48.6)	34.9	31/91.0 (34.1)	25.2	397/549.3 (72.3)	44.6
補正カルシウム減少	2/362.3 (0.6)	0.5	0/370.4 (0.0)	0.0	1/109.1 (0.9)	0.8	3/841.7 (0.4)	0.3

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%=有害事象発現率＝100*n/N.

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）（続き 7）
解析対象集団：SAF

EOI		有害事象							
		親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
		プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	383		384		123		890	
血中カルシウム減少		226/187.0 (120.8)	59.0	129/278.5 (46.3)	33.6	30/91.7 (32.7)	24.4	385/557.3 (69.1)	43.3
低カルシウム血症		19/352.1 (5.4)	5.0	14/362.0 (3.9)	3.6	0/109.8 (0.0)	0.0	33/824.0 (4.0)	3.7
低リン酸血症		7/357.7 (2.0)	1.8	6/367.2 (1.6)	1.6	1/109.7 (0.9)	0.8	14/834.7 (1.7)	1.6
血中リン減少		2/361.2 (0.6)	0.5	2/369.3 (0.5)	0.5	0/109.8 (0.0)	0.0	4/840.3 (0.5)	0.4
低リン酸血症		5/359.6 (1.4)	1.3	4/368.3 (1.1)	1.0	1/109.7 (0.9)	0.8	10/837.7 (1.2)	1.1
Infusion reaction		100/302.9 (33.0)	26.1	86/323.3 (26.6)	22.4	27/92.3 (29.3)	22.0	213/718.5 (29.6)	23.9

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）（続き 8）
解析対象集団：SAF

EOI	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
	プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
アナフィラキシー反応	1/362.5 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/842.7 (0.1)	0.1
血管浮腫	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
血圧低下	0/363.1 (0.0)	0.0	2/369.4 (0.5)	0.5	0/109.8 (0.0)	0.0	2/842.4 (0.2)	0.2
拡張期血圧上昇	0/363.1 (0.0)	0.0	1/369.6 (0.3)	0.3	0/109.8 (0.0)	0.0	1/842.5 (0.1)	0.1
血圧上昇	1/363.0 (0.3)	0.3	1/369.9 (0.3)	0.3	2/107.9 (1.9)	1.6	4/840.8 (0.5)	0.4
気管支反応性亢進	0/363.1 (0.0)	0.0	1/369.3 (0.3)	0.3	0/109.8 (0.0)	0.0	1/842.3 (0.1)	0.1

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）（続き 9）
解析対象集団：SAF

EOI	有害事象									
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計			
	プラセボ		ONO-5163		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**		
N	383		384		123		890			
気管支痙攣	1/362.9 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.1 (0.1)	0.1		
薬物過敏症	3/361.9 (0.8)	0.8	1/369.3 (0.3)	0.3	1/109.4 (0.9)	0.8	5/840.6 (0.6)	0.6		
眼そう痒症	1/362.4 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/842.6 (0.1)	0.1		
眼瞼浮腫	1/362.1 (0.3)	0.3	2/369.2 (0.5)	0.5	0/109.8 (0.0)	0.0	3/841.1 (0.4)	0.3		
顔面浮腫	5/359.1 (1.4)	1.3	1/370.0 (0.3)	0.3	0/109.8 (0.0)	0.0	6/838.9 (0.7)	0.7		
過敏症	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1		

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）（続き 10）
解析対象集団：SAF

EOI		有害事象							
		親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
		プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	383		384		123		890	
高血圧		34/344.1 (9.9)	8.9	21/357.2 (5.9)	5.5	10/103.3 (9.7)	8.1	65/804.6 (8.1)	7.3
過換気		1/362.9 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.1 (0.1)	0.1
低血圧		40/341.7 (11.7)	10.4	28/354.9 (7.9)	7.3	7/106.3 (6.6)	5.7	75/802.9 (9.3)	8.4
筋肉痛		4/359.8 (1.1)	1.0	2/369.2 (0.5)	0.5	1/109.1 (0.9)	0.8	7/838.1 (0.8)	0.8
非心原性肺水腫		1/362.4 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/842.6 (0.1)	0.1
眼窩周囲浮腫		0/363.1 (0.0)	0.0	0/370.4 (0.0)	0.0	1/108.8 (0.9)	0.8	1/842.3 (0.1)	0.1

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）（続き 11）
解析対象集団：SAF

EOI	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
	プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
アレルギー性そう痒症	0/363.1 (0.0)	0.0	1/370.4 (0.3)	0.3	1/109.0 (0.9)	0.8	2/842.4 (0.2)	0.2
全身性そう痒症	0/363.1 (0.0)	0.0	1/370.2 (0.3)	0.3	0/109.8 (0.0)	0.0	1/843.2 (0.1)	0.1
発熱	14/356.2 (3.9)	3.7	16/362.2 (4.4)	4.2	5/106.5 (4.7)	4.1	35/824.9 (4.2)	3.9
発疹	1/362.8 (0.3)	0.3	3/369.6 (0.8)	0.8	1/108.8 (0.9)	0.8	5/841.2 (0.6)	0.6
全身性皮疹	0/363.1 (0.0)	0.0	1/369.7 (0.3)	0.3	0/109.8 (0.0)	0.0	1/842.6 (0.1)	0.1
そう痒性皮疹	1/362.2 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/842.4 (0.1)	0.1

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた.
n = 有害事象発現例数.
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）（続き 12）
解析対象集団：SAF

EOI	有害事象									
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計			
	プラセボ		ONO-5163		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**		
N	383		384		123		890			
呼吸停止	0/363.1 (0.0)	0.0	1/369.4 (0.3)	0.3	0/109.8 (0.0)	0.0	1/842.4 (0.1)	0.1		
呼吸不全	3/361.9 (0.8)	0.8	3/369.5 (0.8)	0.8	0/109.8 (0.0)	0.0	6/841.3 (0.7)	0.7		
上気道性喘鳴	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1		
突然死	1/363.1 (0.3)	0.3	1/370.4 (0.3)	0.3	1/109.8 (0.9)	0.8	3/843.3 (0.4)	0.3		
顔面腫脹	1/362.1 (0.3)	0.3	1/370.0 (0.3)	0.3	0/109.8 (0.0)	0.0	2/842.0 (0.2)	0.2		
失神	9/357.2 (2.5)	2.3	6/367.7 (1.6)	1.6	3/108.7 (2.8)	2.4	18/833.6 (2.2)	2.0		

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%=有害事象発現率＝100*n/N.

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）（続き 13）
解析対象集団：SAF

EOI	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
	プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
全身性炎症反応症候群	1/362.6 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/842.8 (0.1)	0.1
咽喉絞扼感	1/363.1 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/843.3 (0.1)	0.1
蕁麻疹	3/361.5 (0.8)	0.8	1/369.5 (0.3)	0.3	0/109.8 (0.0)	0.0	4/840.9 (0.5)	0.4
喘鳴	4/360.3 (1.1)	1.0	4/367.9 (1.1)	1.0	0/109.8 (0.0)	0.0	8/838.0 (1.0)	0.9
トルサード ド ポアント／ＱＴ延長	3/361.9 (0.8)	0.8	2/368.7 (0.5)	0.5	0/109.8 (0.0)	0.0	5/840.5 (0.6)	0.6
心電図ＱＴ延長	2/362.9 (0.6)	0.5	2/368.7 (0.5)	0.5	0/109.8 (0.0)	0.0	4/841.4 (0.5)	0.4

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.

表 2.7.6.17-35　留意すべき有害事象の PT 別発現頻度（20120231 試験）（続き 14）
解析対象集団：SAF

EOI	有害事象							
	親試験（20120229試験及び20120230試験）				親試験（20120359試験）		合計	
	プラセボ		ONO-5163		ONO-5163		ONO-5163	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	383		384		123		890	
トルサード　ド　ポアント	1/362.2 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/842.4 (0.1)	0.1
心室性頻脈性不整脈	3/362.2 (0.8)	0.8	4/369.6 (1.1)	1.0	2/109.8 (1.8)	1.6	9/841.6 (1.1)	1.0
トルサード　ド　ポアント	1/362.2 (0.3)	0.3	0/370.4 (0.0)	0.0	0/109.8 (0.0)	0.0	1/842.4 (0.1)	0.1
心室性期外収縮	0/363.1 (0.0)	0.0	2/369.6 (0.5)	0.5	0/109.8 (0.0)	0.0	2/842.6 (0.2)	0.2
心室細動	2/363.1 (0.6)	0.5	2/370.4 (0.5)	0.5	2/109.8 (1.8)	1.6	6/843.3 (0.7)	0.7

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%=有害事象発現率 = 100*n/N.
出典［総括報告書 5.3.5.2-4（20120231 試験）Table 14-6.10 改変］

表 2.7.6.17-36 有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120359 試験）

解析対象集団：SAF

	有害事象	治験薬との因果関係が否定できない有害事象
SOC	ONO-5163	ONO-5163
PT	n （%）	n （%）
N	148	148
全体	72 (48.6)	11 (7.4)
感染症および寄生虫症	16 (10.8)	0 (0.0)
上気道感染	3 (2.0)	0 (0.0)
肺炎	2 (1.4)	0 (0.0)
動静脈グラフト部位感染	1 (0.7)	0 (0.0)
菌血症	1 (0.7)	0 (0.0)
胆道性敗血症	1 (0.7)	0 (0.0)
蜂巣炎	1 (0.7)	0 (0.0)
医療機器関連感染	1 (0.7)	0 (0.0)
毛包炎	1 (0.7)	0 (0.0)
鼻咽頭炎	1 (0.7)	0 (0.0)
骨髄炎	1 (0.7)	0 (0.0)
ブドウ球菌性菌血症	1 (0.7)	0 (0.0)
尿路感染	1 (0.7)	0 (0.0)
膣感染	1 (0.7)	0 (0.0)
細菌性膣炎	1 (0.7)	0 (0.0)
筋骨格系および結合組織障害	12 (8.1)	1 (0.7)
関節痛	4 (2.7)	1 (0.7)
筋痙縮	4 (2.7)	0 (0.0)
四肢痛	2 (1.4)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver16.1Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．

出典［総括報告書 5.3.5.2-5（20120359 試験）Table 14-6.4 及び Table 14-6.8 改変］

表 2.7.6.17-36 有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120359 試験）（続き 1）

