表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）
解析対象集団：SAF

SOC		有害事象	
		プラセボ	ONO-5163
PT		n （%）	n （%）
	N	259	252
全体		210 (81.1)	231 (91.7)
血液およびリンパ系障害		17 (6.6)	12 (4.8)
貧血		14 (5.4)	9 (3.6)
血小板減少症		0 (0.0)	2 (0.8)
免疫性血小板減少性紫斑病		0 (0.0)	1 (0.4)
リンパ節症		0 (0.0)	1 (0.4)
骨髄機能不全		1 (0.4)	0 (0.0)
発熱性好中球減少症		1 (0.4)	0 (0.0)
白血球増加症		1 (0.4)	0 (0.0)
腎性貧血		1 (0.4)	0 (0.0)
心臓障害		26 (10.0)	25 (9.9)
心房細動		5 (1.9)	4 (1.6)
頻脈		8 (3.1)	4 (1.6)
急性心筋梗塞		3 (1.2)	3 (1.2)
徐脈		1 (0.4)	3 (1.2)
うっ血性心不全		4 (1.5)	3 (1.2)
狭心症		3 (1.2)	2 (0.8)
心筋梗塞		2 (0.8)	2 (0.8)
不安定狭心症		1 (0.4)	1 (0.4)
大動脈弁狭窄		0 (0.0)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．
出典［総括報告書 5.3.5.1-4（20120230 試験）Table 14-6.4 改変］

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 1）
解析対象集団：SAF

SOC	有害事象	
	プラセボ	ONO-5163
PT	n （%）	n （%）
N	259	252
心房粗動	1 (0.4)	1 (0.4)
完全房室ブロック	0 (0.0)	1 (0.4)
第一度房室ブロック	1 (0.4)	1 (0.4)
第二度房室ブロック	1 (0.4)	1 (0.4)
心不全	0 (0.0)	1 (0.4)
心筋症	0 (0.0)	1 (0.4)
冠動脈疾患	1 (0.4)	1 (0.4)
冠動脈狭窄	0 (0.0)	1 (0.4)
拡張機能障害	0 (0.0)	1 (0.4)
動悸	1 (0.4)	1 (0.4)
右室肥大	0 (0.0)	1 (0.4)
洞性頻脈	0 (0.0)	1 (0.4)
頻脈性不整脈	0 (0.0)	1 (0.4)
心室性頻脈	0 (0.0)	1 (0.4)
不整脈	1 (0.4)	0 (0.0)
冠動脈硬化症	1 (0.4)	0 (0.0)
右脚ブロック	2 (0.8)	0 (0.0)
心障害	1 (0.4)	0 (0.0)
伝導障害	1 (0.4)	0 (0.0)
左室不全	1 (0.4)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 2）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
左室肥大	1 (0.4)	0 (0.0)
僧帽弁閉鎖不全症	1 (0.4)	0 (0.0)
上室性期外収縮	1 (0.4)	0 (0.0)
上室性頻脈	1 (0.4)	0 (0.0)
心室性期外収縮	1 (0.4)	0 (0.0)
先天性、家族性および遺伝性障害	1 (0.4)	0 (0.0)
心房中隔欠損症	1 (0.4)	0 (0.0)
耳および迷路障害	8 (3.1)	2 (0.8)
回転性めまい	6 (2.3)	2 (0.8)
耳痛	1 (0.4)	0 (0.0)
頭位性回転性めまい	1 (0.4)	0 (0.0)
内分泌障害	4 (1.5)	0 (0.0)
副甲状腺機能亢進症	1 (0.4)	0 (0.0)
甲状腺機能亢進症	1 (0.4)	0 (0.0)
甲状腺機能低下症	1 (0.4)	0 (0.0)
原発性アルドステロン症	1 (0.4)	0 (0.0)
眼障害	11 (4.2)	11 (4.4)
羞明	0 (0.0)	2 (0.8)
白内障	2 (0.8)	1 (0.4)
眼乾燥	0 (0.0)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 3）
解析対象集団：SAF