解析対象集団：SAF

SOC PT		有害事象 ONO-5163 n (%)	治験薬との因果関係が否定できない有害事象 ONO-5163 n (%)
	N	148	148
筋骨格不快感		1 (0.7)	0 (0.0)
頚部痛		1 (0.7)	0 (0.0)
傷害、中毒および処置合併症		11 (7.4)	1 (0.7)
動静脈瘻部位合併症		3 (2.0)	0 (0.0)
処置による低血圧		3 (2.0)	1 (0.7)
移植血管合併症		2 (1.4)	0 (0.0)
動静脈瘻閉塞		1 (0.7)	0 (0.0)
転倒		1 (0.7)	0 (0.0)
血液透析誘発症状		1 (0.7)	0 (0.0)
股関節部骨折		1 (0.7)	0 (0.0)
靱帯捻挫		1 (0.7)	0 (0.0)
血管グラフト血栓症		1 (0.7)	0 (0.0)
胃腸障害		9 (6.1)	4 (2.7)
便秘		2 (1.4)	1 (0.7)
下痢		2 (1.4)	1 (0.7)
悪心		2 (1.4)	1 (0.7)
嘔吐		2 (1.4)	0 (0.0)
上腹部痛		1 (0.7)	0 (0.0)
消化不良		1 (0.7)	1 (0.7)
おくび		1 (0.7)	1 (0.7)

医師から報告された有害事象名は，MedDRA ver16.1Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．

表 2.7.6.17-36 有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120359 試験）（続き 2）

解析対象集団：SAF

SOC PT		有害事象 ONO-5163 n (%)	治験薬との因果関係が否定できない有害事象 ONO-5163 n (%)
	N	148	148
臨床検査		9 (6.1)	3 (2.0)
血中カルシウム減少		5 (3.4)	3 (2.0)
呼吸音異常		2 (1.4)	0 (0.0)
血中ブドウ糖増加		1 (0.7)	0 (0.0)
血中カリウム増加		1 (0.7)	0 (0.0)
神経系障害		9 (6.1)	1 (0.7)
浮動性めまい		3 (2.0)	0 (0.0)
頭痛		3 (2.0)	0 (0.0)
脳血管発作		1 (0.7)	0 (0.0)
痙攣		1 (0.7)	0 (0.0)
錯感覚		1 (0.7)	1 (0.7)
失神寸前の状態		1 (0.7)	0 (0.0)
刺激無反応		1 (0.7)	0 (0.0)
皮膚および皮下組織障害		9 (6.1)	0 (0.0)
多汗症		3 (2.0)	0 (0.0)
ざ瘡		1 (0.7)	0 (0.0)
冷汗		1 (0.7)	0 (0.0)
糖尿病性足病変		1 (0.7)	0 (0.0)
内方発育毛		1 (0.7)	0 (0.0)
そう痒症		1 (0.7)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver16.1Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．

表 2.7.6.17-36 有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120359 試験）（続き 3）
解析対象集団：SAF

SOC PT		有害事象 ONO-5163 n (%)	治験薬との因果関係が否定できない有害事象 ONO-5163 n (%)
	N	148	148
発疹		1 (0.7)	0 (0.0)
蕁麻疹		1 (0.7)	0 (0.0)
呼吸器、胸郭および縦隔障害		8 (5.4)	1 (0.7)
咳嗽		4 (2.7)	0 (0.0)
呼吸困難		1 (0.7)	0 (0.0)
気胸		1 (0.7)	0 (0.0)
肺水腫		1 (0.7)	0 (0.0)
咽喉絞扼感		1 (0.7)	1 (0.7)
一般・全身障害および投与部位の状態		7 (4.7)	1 (0.7)
疲労		2 (1.4)	0 (0.0)
無力症		1 (0.7)	0 (0.0)
胸痛		1 (0.7)	0 (0.0)
異常感		1 (0.7)	0 (0.0)
注射部位疼痛		1 (0.7)	1 (0.7)
倦怠感		1 (0.7)	0 (0.0)
代謝および栄養障害		7 (4.7)	0 (0.0)
高カリウム血症		3 (2.0)	0 (0.0)
高カルシウム血症		2 (1.4)	0 (0.0)
水分過負荷		1 (0.7)	0 (0.0)
高コレステロール血症		1 (0.7)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver16.1Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．

表 2.7.6.17-36 有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120359 試験）（続き 4）
解析対象集団：SAF

SOC PT		有害事象 ONO-5163 n (%)	治験薬との因果関係が否定できない有害事象 ONO-5163 n (%)
	N	148	148
低アルブミン血症		1 (0.7)	0 (0.0)
心臓障害		4 (2.7)	0 (0.0)
急性心筋梗塞		1 (0.7)	0 (0.0)
心停止		1 (0.7)	0 (0.0)
うっ血性心不全		1 (0.7)	0 (0.0)
頻脈		1 (0.7)	0 (0.0)
精神障害		3 (2.0)	0 (0.0)
不安		1 (0.7)	0 (0.0)
うつ病		1 (0.7)	0 (0.0)
失見当識		1 (0.7)	0 (0.0)
精神状態変化		1 (0.7)	0 (0.0)
生殖系および乳房障害		3 (2.0)	0 (0.0)
勃起不全		2 (1.4)	0 (0.0)
前立腺炎		1 (0.7)	0 (0.0)
血管障害		3 (2.0)	0 (0.0)
低血圧		2 (1.4)	0 (0.0)
血管石灰化		1 (0.7)	0 (0.0)
眼障害		2 (1.4)	0 (0.0)
網膜剥離		2 (1.4)	0 (0.0)
内分泌障害		1 (0.7)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver16.1Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．

表 2.7.6.17-36 有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120359 試験）（続き 5）
解析対象集団：SAF

	有害事象	治験薬との因果関係が否定できない有害事象
SOC	ONO-5163	ONO-5163
PT	n （%）	n （%）
N	148	148
副甲状腺機能亢進症	1 (0.7)	0 (0.0)
肝胆道系障害	1 (0.7)	0 (0.0)
胆管閉塞	1 (0.7)	0 (0.0)
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 (0.7)	0 (0.0)
非小細胞肺癌	1 (0.7)	0 (0.0)
腎および尿路障害	1 (0.7)	0 (0.0)
血尿	1 (0.7)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver16.1Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．

出典［総括報告書 5.3.5.2-5（20120359 試験）Table 14-6.4 及び Table 14-6.8 改変］

表 2.7.6.17-37　死亡した被験者の一覧表（20120359 試験）

Treatment Group	Usubject ID	Age (years)	Sex	Race	Ethnicity	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
NOT TREATED	20120359-35966057001	5[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CARDIAC ARREST [心停止]	20[redacted]-12-15	-3	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-30	FATAL
VELCALCETIDE	20120359-35966036001	7[redacted]	M	WHITE	HISPANIC OR LATINO	BILLIARY SEPSIS [胆道性敗血症]	20[redacted]-11-16	18	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-23	FATAL

*1:MedDRA Version 16.1J
VELCALCETIDE = ONO-5163

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

表 2.7.6.17-38　重篤な有害事象の一覧表（20120359 試験）

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
NOT TREATED	20120359-35966002008	ACUTE LEFT OCCIPITAL CEREBROVASCULAR ACCIDENT [脳血管発作]	20[redacted]-11-11	-4	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-11-15	RECOVERED/RESOLVED
NOT TREATED	20120359-35966050002	HYPERKALEMIA [高カリウム血症]	20[redacted]-09-04	-30	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-09-08	RECOVERED/RESOLVED
NOT TREATED	20120359-35966057001	CARDIAC ARREST [心停止]	20[redacted]-12-15	-3	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-30	FATAL
VELCALCETIDE	20120359-35966008001	STROKE [脳血管発作]	20[redacted]-11-21	11	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-04	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966009002	BLOOD SUGAR INCREASED [血中ブドウ糖増加]	20[redacted]-01-06	43	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-01-09	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966009002	NON ST SEGMENT ELEVATION MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-01-10	47	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-25	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966010003	COMMON BILIARY DUCT OBSTRUCTION [胆管閉塞]	20[redacted]-01-03	33	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-06	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966014001	PNEUMONIA [肺炎]	20[redacted]-01-01	42	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-08	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966015006	RIGHT FOURTH TOE SEVERELY INFECTED [限局性感染]	20[redacted]-11-14	-28	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	-	20[redacted]-11-19	RECOVERED/RESOLVED

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
VELCALCETIDE	20120359-35966015006	BILATERAL FEET ULCERS (OSTEOMYLITIS) [骨髄炎]	20[redacted]-12-16	5	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-18	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966019001	WORSENING OF HYPOTENSION DURING HEMODIALYSIS [処置による低血圧]	20[redacted]-10-30	29	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-11-01	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966019001	KNEE PAIN [関節痛]	20[redacted]-11-18	48	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-11-23	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966019007	GENERALIZED BODY ACHES AND PAIN [疼痛]	20[redacted]-11-10	-17	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-11-13	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966022005	DIEULAFOY'S VASCULAR MALFORMATION [デュラフォア血管奇形]	20[redacted]-10-02	-63	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, DEVICE / PROCEDURE INTERVENTION	-	20[redacted]-10-16	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966025002	ANEMIA [貧血]	20[redacted]-11-07	-12	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	-	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-11-12	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966028012	HYPERTENSIVE EMERGENCY [高血圧緊急症]	20[redacted]-11-05	-30	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-11-08	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966031009	NON SMALL CELL CANCER OF THE LUNG [非小細胞肺癌]	20[redacted]-01-27	43	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
VELCALCETIDE	20120359-35966033002	PULMONARY EDEMA [肺水腫]	20[redacted]-11-03	7	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-06	RECOVERED/RESOLVED

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
VELCALCETIDE	20120359-35966036001	BILLIARY SEPSIS [胆道性敗血症]	20[redacted]-11-16	18	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-23	FATAL
VELCALCETIDE	20120359-35966040009	FRACTURED LEFT HIP [股関節部骨折]	20[redacted]-01-10	38	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-28	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966044001	HYPOXEMIA [低酸素症]	20[redacted]-11-21	-20	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-26	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966047004	MENTAL STATUS CHANGES [精神状態変化]	20[redacted]-01-02	25	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-06	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966048002	COLLAPSED LUNG [気胸]	20[redacted]-01-15	49	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-20	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966057002	DIALYSIS INFECTED GRAFT [動静脈グラフト部位感染]	20[redacted]-01-30	44	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-02-10	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966061006	CARDIAC ARREST [心停止]	20[redacted]-01-07	43	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-17	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966061006	PNEUMONIA [肺炎]	20[redacted]-01-07	43	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-17	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966061007	HYPERKALEMIA [高カリウム血症]	20[redacted]-01-11	46	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-01-14	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966061007	INCREASED WEAKNESS [無力症]	20[redacted]-01-11	46	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-01-14	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966062001	FLUID OVERLOAD [水分過負荷]	20[redacted]-01-12	54	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-13	RECOVERED/RESOLVED