SOC	有害事象	
	プラセボ	ONO-5163
PT	n （%）	n （%）
N	259	252
眼出血	0 (0.0)	1 (0.4)
眼痛	1 (0.4)	1 (0.4)
眼瞼下垂	0 (0.0)	1 (0.4)
流涙増加	0 (0.0)	1 (0.4)
全眼球炎	0 (0.0)	1 (0.4)
潰瘍性角膜炎	0 (0.0)	1 (0.4)
霧視	0 (0.0)	1 (0.4)
視力低下	3 (1.2)	1 (0.4)
視力障害	0 (0.0)	1 (0.4)
結膜充血	2 (0.8)	0 (0.0)
眼の炎症	1 (0.4)	0 (0.0)
眼瞼浮腫	1 (0.4)	0 (0.0)
緑内障	1 (0.4)	0 (0.0)
光視症	1 (0.4)	0 (0.0)
胃腸障害	66 (25.5)	80 (31.7)
下痢	26 (10.0)	36 (14.3)
悪心	19 (7.3)	23 (9.1)
嘔吐	8 (3.1)	19 (7.5)
便秘	7 (2.7)	9 (3.6)
腹痛	8 (3.1)	5 (2.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 4）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
上腹部痛	6 (2.3)	4 (1.6)
消化不良	2 (0.8)	3 (1.2)
痔核	0 (0.0)	3 (1.2)
歯痛	1 (0.4)	3 (1.2)
腹部膨満	1 (0.4)	2 (0.8)
憩室	0 (0.0)	2 (0.8)
胃炎	1 (0.4)	2 (0.8)
大腸ポリープ	0 (0.0)	2 (0.8)
下部消化管出血	0 (0.0)	2 (0.8)
腹部不快感	0 (0.0)	1 (0.4)
嚥下障害	0 (0.0)	1 (0.4)
糞塊	0 (0.0)	1 (0.4)
放屁	1 (0.4)	1 (0.4)
胃前庭部毛細血管拡張症	0 (0.0)	1 (0.4)
びらん性胃炎	0 (0.0)	1 (0.4)
胃食道逆流性疾患	2 (0.8)	1 (0.4)
吐血	0 (0.0)	1 (0.4)
痔出血	0 (0.0)	1 (0.4)
裂孔ヘルニア	0 (0.0)	1 (0.4)
口の感覚鈍麻	0 (0.0)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 5）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
大腸出血	0 (0.0)	1 (0.4)
口腔内不快感	0 (0.0)	1 (0.4)
口の錯感覚	0 (0.0)	1 (0.4)
直腸分泌物	0 (0.0)	1 (0.4)
臍ヘルニア	0 (0.0)	1 (0.4)
異常便	1 (0.4)	0 (0.0)
腹水	1 (0.4)	0 (0.0)
齲歯	1 (0.4)	0 (0.0)
十二指腸潰瘍	2 (0.8)	0 (0.0)
便量増加	1 (0.4)	0 (0.0)
変色便	1 (0.4)	0 (0.0)
胃腸出血	1 (0.4)	0 (0.0)
食道炎	1 (0.4)	0 (0.0)
口腔内痛	1 (0.4)	0 (0.0)
膵炎	1 (0.4)	0 (0.0)
食道静脈瘤	1 (0.4)	0 (0.0)
一般・全身障害および投与部位の状態	64 (24.7)	53 (21.0)
末梢性浮腫	6 (2.3)	8 (3.2)
発熱	9 (3.5)	8 (3.2)
無力症	9 (3.5)	5 (2.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 6）
解析対象集団：SAF

SOC PT		有害事象 プラセボ n （%）	 ONO-5163 n （%）
	N	259	252
疼痛		3 (1.2)	5 (2.0)
胸痛		6 (2.3)	4 (1.6)
悪寒		2 (0.8)	4 (1.6)
疲労		3 (1.2)	4 (1.6)
医療機器合併症		7 (2.7)	4 (1.6)
胸部不快感		2 (0.8)	3 (1.2)
熱感		4 (1.5)	3 (1.2)
局所腫脹		2 (0.8)	3 (1.2)
倦怠感		3 (1.2)	3 (1.2)
非心臓性胸痛		3 (1.2)	2 (0.8)
カテーテル留置部位分泌物		0 (0.0)	1 (0.4)
カテーテル留置部位漏出		0 (0.0)	1 (0.4)
カテーテル留置部位血腫		1 (0.4)	1 (0.4)
カテーテル留置部位炎症		0 (0.0)	1 (0.4)
カテーテル留置部位疼痛		0 (0.0)	1 (0.4)
捻髪音		0 (0.0)	1 (0.4)
嚢胞		0 (0.0)	1 (0.4)
医療機器位置異常		0 (0.0)	1 (0.4)
不快感		0 (0.0)	1 (0.4)
溢出		0 (0.0)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 7）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
顔面浮腫	3 (1.2)	1 (0.4)
顔面痛	0 (0.0)	1 (0.4)
異常感	1 (0.4)	1 (0.4)
異常高熱	0 (0.0)	1 (0.4)
炎症	3 (1.2)	1 (0.4)
インフルエンザ様疾患	5 (1.9)	1 (0.4)
突然死	1 (0.4)	1 (0.4)
恥骨上痛	0 (0.0)	1 (0.4)
外科手術不成功	0 (0.0)	1 (0.4)
口渇	0 (0.0)	1 (0.4)
医療機器関連の血栓症	2 (0.8)	1 (0.4)
血管穿刺部位血腫	0 (0.0)	1 (0.4)
適用部位小水疱	1 (0.4)	0 (0.0)
カテーテル留置部位出血	1 (0.4)	0 (0.0)
薬物不耐性	1 (0.4)	0 (0.0)
閉塞性ヘルニア	1 (0.4)	0 (0.0)
注入部位疼痛	1 (0.4)	0 (0.0)
限局性浮腫	1 (0.4)	0 (0.0)
医療機器使用部位反応	1 (0.4)	0 (0.0)
浮腫	2 (0.8)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 8）
解析対象集団：SAF

SOC	有害事象	
	プラセボ	ONO-5163
PT	n （%）	n （%）
N	259	252
肝胆道系障害	6 (2.3)	5 (2.0)
胆石症	4 (1.5)	3 (1.2)
胆管炎	0 (0.0)	1 (0.4)
急性肝炎	0 (0.0)	1 (0.4)
肝脾腫大	0 (0.0)	1 (0.4)
胆嚢炎	1 (0.4)	0 (0.0)
急性胆嚢炎	1 (0.4)	0 (0.0)
免疫系障害	0 (0.0)	4 (1.6)
季節性アレルギー	0 (0.0)	3 (1.2)
食物アレルギー	0 (0.0)	1 (0.4)
感染症および寄生虫症	82 (31.7)	73 (29.0)
上気道感染	16 (6.2)	13 (5.2)
蜂巣炎	7 (2.7)	10 (4.0)
尿路感染	6 (2.3)	9 (3.6)
気管支炎	4 (1.5)	7 (2.8)
鼻咽頭炎	10 (3.9)	7 (2.8)
肺炎	12 (4.6)	5 (2.0)
動静脈瘻部位感染	2 (0.8)	4 (1.6)
医療機器関連感染	1 (0.4)	3 (1.2)
胃腸炎	4 (1.5)	3 (1.2)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 9）
解析対象集団：SAF

SOC		有害事象	
		プラセボ	ONO-5163
PT		n （%）	n （%）
	N	259	252
副鼻腔炎		0 (0.0)	3 (1.2)
菌血症		0 (0.0)	2 (0.8)
インフルエンザ		5 (1.9)	2 (0.8)
限局性感染		1 (0.4)	2 (0.8)
敗血症		2 (0.8)	2 (0.8)
歯膿瘍		1 (0.4)	2 (0.8)
動静脈グラフト部位膿瘍		1 (0.4)	1 (0.4)
熱傷部感染		0 (0.0)	1 (0.4)
膀胱炎		0 (0.0)	1 (0.4)
憩室炎		1 (0.4)	1 (0.4)
耳感染		0 (0.0)	1 (0.4)
眼感染		0 (0.0)	1 (0.4)
真菌感染		0 (0.0)	1 (0.4)
せつ		1 (0.4)	1 (0.4)
壊疽		1 (0.4)	1 (0.4)
ウイルス性胃腸炎		1 (0.4)	1 (0.4)
帯状疱疹		0 (0.0)	1 (0.4)
帯状疱疹性髄膜脳炎		0 (0.0)	1 (0.4)
感染性大腸炎		0 (0.0)	1 (0.4)
無菌性髄膜炎		0 (0.0)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた.