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time *	Outcome of Serious Adverse Event
VELCALCETIDE	20120359-35966063003	STAPHYLOCOCCAL BACTEREMIA [ブドウ球菌性菌血症]	20[redacted]-12-20 *	1	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-07 *	RECOVERED/RESOLVED
VELCALCETIDE	20120359-35966063003	EXTREMELY ATYPICAL CHEST PAIN OF UNKNOWN ORIGIN [胸痛]	20[redacted]-01-11	23	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-01-12	RECOVERED/RESOLVED

*1:MedDRA Version 16.1J
VELCALCETIDE = ONO-5163

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

表 2.7.6.17-39　投与中止に至った有害事象の一覧表（20120359 試験）

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
VELCALCETIDE	20120359-35966008004	DIARRHEA RECURRENT [下痢]	20[redacted]-11-18	6	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-11-20	-
VELCALCETIDE	20120359-35966025003	AV FISTULA OCCLUSION [動静脈瘻閉塞]	20[redacted]-12-13	26	MODERATE	NO	-	DRUG WITHDRAWN	SURGICAL INTERVENTION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-12-14	-

*1:MedDRA Version 16.1J
VELCALCETIDE = ONO-5163

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）
解析対象集団：FAS

SOC	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
全体	87/37.6 (231.6)	42.2	83/36.5 (227.4)	43.0	37/12.6 (293.5)	26.6	207/86.7 (238.8)	38.5
血液およびリンパ系障害	4/54.6 (7.3)	1.9	3/51.5 (5.8)	1.6	0/17.3 (0.0)	0.0	7/123.5 (5.7)	1.3
腎性貧血	2/55.0 (3.6)	1.0	1/52.0 (1.9)	0.5	0/17.3 (0.0)	0.0	3/124.3 (2.4)	0.6
貧血	1/55.4 (1.8)	0.5	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	2/124.8 (1.6)	0.4
好中球減少症	1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
汎血球減少症	0/55.5 (0.0)	0.0	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.
出典［総括報告書 5.3.5.2-6（20130213 試験）Table 14-6.2 改変］

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 1）
解析対象集団：FAS

	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
SOC	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
心臓障害	9/54.0 (16.7)	4.4	9/51.1 (17.6)	4.7	1/17.3 (5.8)	0.7	19/122.3 (15.5)	3.5
動悸	2/54.9 (3.6)	1.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	3/124.2 (2.4)	0.6
頻脈	3/55.2 (5.4)	1.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	3/124.7 (2.4)	0.6
心房細動	0/55.5 (0.0)	0.0	2/51.9 (3.9)	1.0	0/17.3 (0.0)	0.0	2/124.6 (1.6)	0.4
徐脈	1/55.3 (1.8)	0.5	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	2/124.9 (1.6)	0.4
心停止	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	1/17.3 (5.8)	0.7	2/125.0 (1.6)	0.4

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 2）
解析対象集団：FAS

SOC	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
急性心筋梗塞	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
狭心症	1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
うっ血性心不全	1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
心筋症	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
心筋梗塞	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
心筋虚血	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 3）
解析対象集団：FAS

	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
SOC	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
洞性頻脈	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
先天性、家族性および遺伝性障害	2/54.9 (3.6)	1.0	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	2/124.5 (1.6)	0.4
胃腸管動静脈奇形	1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
孔脳症	1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
内分泌障害	1/55.3 (1.8)	0.5	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	2/124.8 (1.6)	0.4
副甲状腺機能亢進症	1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 4）
解析対象集団：FAS

	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
SOC	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
甲状腺機能低下症	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
眼障害	3/54.5 (5.5)	1.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	3/124.0 (2.4)	0.6
結膜出血	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
眼出血	1/54.7 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.3 (0.8)	0.2
緑内障	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
胃腸障害	19/52.2 (36.4)	9.2	19/49.3 (38.5)	9.8	8/15.8 (50.7)	5.8	46/117.3 (39.2)	8.6

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 5）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
		シナカルセト		ONO-5163		ONO-5163			
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
下痢		4/54.7 (7.3)	1.9	7/51.2 (13.7)	3.6	3/17.0 (17.6)	2.2	14/122.9 (11.4)	2.6
悪心		4/54.9 (7.3)	1.9	5/51.1 (9.8)	2.6	1/16.9 (5.9)	0.7	10/122.9 (8.1)	1.9
嘔吐		4/54.8 (7.3)	1.9	5/51.3 (9.7)	2.6	1/17.3 (5.8)	0.7	10/123.4 (8.1)	1.9
腹痛		3/55.0 (5.5)	1.5	4/51.7 (7.7)	2.1	1/17.2 (5.8)	0.7	8/123.9 (6.5)	1.5
消化不良		3/54.9 (5.5)	1.5	0/52.3 (0.0)	0.0	2/16.7 (12.0)	1.4	5/123.9 (4.0)	0.9
上腹部痛		2/55.4 (3.6)	1.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	3/124.9 (2.4)	0.6

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 6）
解析対象集団：FAS

SOC / PT		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
便秘		1/55.3 (1.8)	0.5	2/51.7 (3.9)	1.0	0/17.3 (0.0)	0.0	3/124.3 (2.4)	0.6
胃炎		2/55.2 (3.6)	1.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	3/124.6 (2.4)	0.6
腹部不快感		0/55.5 (0.0)	0.0	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
腹部ヘルニア		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
腹水		1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
糞塊		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 7）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
胃ポリープ		1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
胃潰瘍		1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
胃腸出血		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.1 (5.9)	0.7	1/124.8 (0.8)	0.2
痔出血		0/55.5 (0.0)	0.0	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
裂孔ヘルニア		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
イレウス		1/55.5 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 8）
解析対象集団：FAS

SOC / PT		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
		シナカルセト		ONO-5163		ONO-5163			
		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
単径ヘルニア		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
歯痛		0/55.5 (0.0)	0.0	1/51.8 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.6 (0.8)	0.2
上部消化管出血		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
一般・全身障害および投与部位の状態		12/53.4 (22.5)	5.8	9/50.6 (17.8)	4.7	5/16.5 (30.2)	3.6	26/120.5 (21.6)	4.8
末梢性浮腫		3/54.7 (5.5)	1.5	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	4/124.1 (3.2)	0.7
無力症		2/55.2 (3.6)	1.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	3/124.6 (2.4)	0.6

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 9）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
胸痛		0/55.5 (0.0)	0.0	2/51.8 (3.9)	1.0	1/17.2 (5.8)	0.7	3/124.5 (2.4)	0.6
倦怠感		0/55.5 (0.0)	0.0	1/52.0 (1.9)	0.5	2/17.2 (11.7)	1.4	3/124.7 (2.4)	0.6
医療機器合併症		2/55.2 (3.6)	1.0	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	2/124.8 (1.6)	0.4
疼痛		1/55.5 (1.8)	0.5	0/52.3 (0.0)	0.0	1/17.0 (5.9)	0.7	2/124.7 (1.6)	0.4
末梢腫脹		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	1/16.8 (5.9)	0.7	2/124.5 (1.6)	0.4
発熱		2/54.8 (3.6)	1.0	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	2/124.4 (1.6)	0.4

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 10）
解析対象集団：FAS

SOC / PT		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
医療機器関連の血栓症		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	1/17.2 (5.8)	0.7	2/124.9 (1.6)	0.4
悪寒		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
疲労		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
治癒不良		0/55.5 (0.0)	0.0	1/51.8 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.6 (0.8)	0.2
非心臓性胸痛		1/55.5 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
全身性炎症反応症候群		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 11）
解析対象集団：FAS

SOC	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
肝胆道系障害	1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	2/124.7 (1.6)	0.4
胆石症	1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
肝損傷	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
免疫系障害	0/55.5 (0.0)	0.0	1/52.0 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
薬物過敏症	0/55.5 (0.0)	0.0	1/52.0 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
感染症および寄生虫症	23/50.9 (45.2)	11.2	25/48.5 (51.5)	13.0	11/16.3 (67.5)	7.9	59/115.7 (51.0)	11.0

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 12）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
鼻咽頭炎		4/54.9 (7.3)	1.9	1/52.2 (1.9)	0.5	3/17.0 (17.7)	2.2	8/124.0 (6.5)	1.5
上気道感染		1/55.3 (1.8)	0.5	4/51.7 (7.7)	2.1	2/16.9 (11.8)	1.4	7/123.9 (5.6)	1.3
気管支炎		2/55.1 (3.6)	1.0	3/51.9 (5.8)	1.6	0/17.3 (0.0)	0.0	5/124.2 (4.0)	0.9
肺炎		2/55.2 (3.6)	1.0	3/51.8 (5.8)	1.6	0/17.3 (0.0)	0.0	5/124.3 (4.0)	0.9
尿路感染		2/54.8 (3.7)	1.0	3/52.0 (5.8)	1.6	0/17.3 (0.0)	0.0	5/124.1 (4.0)	0.9
胃腸炎		3/54.4 (5.5)	1.5	0/52.3 (0.0)	0.0	1/17.2 (5.8)	0.7	4/123.8 (3.2)	0.7

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e＝n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 13）
解析対象集団：FAS

SOC / PT	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
限局性感染	0/55.5 (0.0)	0.0	3/51.2 (5.9)	1.6	0/17.3 (0.0)	0.0	3/124.0 (2.4)	0.6
敗血症	2/55.1 (3.6)	1.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	3/124.6 (2.4)	0.6
蜂巣炎	0/55.5 (0.0)	0.0	2/51.5 (3.9)	1.0	0/17.3 (0.0)	0.0	2/124.3 (1.6)	0.4
結膜炎	0/55.5 (0.0)	0.0	1/52.3 (1.9)	0.5	1/17.3 (5.8)	0.7	2/125.0 (1.6)	0.4
医療機器関連感染	0/55.5 (0.0)	0.0	1/51.8 (1.9)	0.5	1/17.3 (5.8)	0.7	2/124.6 (1.6)	0.4
気道感染	1/55.4 (1.8)	0.5	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	2/124.9 (1.6)	0.4