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 10）
解析対象集団：SAF

SOC PT		有害事象 プラセボ n （%）	 ONO-5163 n （%）
	N	259	252
髄膜炎菌性敗血症		0 (0.0)	1 (0.4)
眼帯状疱疹		0 (0.0)	1 (0.4)
口腔カンジダ症		0 (0.0)	1 (0.4)
骨髄炎		3 (1.2)	1 (0.4)
爪囲炎		0 (0.0)	1 (0.4)
前立腺膿瘍		0 (0.0)	1 (0.4)
気道感染		4 (1.5)	1 (0.4)
鼻炎		1 (0.4)	1 (0.4)
ライノウイルス感染		0 (0.0)	1 (0.4)
細菌性副鼻腔炎		0 (0.0)	1 (0.4)
植皮感染		0 (0.0)	1 (0.4)
皮膚感染		0 (0.0)	1 (0.4)
ブドウ球菌性菌血症		1 (0.4)	1 (0.4)
ブドウ球菌性敗血症		1 (0.4)	1 (0.4)
皮下組織膿瘍		0 (0.0)	1 (0.4)
気管炎		0 (0.0)	1 (0.4)
ウイルス感染		3 (1.2)	1 (0.4)
ウイルス性心筋炎		0 (0.0)	1 (0.4)
創傷感染		1 (0.4)	1 (0.4)
腹部膿瘍		1 (0.4)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 11）
解析対象集団：SAF

SOC	有害事象	
	プラセボ	ONO-5163
PT	n （%）	n （%）
N	259	252
四肢膿瘍	1 (0.4)	0 (0.0)
虫垂炎	1 (0.4)	0 (0.0)
動静脈グラフト部位感染	1 (0.4)	0 (0.0)
細菌性敗血症	1 (0.4)	0 (0.0)
クロストリジウム・ディフィシレ大腸炎	1 (0.4)	0 (0.0)
クロストリジウム・ディフィシレ性敗血症	1 (0.4)	0 (0.0)
医療機器関連敗血症	1 (0.4)	0 (0.0)
糖尿病性足感染	1 (0.4)	0 (0.0)
伝染性紅斑	1 (0.4)	0 (0.0)
移植片感染	1 (0.4)	0 (0.0)
咬傷感染	1 (0.4)	0 (0.0)
椎間板炎	1 (0.4)	0 (0.0)
メタニューモウイルス感染	1 (0.4)	0 (0.0)
食道カンジダ症	1 (0.4)	0 (0.0)
爪真菌症	1 (0.4)	0 (0.0)
耳下腺炎	1 (0.4)	0 (0.0)
歯周炎	1 (0.4)	0 (0.0)
咽頭炎	2 (0.8)	0 (0.0)
細菌性咽頭炎	1 (0.4)	0 (0.0)
術後膿瘍	1 (0.4)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 12）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
膿皮症	1 (0.4)	0 (0.0)
敗血症症候群	1 (0.4)	0 (0.0)
ストーマ部感染	1 (0.4)	0 (0.0)
股部白癬	1 (0.4)	0 (0.0)
細菌性尿路感染	3 (1.2)	0 (0.0)
腸球菌性尿路感染	1 (0.4)	0 (0.0)
真菌性尿路感染	1 (0.4)	0 (0.0)
腟感染	1 (0.4)	0 (0.0)
傷害、中毒および処置合併症	58 (22.4)	66 (26.2)
動静脈瘻部位合併症	12 (4.6)	16 (6.3)
転倒	9 (3.5)	12 (4.8)
血管グラフト血栓症	5 (1.9)	8 (3.2)
処置による低血圧	6 (2.3)	7 (2.8)
動静脈瘻血栓症	4 (1.5)	5 (2.0)
挫傷	2 (0.8)	5 (2.0)
四肢損傷	2 (0.8)	4 (1.6)
創傷	5 (1.9)	4 (1.6)
動静脈瘻部位出血	2 (0.8)	3 (1.2)
擦過傷	1 (0.4)	3 (1.2)
移植血管合併症	4 (1.5)	3 (1.2)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 13）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
動静脈瘻瘤	1 (0.4)	2 (0.8)
裂傷	2 (0.8)	2 (0.8)
処置による疼痛	3 (1.2)	2 (0.8)
熱傷	1 (0.4)	2 (0.8)
脛骨骨折	1 (0.4)	2 (0.8)
顔面損傷	0 (0.0)	1 (0.4)
大腿骨骨折	1 (0.4)	1 (0.4)
移植片血栓症	0 (0.0)	1 (0.4)
切開部位痛	0 (0.0)	1 (0.4)
関節損傷	1 (0.4)	1 (0.4)
肉離れ	2 (0.8)	1 (0.4)
処置後出血	1 (0.4)	1 (0.4)
術後呼吸不全	0 (0.0)	1 (0.4)
処置による高血圧	0 (0.0)	1 (0.4)
処置による悪心	2 (0.8)	1 (0.4)
処置による嘔吐	0 (0.0)	1 (0.4)
植皮生着不全	0 (0.0)	1 (0.4)
硬膜下血腫	0 (0.0)	1 (0.4)
各種物質毒性	0 (0.0)	1 (0.4)
移植血管閉塞	0 (0.0)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 14）
解析対象集団：SAF