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%＝有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 14）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
ウイルス性気道感染		1/55.4 (1.8)	0.5	1/52.3 (1.9)	0.5	0/17.3 (0.0)	0.0	2/125.0 (1.6)	0.4
急性扁桃炎		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
肛門膿瘍		1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
動静脈瘻部位感染		1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
ウイルス性気管支炎		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
気管支肺炎		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 15）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
クロストリジウム・ディフィシレ大腸炎		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
クロストリジウム・ディフィシレ感染		0/55.5 (0.0)	0.0	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
医療機器関連敗血症		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
心内膜炎		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
喉頭蓋炎		0/55.5 (0.0)	0.0	1/52.0 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
眼感染		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 16）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
壊疽		0/55.5 (0.0)	0.0	1/51.8 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.6 (0.8)	0.2
歯肉炎		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
寄生虫感染		1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
インフルエンザ		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
骨髄炎		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
鼻炎		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.2 (5.8)	0.7	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e＝n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 17）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
敗血症性ショック		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
副鼻腔炎		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
皮膚感染		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
皮下組織膿瘍		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
歯膿瘍		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
細菌性上気道感染		1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 18）
解析対象集団：FAS

SOC	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
ウイルス感染	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
ウイルス性上気道感染	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
創傷感染	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
傷害、中毒および処置合併症	15/52.7 (28.5)	7.3	8/50.3 (15.9)	4.1	7/16.0 (43.8)	5.0	30/119.0 (25.2)	5.6
動静脈瘻部位合併症	2/55.2 (3.6)	1.0	0/52.3 (0.0)	0.0	2/16.8 (11.9)	1.4	4/124.3 (3.2)	0.7
転倒	1/55.3 (1.8)	0.5	1/52.2 (1.9)	0.5	2/17.0 (11.8)	1.4	4/124.5 (3.2)	0.7

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた.
n = 有害事象発現例数.
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 19）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
裂傷		1/55.3 (1.8)	0.5	1/52.1 (1.9)	0.5	2/16.9 (11.8)	1.4	4/124.3 (3.2)	0.7
動静脈瘻血栓症		1/55.3 (1.8)	0.5	1/52.0 (1.9)	0.5	0/17.3 (0.0)	0.0	2/124.6 (1.6)	0.4
頭部損傷		1/55.2 (1.8)	0.5	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	2/124.4 (1.6)	0.4
処置による低血圧		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	1/17.2 (5.8)	0.7	2/124.9 (1.6)	0.4
移植血管合併症		1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	1/17.2 (5.8)	0.7	2/124.6 (1.6)	0.4
足関節部骨折		1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 20）
解析対象集団：FAS

SOC / PT		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
		シナカルセト		ONO-5163		ONO-5163			
		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
動静脈瘻閉塞		1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
動静脈瘻部位出血		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
挫傷		0/55.5 (0.0)	0.0	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
切開部位炎症		0/55.5 (0.0)	0.0	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
肉離れ		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
処置後出血		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.2 (5.8)	0.7	1/124.9 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 21）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
処置後腫脹		1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
処置による頭痛		1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
処置による高血圧		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
肋骨骨折		1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
引っかき傷		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
シャント閉塞		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e＝n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 22）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
熱傷		0/55.5 (0.0)	0.0	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.6 (0.8)	0.2
血管確保合併症		1/55.5 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
血管グラフト血栓症		1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
臨床検査		28/48.6 (57.7)	13.6	25/48.0 (52.1)	13.0	6/17.0 (35.4)	4.3	59/113.5 (52.0)	11.0
血中カルシウム減少		22/50.3 (43.7)	10.7	20/49.0 (40.8)	10.4	4/17.0 (23.5)	2.9	46/116.3 (39.5)	8.6
血中副甲状腺ホルモン減少		2/55.1 (3.6)	1.0	2/51.9 (3.9)	1.0	0/17.3 (0.0)	0.0	4/124.3 (3.2)	0.7

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 23）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
血中カリウム増加		2/54.8 (3.7)	1.0	2/51.7 (3.9)	1.0	0/17.3 (0.0)	0.0	4/123.7 (3.2)	0.7
血中リン増加		2/54.7 (3.7)	1.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	3/124.2 (2.4)	0.6
アラニンアミノトランスフェラーゼ増加		1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	2/124.7 (1.6)	0.4
血中アルカリホスファターゼ増加		1/54.9 (1.8)	0.5	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	2/124.4 (1.6)	0.4
補正カルシウム減少		1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
アスパラギン酸アミノトランスフェラーゼ増加		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 24）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
血中アルブミン減少		1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
血中カルシウム増加		1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
結腸内視鏡検査		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
好酸球数増加		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
国際標準比増加		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
便潜血陽性		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e＝n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 25）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
体重増加		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
代謝および栄養障害		9/54.1 (16.6)	4.4	11/50.2 (21.9)	5.7	5/16.5 (30.4)	3.6	25/120.8 (20.7)	4.6
高カリウム血症		2/55.1 (3.6)	1.0	4/51.9 (7.7)	2.1	1/17.3 (5.8)	0.7	7/124.3 (5.6)	1.3
ビタミンD欠乏		1/55.1 (1.8)	0.5	3/51.4 (5.8)	1.6	0/17.3 (0.0)	0.0	4/123.8 (3.2)	0.7
水分過負荷		0/55.5 (0.0)	0.0	2/52.0 (3.8)	1.0	1/17.1 (5.9)	0.7	3/124.5 (2.4)	0.6
高リン酸塩血症		1/55.4 (1.8)	0.5	1/51.9 (1.9)	0.5	1/17.3 (5.8)	0.7	3/124.5 (2.4)	0.6

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e＝n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 26）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
食欲減退		2/55.4 (3.6)	1.0	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	2/125.0 (1.6)	0.4
低リン酸血症		0/55.5 (0.0)	0.0	2/51.8 (3.9)	1.0	0/17.3 (0.0)	0.0	2/124.6 (1.6)	0.4
アルカローシス		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
カルシフィラキシス		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/16.8 (5.9)	0.7	1/124.6 (0.8)	0.2
高血糖		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.2 (5.8)	0.7	1/124.9 (0.8)	0.2
低カルシウム血症		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%＝有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 27）
解析対象集団：FAS

SOC / PT	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
低カリウム血症	1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
筋骨格系および結合組織障害	13/53.3 (24.4)	6.3	11/50.0 (22.0)	5.7	5/16.4 (30.5)	3.6	29/119.7 (24.2)	5.4
筋痙縮	5/54.6 (9.2)	2.4	2/52.1 (3.8)	1.0	1/17.1 (5.9)	0.7	8/123.8 (6.5)	1.5
四肢痛	3/54.8 (5.5)	1.5	3/51.6 (5.8)	1.6	1/17.3 (5.8)	0.7	7/123.7 (5.7)	1.3
背部痛	2/55.2 (3.6)	1.0	2/51.6 (3.9)	1.0	1/17.2 (5.8)	0.7	5/124.1 (4.0)	0.9
筋力低下	1/55.4 (1.8)	0.5	1/52.1 (1.9)	0.5	1/17.0 (5.9)	0.7	3/124.5 (2.4)	0.6

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e＝n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 28）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
		シナカルセト		ONO-5163		ONO-5163			
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
関節炎		1/55.3 (1.8)	0.5	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	2/124.5 (1.6)	0.4
骨痛		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
関節滲出液		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
四肢不快感		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/16.9 (5.9)	0.7	1/124.6 (0.8)	0.2
筋骨格系胸痛		1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
筋骨格硬直		0/55.5 (0.0)	0.0	1/51.7 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.5 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 29）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
頚部痛		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
変形性関節症		0/55.5 (0.0)	0.0	1/52.3 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
脊椎痛		1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
腱石灰化		1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
斜頚		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
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）		3/54.9 (5.5)	1.5	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	4/124.3 (3.2)	0.7

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 30）
解析対象集団：FAS

	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
SOC	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
皮膚有棘細胞癌	2/55.1 (3.6)	1.0	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	2/124.6 (1.6)	0.4
メラノサイト性母斑	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
良性副甲状腺腫瘍	1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
神経系障害	10/54.0 (18.5)	4.9	8/51.0 (15.7)	4.1	7/15.8 (44.3)	5.0	25/120.8 (20.7)	4.6
頭痛	2/55.0 (3.6)	1.0	2/52.1 (3.8)	1.0	1/16.9 (5.9)	0.7	5/124.1 (4.0)	0.9
浮動性めまい	2/55.1 (3.6)	1.0	1/52.0 (1.9)	0.5	1/16.8 (5.9)	0.7	4/123.9 (3.2)	0.7

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e＝n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 31）
解析対象集団：FAS

SOC / PT		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
失神		1/55.4 (1.8)	0.5	3/52.0 (5.8)	1.6	0/17.3 (0.0)	0.0	4/124.7 (3.2)	0.7
錯感覚		1/55.4 (1.8)	0.5	2/51.8 (3.9)	1.0	0/17.3 (0.0)	0.0	3/124.5 (2.4)	0.6
痙攣		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	1/17.2 (5.8)	0.7	2/124.9 (1.6)	0.4
てんかん		1/55.5 (1.8)	0.5	0/52.3 (0.0)	0.0	1/17.1 (5.8)	0.7	2/124.9 (1.6)	0.4
一過性脳虚血発作		1/55.5 (1.8)	0.5	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	2/124.7 (1.6)	0.4
脳損傷		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 32）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
頚動脈狭窄		0/55.5 (0.0)	0.0	1/52.0 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
脳出血		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
味覚異常		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
ジスキネジア		1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
過眠症		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.2 (5.8)	0.7	1/124.9 (0.8)	0.2
筋緊張低下		1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e＝n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 33）
解析対象集団：FAS

SOC	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
下肢静止不能症候群	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.1 (5.8)	0.7	1/124.9 (0.8)	0.2
傾眠	1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
くも膜下出血	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
精神障害	3/54.9 (5.5)	1.5	2/52.1 (3.8)	1.0	2/17.2 (11.6)	1.4	7/124.1 (5.6)	1.3
うつ病	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	1/17.2 (5.8)	0.7	2/124.9 (1.6)	0.4
不眠症	2/55.0 (3.6)	1.0	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	2/124.5 (1.6)	0.4

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%＝有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 34）
解析対象集団：FAS

SOC / PT	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
精神状態変化	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	1/17.3 (5.8)	0.7	2/124.8 (1.6)	0.4
不安	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
腎および尿路障害	3/54.9 (5.5)	1.5	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	4/124.3 (3.2)	0.7
腎嚢胞	1/55.2 (1.8)	0.5	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	2/124.6 (1.6)	0.4
血尿	1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
尿道狭窄	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 35）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
生殖系および乳房障害		4/54.5 (7.3)	1.9	2/52.0 (3.8)	1.0	0/17.3 (0.0)	0.0	6/123.8 (4.8)	1.1
勃起不全		2/55.3 (3.6)	1.0	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	2/124.9 (1.6)	0.4
月経困難症		1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
不正子宮出血		1/55.0 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.6 (0.8)	0.2
骨盤痛		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
腟分泌物		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 36）
解析対象集団：FAS

	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
SOC	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
呼吸器、胸郭および縦隔障害	5/54.3 (9.2)	2.4	3/51.4 (5.8)	1.6	2/17.2 (11.6)	1.4	10/122.9 (8.1)	1.9
呼吸困難	3/55.1 (5.4)	1.5	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	4/124.3 (3.2)	0.7
咳嗽	1/55.4 (1.8)	0.5	2/51.8 (3.9)	1.0	0/17.3 (0.0)	0.0	3/124.5 (2.4)	0.6
鼻出血	1/55.2 (1.8)	0.5	1/52.1 (1.9)	0.5	1/17.2 (5.8)	0.7	3/124.5 (2.4)	0.6
レスピレータ依存	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
肺高血圧症	1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%＝有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 37）
解析対象集団：FAS

SOC / PT		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
肺水腫		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
肺痛		1/55.0 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.5 (0.8)	0.2
皮膚および皮下組織障害		3/54.9 (5.5)	1.5	2/51.7 (3.9)	1.0	0/17.3 (0.0)	0.0	5/123.9 (4.0)	0.9
そう痒症		2/55.0 (3.6)	1.0	1/51.8 (1.9)	0.5	0/17.3 (0.0)	0.0	3/124.1 (2.4)	0.6
日光角化症		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
皮膚亀裂		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 38）
解析対象集団：FAS

SOC / PT		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
血管障害		14/53.3 (26.3)	6.8	6/50.7 (11.8)	3.1	3/17.2 (17.5)	2.2	23/121.2 (19.0)	4.3
高血圧		7/54.3 (12.9)	3.4	3/51.7 (5.8)	1.6	2/17.3 (11.6)	1.4	12/123.2 (9.7)	2.2
低血圧		3/55.4 (5.4)	1.5	1/52.3 (1.9)	0.5	1/17.2 (5.8)	0.7	5/124.9 (4.0)	0.9
腕頭静脈狭窄		0/55.5 (0.0)	0.0	1/51.8 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.6 (0.8)	0.2
高血圧緊急症		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
起立性低血圧		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-40　有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 39）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
末梢血管障害		0/55.5 (0.0)	0.0	1/51.7 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.5 (0.8)	0.2
上大静脈症候群		1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
静脈閉塞		1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.
出典［総括報告書 5.3.5.2-6（20130213 試験）Table 14-6.2 改変］

表 2.7.6.17-41　治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20130213 試験）
解析対象集団：FAS

	治験薬との因果関係が否定できない有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
SOC	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
全体	28/49.1 (57.1)	13.6	28/47.3 (59.2)	14.5	5/17.0 (29.5)	3.6	61/113.3 (53.8)	11.3
胃腸障害	3/54.9 (5.5)	1.5	6/51.1 (11.7)	3.1	0/17.3 (0.0)	0.0	9/123.3 (7.3)	1.7
悪心	2/55.0 (3.6)	1.0	5/51.2 (9.8)	2.6	0/17.3 (0.0)	0.0	7/123.5 (5.7)	1.3
下痢	1/55.3 (1.8)	0.5	3/51.4 (5.8)	1.6	0/17.3 (0.0)	0.0	4/124.0 (3.2)	0.7
嘔吐	1/55.1 (1.8)	0.5	3/51.6 (5.8)	1.6	0/17.3 (0.0)	0.0	4/124.0 (3.2)	0.7

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n＝治験薬との因果関係が否定できない有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率 = 100 n/ e.
**%＝治験薬との因果関係が否定できない有害事象発現率 = 100*n/N.
出典［総括報告書 5.3.5.2-6（20130213 試験）Table 14-6.4 改変］

表 2.7.6.17-41　治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 1）
解析対象集団：FAS

	治験薬との因果関係が否定できない有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
SOC	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
腹部不快感	0/55.5 (0.0)	0.0	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
上腹部痛	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
肝胆道系障害	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
肝損傷	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
臨床検査	22/49.9 (44.1)	10.7	22/48.6 (45.2)	11.4	5/17.0 (29.5)	3.6	49/115.5 (42.4)	9.1

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n = 治験薬との因果関係が否定できない有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率 = 100 n/ e.
**% = 治験薬との因果関係が否定できない有害事象発現率 = 100*n/N.

表 2.7.6.17-41　治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 2）
解析対象集団：FAS

	治験薬との因果関係が否定できない有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
SOC	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
血中カルシウム減少	21/50.5 (41.6)	10.2	20/49.0 (40.8)	10.4	4/17.0 (23.5)	2.9	45/116.5 (38.6)	8.4
血中副甲状腺ホルモン減少	2/55.1 (3.6)	1.0	2/51.9 (3.9)	1.0	0/17.3 (0.0)	0.0	4/124.3 (3.2)	0.7
アラニンアミノトランスフェラーゼ増加	1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	2/124.7 (1.6)	0.4
補正カルシウム減少	1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
アスパラギン酸アミノトランスフェラーゼ増加	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n = 治験薬との因果関係が否定できない有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率 = 100 n/ e.
**% = 治験薬との因果関係が否定できない有害事象発現率 = 100*n/N.

表 2.7.6.17-41　治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 3）
解析対象集団：FAS

	治験薬との因果関係が否定できない有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
SOC	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
血中アルカリホスファターゼ増加	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
好酸球数増加	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
代謝および栄養障害	2/55.4 (3.6)	1.0	2/51.8 (3.9)	1.0	0/17.3 (0.0)	0.0	4/124.5 (3.2)	0.7
低リン酸血症	0/55.5 (0.0)	0.0	2/51.8 (3.9)	1.0	0/17.3 (0.0)	0.0	2/124.6 (1.6)	0.4
食欲減退	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n＝治験薬との因果関係が否定できない有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e＝n/e (yrs); r＝曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率＝100 n/ e.
**%＝治験薬との因果関係が否定できない有害事象発現率＝100*n/N.

表 2.7.6.17-41　治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 4）
解析対象集団：FAS

	治験薬との因果関係が否定できない有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
SOC	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
低カルシウム血症	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
筋骨格系および結合組織障害	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
筋痙縮	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
神経系障害	2/55.3 (3.6)	1.0	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	2/124.9 (1.6)	0.4
味覚異常	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n＝治験薬との因果関係が否定できない有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率 = 100 n/ e.
**% = 治験薬との因果関係が否定できない有害事象発現率 = 100*n/N.

表 2.7.6.17-41　治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 5）
解析対象集団：FAS

	治験薬との因果関係が否定できない有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
SOC	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
錯感覚	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
精神障害	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
不安	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
皮膚および皮下組織障害	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
そう痒症	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n＝治験薬との因果関係が否定できない有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率 = 100 n/ e.
**% = 治験薬との因果関係が否定できない有害事象発現率 = 100*n/N.
出典［総括報告書 5.3.5.2-6（20130213 試験）Table 14-6.4 改変］

表 2.7.6.17-42　死亡した被験者の一覧表（20130213 試験）

Treatment Group	Usubject ID	Age (years)	Sex	Race	Ethnicity	Reported Term for the Adverse Event [Preferred Term[1]]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120360-36021004003	5[redacted]	F	WHITE	NOT HISPANIC OR LATINO	PROGRESSIVE SEPSIS [敗血症]	20[redacted]-09-19	22	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-09-26	FATAL
AMG 416	20120360-36066059001	4[redacted]	M	ASIAN	NOT HISPANIC OR LATINO	INTERNAL HEMORRHAGE (BRAIN) [脳出血]	20[redacted]-09-22	19	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-03	FATAL
AMG 416	20120360-36066059001	4[redacted]	M	ASIAN	NOT HISPANIC OR LATINO	WORSENING HYPERTENSION [高血圧]	20[redacted]-09-22	19	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-03	NOT RECOVERED/NOT RESOLVED
AMG 416	KAI-4169-005-0511-1515	5[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CHEST PAIN [胸痛]	20[redacted]-08-04	4	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-08	RECOVERED/RESOLVED

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

Treatment Group	Usubject ID	Age (years)	Sex	Race	Ethnicity	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	KAI-4169-005-0511-1515	5[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ANOXIC BRAIN INJURY [脳損傷]	20[redacted]-08-22	22	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-09-08	FATAL
AMG 416	KAI-4169-005-0511-1515	5[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CARDIAC ARREST [心停止]	20[redacted]-08-22	22	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-08	RECOVERED/RESOLVED
AMG 416	KAI-4169-005-0511-1532	6[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	MALFUNTIONING HEMODIALYSIS CATHETER [医療機器合併症]	20[redacted]-07-14	-2	MODERATE	NO	-	DOSE NOT CHANGED	DEVICE / PROCEDURE INTERVENTION	-	20[redacted]-07-14 *	-
AMG 416	KAI-4169-005-0511-1532	6[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	LOWER GASTROINTESTINAL BLEED [胃腸出血]	20[redacted]-10-20	97	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-19	RECOVERED/RESOLVED

年齢以外のマスキングにおいて,
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

Treatment Group	Usubject ID	Age (years)	Sex	Race	Ethnicity	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time *	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time *	Outcome of Serious Adverse Event
AMG 416	KAI-4169-005-0511-1532	6[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CENTRAL VENOUS CATHETER ASSOCIATED MRSA BACTEREMIA [医療機器関連感染]	20[redacted]-01-02 *	171	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-19 *	RECOVERED/RESOLVED
AMG 416	KAI-4169-005-0511-1532	6[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-01-03 *	172	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-19 *	RECOVERED/RESOLVED
AMG 416	KAI-4169-005-0511-1532	6[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	VENTILATOR DEPENDENT RESPIRATORY FAILURE [レスピレータ依存]	20[redacted]-01-03 *	172	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-19 *	FATAL
AMG 416	KAI-4169-005-0511-1532	6[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	MITRAL VALVE ENDOCARDITIS [心内膜炎]	20[redacted]-01-07	176	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-19	RECOVERED/RESOLVED
NOT TREATED	20120359-35966031011	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	BOWEL OBSTRUCTION [腸閉塞]	20[redacted]-01-27	-	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	-	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-01-30	RECOVERED/RESOLVED
NOT TREATED	20120359-35966031011	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	HYPERPOTASSEMIA [高カリウム血症]	20[redacted]-01-27	-	SEVERE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-01-30	RECOVERED/RESOLVED

年齢以外のマスキングにおいて,
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

Treatment Group	Usubject ID	Age (years)	Sex	Race	Ethnicity	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
NOT TREATED	20120359-35966031011	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	HYPOTENSION [低血圧]	20[redacted]-01-27	-	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-01-30	RECOVERED/RESOLVED
NOT TREATED	20120359-35966031011	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	VENTRICULAR FIBRILLATION [心室細動]	20[redacted]-01-30	-	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Is Life Threatening, Other Medically Important Serious Event	-	UNKNOWN	-	20[redacted]-01-30	FATAL

*1:MedDRA Version 17.1J
AMG 416 = ONO-5163

年齢以外のマスキングにおいて,
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）
解析対象集団：FAS

SOC / PT	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
全体	21/52.8 (39.8)	10.2	25/48.2 (51.9)	13.0	10/15.9 (63.0)	7.2	56/116.8 (47.9)	10.4
血液およびリンパ系障害	1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
好中球減少症	1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
心臓障害	3/55.0 (5.5)	1.5	7/51.5 (13.6)	3.6	1/17.3 (5.8)	0.7	11/123.8 (8.9)	2.0
心房細動	0/55.5 (0.0)	0.0	2/51.9 (3.9)	1.0	0/17.3 (0.0)	0.0	2/124.6 (1.6)	0.4
心停止	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	1/17.3 (5.8)	0.7	2/125.0 (1.6)	0.4

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e＝n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.
出典［総括報告書 5.3.5.2-6（20130213 試験）Table 14-6.3 改変］

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 1）
解析対象集団：FAS

SOC	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
急性心筋梗塞	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
狭心症	1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
徐脈	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
うっ血性心不全	1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
心筋症	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
心筋梗塞	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 2）
解析対象集団：FAS

SOC	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
心筋虚血	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
先天性、家族性および遺伝性障害	1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
孔脳症	1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
胃腸障害	2/55.2 (3.6)	1.0	3/52.1 (5.8)	1.6	2/17.0 (11.7)	1.4	7/124.3 (5.6)	1.3
嘔吐	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	1/17.3 (5.8)	0.7	2/125.0 (1.6)	0.4
腹水	1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%＝有害事象発現率 = 100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 3）
解析対象集団：FAS

SOC	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
便秘	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
下痢	0/55.5 (0.0)	0.0	1/52.3 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
胃腸出血	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.1 (5.9)	0.7	1/124.8 (0.8)	0.2
イレウス	1/55.5 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
悪心	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
上部消化管出血	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 4）
解析対象集団：FAS

	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
SOC	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
一般・全身障害および投与部位の状態	3/55.1 (5.4)	1.5	4/51.7 (7.7)	2.1	1/17.2 (5.8)	0.7	8/124.0 (6.5)	1.5
胸痛	0/55.5 (0.0)	0.0	1/52.3 (1.9)	0.5	1/17.2 (5.8)	0.7	2/124.9 (1.6)	0.4
無力症	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
治癒不良	0/55.5 (0.0)	0.0	1/51.8 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.6 (0.8)	0.2
非心臓性胸痛	1/55.5 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
発熱	1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e＝n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 5）
解析対象集団：FAS

	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
SOC	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
全身性炎症反応症候群	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
医療機器関連の血栓症	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
肝胆道系障害	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
肝損傷	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
感染症および寄生虫症	8/54.0 (14.8)	3.9	12/50.2 (23.9)	6.2	2/17.2 (11.6)	1.4	22/121.3 (18.1)	4.1
肺炎	2/55.2 (3.6)	1.0	3/51.8 (5.8)	1.6	0/17.3 (0.0)	0.0	5/124.3 (4.0)	0.9

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた.
n＝有害事象発現例数.
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 6）
解析対象集団：FAS

SOC	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
敗血症	2/55.1 (3.6)	1.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	3/124.6 (2.4)	0.6
胃腸炎	1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	1/17.2 (5.8)	0.7	2/124.5 (1.6)	0.4
尿路感染	0/55.5 (0.0)	0.0	2/52.0 (3.8)	1.0	0/17.3 (0.0)	0.0	2/124.8 (1.6)	0.4
動静脈瘻部位感染	1/55.2 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
気管支肺炎	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
蜂巣炎	0/55.5 (0.0)	0.0	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e＝n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 7）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
		シナカルセト		ONO-5163		ONO-5163			
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
医療機器関連感染		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
医療機器関連敗血症		1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
心内膜炎		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
喉頭蓋炎		0/55.5 (0.0)	0.0	1/52.0 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
壊疽		0/55.5 (0.0)	0.0	1/51.8 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.6 (0.8)	0.2
インフルエンザ		0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 8）
解析対象集団：FAS

SOC	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
限局性感染	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
骨髄炎	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
ウイルス性気道感染	0/55.5 (0.0)	0.0	1/52.3 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
敗血症性ショック	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
皮膚感染	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
皮下組織膿瘍	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 9）
解析対象集団：FAS

SOC	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
創傷感染	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
傷害、中毒および処置合併症	5/54.7 (9.1)	2.4	3/51.5 (5.8)	1.6	3/17.1 (17.6)	2.2	11/123.3 (8.9)	2.0
動静脈瘻部位合併症	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	1/17.2 (5.8)	0.7	2/124.9 (1.6)	0.4
動静脈瘻血栓症	1/55.3 (1.8)	0.5	1/52.0 (1.9)	0.5	0/17.3 (0.0)	0.0	2/124.6 (1.6)	0.4
動静脈瘻閉塞	1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
動静脈瘻部位出血	0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e＝n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 10）
解析対象集団：FAS

SOC	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
転倒	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
処置後出血	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.2 (5.8)	0.7	1/124.9 (0.8)	0.2
処置による低血圧	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
熱傷	0/55.5 (0.0)	0.0	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.6 (0.8)	0.2
移植血管合併症	1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2
血管グラフト血栓症	1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 11）
解析対象集団：FAS

SOC / PT	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
臨床検査	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
結腸内視鏡検査	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
代謝および栄養障害	1/55.4 (1.8)	0.5	1/52.1 (1.9)	0.5	2/16.6 (12.0)	1.4	4/124.2 (3.2)	0.7
高カリウム血症	1/55.4 (1.8)	0.5	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	2/124.9 (1.6)	0.4
カルシフィラキシス	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/16.8 (5.9)	0.7	1/124.6 (0.8)	0.2
水分過負荷	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.1 (5.9)	0.7	1/124.8 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 12）
解析対象集団：FAS

	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
SOC	シナカルセト		ONO-5163		ONO-5163		合計	
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
筋骨格系および結合組織障害	2/55.2 (3.6)	1.0	0/52.3 (0.0)	0.0	1/17.2 (5.8)	0.7	3/124.7 (2.4)	0.6
背部痛	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.2 (5.8)	0.7	1/125.0 (0.8)	0.2
筋痙縮	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
腱石灰化	1/55.3 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
神経系障害	2/55.4 (3.6)	1.0	4/51.7 (7.7)	2.1	2/17.1 (11.7)	1.4	8/124.2 (6.4)	1.5
失神	1/55.4 (1.8)	0.5	3/52.0 (5.8)	1.6	0/17.3 (0.0)	0.0	4/124.7 (3.2)	0.7

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**%＝有害事象発現率 = 100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 13）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
		シナカルセト		ONO-5163		ONO-5163			
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
一過性脳虚血発作		1/55.5 (1.8)	0.5	1/51.9 (1.9)	0.5	0/17.3 (0.0)	0.0	2/124.7 (1.6)	0.4
脳損傷		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
頚動脈狭窄		0/55.5 (0.0)	0.0	1/52.0 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
脳出血		0/55.5 (0.0)	0.0	1/52.2 (1.9)	0.5	0/17.3 (0.0)	0.0	1/125.0 (0.8)	0.2
過眠症		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.2 (5.8)	0.7	1/124.9 (0.8)	0.2
くも膜下出血		0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 14）
解析対象集団：FAS

SOC / PT	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
精神障害	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
精神状態変化	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2
腎および尿路障害	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
腎嚢胞	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
呼吸器、胸郭および縦隔障害	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	1/17.3 (5.8)	0.7	2/124.9 (1.6)	0.4
レスピレータ依存	0/55.5 (0.0)	0.0	0/52.3 (0.0)	0.0	1/17.3 (5.8)	0.7	1/125.0 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r = 曝露期間で調整した人年法（100人年）による有害事象発現率 = 100 n/ e.
**% = 有害事象発現率 = 100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 15）
解析対象集団：FAS

SOC	有害事象							
	親試験（20120360試験）				親試験（20120334試験及び 20120231試験）		合計	
	シナカルセト		ONO-5163		ONO-5163			
PT	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
N	206		193		139		538	
肺水腫	0/55.5 (0.0)	0.0	1/52.1 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
血管障害	3/54.7 (5.5)	1.5	2/51.5 (3.9)	1.0	0/17.3 (0.0)	0.0	5/123.4 (4.1)	0.9
高血圧	0/55.5 (0.0)	0.0	1/52.0 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.8 (0.8)	0.2
高血圧緊急症	1/55.4 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.9 (0.8)	0.2
末梢血管障害	0/55.5 (0.0)	0.0	1/51.7 (1.9)	0.5	0/17.3 (0.0)	0.0	1/124.5 (0.8)	0.2
上大静脈症候群	1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた.
n＝有害事象発現例数.
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
n/e＝n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.

表 2.7.6.17-43　重篤な有害事象の SOC・PT 別発現頻度（20130213 試験）（続き 16）
解析対象集団：FAS

SOC		有害事象							
		親試験（20120360試験）				親試験（20120334試験及び 20120231試験）			
		シナカルセト		ONO-5163		ONO-5163		合計	
PT		n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**	n/e(r)*	(%)**
	N	206		193		139		538	
静脈閉塞		1/55.1 (1.8)	0.5	0/52.3 (0.0)	0.0	0/17.3 (0.0)	0.0	1/124.7 (0.8)	0.2

医師から報告された有害事象名は，MedDRA ver17.1Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
n/e = n/e (yrs); r＝曝露期間で調整した人年法（100人年）による有害事象発現率＝100 n/ e.
**%＝有害事象発現率＝100*n/N.
出典［総括報告書 5.3.5.2-6（20130213 試験）Table 14-6.3 改変］

表 2.7.6.17-44　重篤な有害事象の一覧表（20130213 試験）

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120229-22921001001	LIVER INJURY [肝損傷]	20[redacted]-01-06	20	MODERATE	YES	Other Medically Important Serious Event	DRUG INTERRUPTED	NO ACTION TAKEN	RELATED	20[redacted]-02-02	RECOVERED/RESOLVED
AMG 416	20120229-22929007002	DILATATION OF THE CIMINO FISTULE OPERATION [動静脈瘻部位合併症]	20[redacted]-12-10	73	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416	20120229-22966009003	HYPERSOMNOLENCE TO DILAUDID [過眠症]	20[redacted]-11-27 *	16	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-30 *	RECOVERED/RESOLVED
AMG 416	20120229-22966009003	FALL [転倒]	20[redacted]-01-12 *	62	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-17 *	RECOVERED/RESOLVED
AMG 416	20120229-22966009003	SUBARACHNOID HEMORRHAGE [くも膜下出血]	20[redacted]-01-12	62	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-17	RECOVERED/RESOLVED
AMG 416	20120230-23058008010	LOW BACK PAIN [背部痛]	20[redacted]-12-23	14	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-24	RECOVERED/RESOLVED
AMG 416	20120230-23066036013	GASTROENTERITIS [胃腸炎]	20[redacted]-12-14	20	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-16	RECOVERED/RESOLVED
AMG 416	20120230-23066046007	VOMITING [嘔吐]	20[redacted]-01-11	12	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-14	RECOVERED/RESOLVED
AMG 416	20120360-36012007003	MUSCULAR CRAMPS [筋痙縮]	20[redacted]-12-11	15	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-16	RECOVERED/RESOLVED
AMG 416	20120360-36012007003	WEAKNESS [無力症]	20[redacted]-12-11	15	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-16	RECOVERED/RESOLVED

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120360-36013002001	CALCIFYING TENDINOPATHY OF M. SUPRASPINATUS LEFT [腱石灰化]	20[redacted]-11-17	40	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-22	RECOVERED/RESOLVED
AMG 416	20120360-36016003002	PNEUMONIA [肺炎]	20[redacted]-09-19	89	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-09-23	RECOVERED/RESOLVED
AMG 416	20120360-36016004002	ISCHEMIC HEART DISEASE [心筋虚血]	20[redacted]-09-23	-42	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	-	20[redacted]-10-03	RECOVERED/RESOLVED
AMG 416	20120360-36016004004	PULMONARY EDEMA [肺水腫]	20[redacted]-11-23	76	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-11-26	RECOVERED/RESOLVED
AMG 416	20120360-36016004008	KIDNEY CIST [腎嚢胞]	20[redacted]-11-18	72	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-23	RECOVERED/RESOLVED
AMG 416	20120360-36016004008	URINARY INFECTION [尿路感染]	20[redacted]-12-03	87	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-17	RECOVERED/RESOLVED
AMG 416	20120360-36016004009	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-10-30	39	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-03	RECOVERED/RESOLVED
AMG 416	20120360-36016005005	BILATERAL PNEUMONIA [肺炎]	20[redacted]-12-09	32	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120360-36021003001	WORSENED HYPERTENSIO [高血圧]	20[redacted]-10-13	19	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-23 *	RECOVERED/RESOLVED
AMG 416	20120360-36021003001	WORSENED HYPERTENSION [高血圧]	20[redacted]-12-23	90	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-04 *	RECOVERED/RESOLVED
AMG 416	20120360-36021003001	BRONCHOPNEUMONIA [気管支肺炎]	20[redacted]-12-29	96	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-04	RECOVERED/RESOLVED
AMG 416	20120360-36021004003	PROGRESSIVE SEPSIS [敗血症]	20[redacted]-09-19	22	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-09-26	FATAL
AMG 416	20120360-36022004001	URINARY TRACT INFECTION [尿路感染]	20[redacted]-12-12	103	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-12-22	RECOVERED/RESOLVED
AMG 416	20120360-36022004003	ANGINA PECTORIS [狭心症]	20[redacted]-11-12	10	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-13	RECOVERED/RESOLVED
AMG 416	20120360-36027002004	THROMBOSIS OF ARTERIOVENOUS GRAFT [血管グラフト血栓症]	20[redacted]-10-30	11	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-01	RECOVERED/RESOLVED
AMG 416	20120360-36027002004	REPEATED OCCLUSIONS OF A-V ANASTOMOSIS [動静脈瘻閉塞]	20[redacted]-11-12	24	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-14	RECOVERED/RESOLVED
AMG 416	20120360-36027007003	GASTROENTERITIS [胃腸炎]	20[redacted]-08-17	21	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-08-29	RECOVERED/RESOLVED

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AMG 416	20120360-36027007003	SUPERIOR VENA CAVA SYNDROME [上大静脈症候群]	20[redacted]-09-08	43	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-09	RECOVERED/RESOLVED
AMG 416	20120360-36027007003	FEVER [発熱]	20[redacted]-10-11	76	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-10-16	RECOVERED/RESOLVED
AMG 416	20120360-36027007003	NEUTROPENIA [好中球減少症]	20[redacted]-10-15	80	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-17	RECOVERED/RESOLVED
AMG 416	20120360-36027007007	BLOOD STREAM INFECTION [敗血症]	20[redacted]-08-26	2	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-09-01	RECOVERED/RESOLVED
AMG 416	20120360-36027007007	OBSTRUCTION OF THE LEFT SUBCLAVIAN VEIN [静脈閉塞]	20[redacted]-09-15	22	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-17	RECOVERED/RESOLVED
AMG 416	20120360-36027007007	OEDEMA AVG [移植血管合併症]	20[redacted]-09-15	22	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-17	RECOVERED/RESOLVED
AMG 416	20120360-36027007007	LEFT CEREBELLAR HEMISPHERE PORENCEPHALY [孔脳症]	20[redacted]-09-16	23	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-17	RECOVERED/RESOLVED
AMG 416	20120360-36027007007	ASCITES [腹水]	20[redacted]-10-06	43	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED

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AMG 416	20120360-36027008002	VIRAL RESPIRATORY INFECTION [ウイルス性気道感染]	20[redacted]-01-15	113	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-17	RECOVERED/RESOLVED
AMG 416	20120360-36029001004	PNEUMONIA [肺炎]	20[redacted]-11-18	41	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-11-29 *	RECOVERED/RESOLVED
AMG 416	20120360-36029007003	SUBCUTAN INFECTION [皮膚感染]	20[redacted]-12-24	64	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-23	RECOVERED/RESOLVED
AMG 416	20120360-36029012003	CIMINO FISTULE INFLAMMATION. [動静脈瘻部位合併症]	20[redacted]-12-23	90	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-30	RECOVERED/RESOLVED
AMG 416	20120360-36029012020	NON COMPACT CARDIOMYOPATHY [心筋症]	20[redacted]-12-09	14	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-12-09	RECOVERED/RESOLVED
AMG 416	20120360-36033011004	THROMBOSIS OF THE FISTULA [動静脈瘻血栓症]	20[redacted]-11-25	36	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-11-29	RECOVERED/RESOLVED
AMG 416	20120360-36033011004	CVC RELATED SEPSIS [医療機器関連敗血症]	20[redacted]-12-01	42	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-12-11	RECOVERED/RESOLVED
AMG 416	20120360-36036001004	EPIGLOTITIS ACUTE [喉頭蓋炎]	20[redacted]-10-16	80	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-23	RECOVERED/RESOLVED

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AMG 416	20120360-36036004001	TRANSIANT ISCHAEMIC ATTACK [一過性脳虚血発作]	20[redacted]-01-15	142	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-19	RECOVERED/RESOLVED
AMG 416	20120360-36036004002	PARTIAL THROMBOSIS OF ARTERIOVENOUS FISTULAE [動静脈瘻血栓症]	20[redacted]-10-01	36	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-10 *	RECOVERED/RESOLVED
AMG 416	20120360-36043003003	SKIN ABSCESS ON HEAD [皮下組織膿瘍]	20[redacted]-12-30	56	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-02-04	RECOVERED/RESOLVED
AMG 416	20120360-36048005001	TIA [一過性脳虚血発作]	20[redacted]-09-23	57	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-26	RECOVERED/RESOLVED
AMG 416	20120360-36048005001	CAROTID ARTERY STENOSIS [頚動脈狭窄]	20[redacted]-10-07	71	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-19	RECOVERED/RESOLVED
AMG 416	20120360-36048005001	TIA [一過性脳虚血発作]	20[redacted]-10-10	74	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-19	RECOVERED/RESOLVED
AMG 416	20120360-36048005001	ATRIAL FIBRILLATION WITH RAPID VENTRICULAR ACTION [心房細動]	20[redacted]-11-13	108	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-21 *	RECOVERED/RESOLVED
AMG 416	20120360-36048005001	SYNCOPE [失神]	20[redacted]-12-27	152	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-03	RECOVERED/RESOLVED
AMG 416	20120360-36048010001	INTRADIALYTIC HYPOTENSION [処置による低血圧]	20[redacted]-12-22	11	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-24	RECOVERED/RESOLVED
AMG 416	20120360-36048010001	SYNCOPE HYPOTENSIVE [失神]	20[redacted]-12-22	11	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-24	RECOVERED/RESOLVED
AMG 416	20120360-36049004008	RIGHT FOOT INFECTION [限局性感染]	20[redacted]-11-20	57	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-22	RECOVERED/RESOLVED

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AMG 416	20120360-36049004008	SEPTIC SHOCK [敗血症性ショック]	20[redacted]-11-29	66	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-12-15	RECOVERED/RESOLVED
AMG 416	20120360-36049004008	UPPER GASTROINTESTINAL BLEEDING [上部消化管出血]	20[redacted]-11-29	66	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-12-08 *	RECOVERED/RESOLVED
AMG 416	20120360-36051011010	VASCULAR ACCESS THROMBOSIS [医療機器関連の血栓症]	20[redacted]-12-05	61	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-23	RECOVERED/RESOLVED
AMG 416	20120360-36058008003	NON Q WAVE MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-12-29	159	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-12-30	RECOVERED/RESOLVED
AMG 416	20120360-36059004001	FISTULA PUNCTURE HOLE BLEEDING [動静脈瘻部位出血]	20[redacted]-12-28 *	119	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-12-31 *	RECOVERED/RESOLVED
AMG 416	20120360-36059004001	DIARRHOEA [下痢]	20[redacted]-01-12	134	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-15	RECOVERED/RESOLVED
AMG 416	20120360-36060009003	NSTEMI [急性心筋梗塞]	20[redacted]-12-23	58	MODERATE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED

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AMG 416	20120360-36060009003	SIRS [全身性炎症反応症候群]	20[redacted]-12-23	58	MODERATE	YES	Is Life Threatening, Other Medically Important Serious Event	DRUG INTERRUPTED	NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-01-02	RECOVERED/RESOLVED
AMG 416	20120360-36063001001	ILEUS [イレウス]	20[redacted]-01-14	86	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-17	RECOVERED/RESOLVED
AMG 416	20120360-36066004005	NON CARDIAC CHEST PAIN [非心臓性胸痛]	20[redacted]-01-14	34	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-16	RECOVERED/RESOLVED
AMG 416	20120360-36066010001	INFECTED ARTERIOVENOUS FISTULA [動静脈瘻部位感染]	20[redacted]-10-08	52	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-22	RECOVERED/RESOLVED
AMG 416	20120360-36066010001	COLONOSCOPY [結腸内視鏡検査]	20[redacted]-12-19	124	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-21	RECOVERED/RESOLVED
AMG 416	20120360-36066013005	PERIPHERAL VASCULAR DISEASE [末梢血管障害]	20[redacted]-07-09	23	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-07-30	RECOVERED/RESOLVED
AMG 416	20120360-36066013005	GANGRENOUS LEFT FOOT [壊疽]	20[redacted]-08-15	60	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-02	RECOVERED/RESOLVED
AMG 416	20120360-36066013005	NON-HEALING WOUND RIGHT TRANSMETATARSAL AMPUTATION SITE [治癒不良]	20[redacted]-08-15	60	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-02	RECOVERED/RESOLVED

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AMG 416	20120360-36066013005	NON-HEALING WOUND LEFT BELOW THE KNEE STUMP [治癒不良]	20[redacted]-09-26 *	102	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-10-01 *	RECOVERED/RESOLVED
AMG 416	20120360-36066013005	CARDIAC ARREST [心停止]	20[redacted]-01-06 *	204	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-01-06 *	RECOVERED/RESOLVED
AMG 416	20120360-36066013005	PNEUMONIA [肺炎]	20[redacted]-01-06 *	204	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-17 *	RECOVERED/RESOLVED
AMG 416	20120360-36066013005	SEPSIS [敗血症]	20[redacted]-01-06 *	204	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-17	RECOVERED/RESOLVED
AMG 416	20120360-36066013005	WOUND INFECTION [創傷感染]	20[redacted]-01-06	204	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416	20120360-36066013009	HYPERKALEMIA [高カリウム血症]	20[redacted]-12-01	168	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-12-02	RECOVERED/RESOLVED

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AMG 416	20120360-36066013009	INFLUENZA [インフルエンザ]	20[redacted]-12-01	168	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-12-04	RECOVERED/RESOLVED
AMG 416	20120360-36066013009	PNEUMONIA [肺炎]	20[redacted]-12-01	168	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-04	RECOVERED/RESOLVED
AMG 416	20120360-36066013011	BRADYCARDIA [徐脈]	20[redacted]-01-11	195	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-17	RECOVERED/RESOLVED
AMG 416	20120360-36066013011	SYNCOPE [失神]	20[redacted]-01-11	195	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-17	RECOVERED/RESOLVED
AMG 416	20120360-36066034009	HYPERTENSIVE EMERGENCY [高血圧緊急症]	20[redacted]-12-01	85	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-06	RECOVERED/RESOLVED
AMG 416	20120360-36066034019	CHEST PAIN [胸痛]	20[redacted]-01-12	141	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-14	RECOVERED/RESOLVED
AMG 416	20120360-36066041005	BURN TO RIGHT FOOT [熱傷]	20[redacted]-08-26	49	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416	20120360-36066041005	CELLULITIS [蜂巣炎]	20[redacted]-09-05	59	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-09-09	RECOVERED/RESOLVED

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120360-36066041005	WORSENING OF BURN TO RIGHT FOOT [熱傷]	20[redacted]-09-05	59	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-09-09	RECOVERED/RESOLVED
AMG 416	20120360-36066041005	RIGHT FOOT BIG TOE NON HEALING BURN ULCER SECONDARY TO BURN [熱傷]	20[redacted]-10-24	108	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416	20120360-36066056006	CORONARY ISCHEMIA [心筋虚血]	20[redacted]-11-13	59	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-11-19	RECOVERED/RESOLVED
AMG 416	20120360-36066059001	INTERNAL HEMORRHAGE (BRAIN) [脳出血]	20[redacted]-09-22	19	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-03	FATAL
AMG 416	20120360-36066059001	WORSENING HYPERTENSION [高血圧]	20[redacted]-09-22	19	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-03	NOT RECOVERED/NOT RESOLVED
AMG 416	20120360-36066059005	HYPERKALEMIA [高カリウム血症]	20[redacted]-09-16	23	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-18	RECOVERED/RESOLVED
AMG 416	20120360-36066083002	CONSTIPATION [便秘]	20[redacted]-12-24	51	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-25	RECOVERED/RESOLVED

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120360-36066083002	NAUSEA [悪心]	20[redacted]-12-24	51	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-25	RECOVERED/RESOLVED
AMG 416	20120360-36066083002	VOMITING [嘔吐]	20[redacted]-12-24 *	51	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-25 *	RECOVERED/RESOLVED
AMG 416	20120360-36066083002	NAUSEA [悪心]	20[redacted]-01-08 *	66	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-01-10 *	RECOVERED/RESOLVED
AMG 416	20120360-36066083002	VOMITING [嘔吐]	20[redacted]-01-08	66	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-01-10	RECOVERED/RESOLVED
AMG 416	20120360-36066083006	OSTEOMYELITIS [骨髄炎]	20[redacted]-11-19	8	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-22	RECOVERED/RESOLVED
AMG 416	20120360-36066086002	RAPID ATRIALFIBRILLATION [心房細動]	20[redacted]-10-23	22	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-27	RECOVERED/RESOLVED
AMG 416	20120360-36066086002	SYNCOPE [失神]	20[redacted]-10-23	22	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-27	RECOVERED/RESOLVED
AMG 416	KAI-4169-005-0511-1505	CALCIPHYLAXIS [カルシフィラキシス]	20[redacted]-08-01	10	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	KAI-4169-005-0511-1505	PAIN DUE TO CALCIPHYLAXIS [カルシフィラキシス]	20[redacted]-09-11	51	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416	KAI-4169-005-0511-1505	BLEEDING FROM BIOPSY SITE OF PANNUS [処置後出血]	20[redacted]-12-01	132	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416	KAI-4169-005-0511-1515	CHEST PAIN [胸痛]	20[redacted]-08-04	4	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-08	RECOVERED/RESOLVED
AMG 416	KAI-4169-005-0511-1515	ANOXIC BRAIN INJURY [脳損傷]	20[redacted]-08-22	22	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-09-08	FATAL
AMG 416	KAI-4169-005-0511-1515	CARDIAC ARREST [心停止]	20[redacted]-08-22	22	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-08 *	RECOVERED/RESOLVED
AMG 416	KAI-4169-005-0511-1532	LOWER GASTROINTESTINAL BLEED [胃腸出血]	20[redacted]-10-20 *	97	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-19 *	RECOVERED/RESOLVED
AMG 416	KAI-4169-005-0511-1532	CENTRAL VENOUS CATHETER ASSOCIATED MRSA BACTEREMIA [医療機器関連感染]	20[redacted]-01-02	171	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-19 *	RECOVERED/RESOLVED

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time *	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time *	Outcome of Serious Adverse Event
AMG 416	KAI-4169-005-0511-1532	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-01-03 *	172	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-19 *	RECOVERED/RESOLVED
AMG 416	KAI-4169-005-0511-1532	VENTILATOR DEPENDENT RESPIRATORY FAILURE [レスピレータ依存]	20[redacted]-01-03 *	172	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-19 *	FATAL
AMG 416	KAI-4169-005-0511-1532	MITRAL VALVE ENDOCARDITIS [心内膜炎]	20[redacted]-01-07	176	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-19	RECOVERED/RESOLVED
AMG 416	KAI-4169-005-0511-1537	FLUID OVERLOAD [水分過負荷]	20[redacted]-10-27	104	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-30	RECOVERED/RESOLVED
NOT TREATED	20120230-23066152013	PNEUMONIA [肺炎]	20[redacted]-02-28	-	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-03	RECOVERED/RESOLVED
NOT TREATED	20120359-35966031011	BOWEL OBSTRUCTION [腸閉塞]	20[redacted]-01-27	-	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	-	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-01-30	RECOVERED/RESOLVED
NOT TREATED	20120359-35966031011	HYPERPOTASSEMIA [高カリウム血症]	20[redacted]-01-27	-	SEVERE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-01-30	RECOVERED/RESOLVED
NOT TREATED	20120359-35966031011	HYPOTENSION [低血圧]	20[redacted]-01-27	-	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-01-30	RECOVERED/RESOLVED

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
NOT TREATED	20120359-35966031011	VENTRICULAR FIBRILLATION [心室細動]	20[redacted]-01-30	-	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Is Life Threatening, Other Medically Important Serious Event	-	UNKNOWN	-	20[redacted]-01-30	FATAL
NOT TREATED	20120360-36025013005	GRIPPAL SYNDROME [インフルエンザ]	20[redacted]-12-19	45	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-23	RECOVERED/RESOLVED

*1:MedDRA Version 17.1J
AMG 416 = ONO-5163

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表 2.7.6.17-45　投与中止に至った有害事象の一覧表（20130213 試験）

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120360-36051007027	STOMACH ACHE [上腹部痛]	20[redacted]-12-24	34	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-12-29	-
AMG 416	20120360-36051007041	NAUSEA [悪心]	20[redacted]-11-25	6	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-12-08	-
AMG 416	20120360-36051007041	VOMITING [嘔吐]	20[redacted]-11-25	6	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-12-08	-
AMG 416	20120360-36051007043	NAUSEA [悪心]	20[redacted]-12-22	32	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-12-28	-
AMG 416	20120360-36058010003	VOMITING [嘔吐]	20[redacted]-09-10	73	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	-	-
AMG 416	20120360-36058010003	ANXIETY [不安]	20[redacted]-09-15	78	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	-	-
AMG 416	20120360-36066029006	NAUSEA [悪心]	20[redacted]-09-29	4	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-30	-
AMG 416	20120360-36066029006	VOMITING [嘔吐]	20[redacted]-09-29	4	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-30	-

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