SOC PT		有害事象 プラセボ n （%）	 ONO-5163 n （%）
	N	259	252
創合併症		0 (0.0)	1 (0.4)
術後激越		1 (0.4)	0 (0.0)
術後貧血		1 (0.4)	0 (0.0)
動静脈瘻閉塞		3 (1.2)	0 (0.0)
動静脈瘻部位血腫		2 (0.8)	0 (0.0)
剥離骨折		1 (0.4)	0 (0.0)
第２度熱傷		1 (0.4)	0 (0.0)
鎖骨骨折		1 (0.4)	0 (0.0)
移植腎の合併症		1 (0.4)	0 (0.0)
脳振盪		1 (0.4)	0 (0.0)
眼挫傷		1 (0.4)	0 (0.0)
顔面骨骨折		1 (0.4)	0 (0.0)
移植片合併症		1 (0.4)	0 (0.0)
手骨折		1 (0.4)	0 (0.0)
股関節部骨折		1 (0.4)	0 (0.0)
切開部位出血		1 (0.4)	0 (0.0)
靭帯捻挫		1 (0.4)	0 (0.0)
眼窩周囲出血		1 (0.4)	0 (0.0)
術後発熱		1 (0.4)	0 (0.0)
処置による頭痛		1 (0.4)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 15）
解析対象集団：SAF

SOC	有害事象	
	プラセボ	ONO-5163
PT	n （%）	n （%）
N	259	252
肋骨骨折	1 (0.4)	0 (0.0)
シャント狭窄	1 (0.4)	0 (0.0)
ストーマ部疼痛	1 (0.4)	0 (0.0)
臨床検査	57 (22.0)	179 (71.0)
血中カルシウム減少	31 (12.0)	168 (66.7)
血中カルシウム増加	1 (0.4)	7 (2.8)
血中副甲状腺ホルモン減少	3 (1.2)	6 (2.4)
心電図ＱＴ延長	1 (0.4)	3 (1.2)
肝酵素上昇	0 (0.0)	3 (1.2)
静脈圧上昇	1 (0.4)	2 (0.8)
アスパラギン酸アミノトランスフェラーゼ増加	1 (0.4)	1 (0.4)
出血時間延長	0 (0.0)	1 (0.4)
血中マグネシウム減少	0 (0.0)	1 (0.4)
体温上昇	1 (0.4)	1 (0.4)
凝固時間延長	0 (0.0)	1 (0.4)
心電図ＰＲ延長	0 (0.0)	1 (0.4)
心電図ＳＴ部分下降	0 (0.0)	1 (0.4)
瘻造影	2 (0.8)	1 (0.4)
ヘリコバクター検査陽性	0 (0.0)	1 (0.4)
腎スキャン異常	0 (0.0)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 16）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
体重減少	1 (0.4)	1 (0.4)
体重増加	1 (0.4)	1 (0.4)
アラニンアミノトランスフェラーゼ増加	1 (0.4)	0 (0.0)
血管造影	1 (0.4)	0 (0.0)
血中アルカリホスファターゼ増加	2 (0.8)	0 (0.0)
血中ビリルビン増加	1 (0.4)	0 (0.0)
血中クレアチンホスホキナーゼ増加	1 (0.4)	0 (0.0)
血中ブドウ糖減少	1 (0.4)	0 (0.0)
血中カリウム増加	4 (1.5)	0 (0.0)
血圧上昇	2 (0.8)	0 (0.0)
尿中血陽性	1 (0.4)	0 (0.0)
心カテーテル	1 (0.4)	0 (0.0)
胸部Ｘ線異常	1 (0.4)	0 (0.0)
透析効果検査	1 (0.4)	0 (0.0)
心電図Ｔ波逆転	1 (0.4)	0 (0.0)
心拍数増加	1 (0.4)	0 (0.0)
国際標準比増加	1 (0.4)	0 (0.0)
眼圧上昇	1 (0.4)	0 (0.0)
総鉄結合能減少	1 (0.4)	0 (0.0)
トロポニン増加	1 (0.4)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 17）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n　(%)	 ONO-5163 n　(%)
N	259	252
代謝および栄養障害	39 (15.1)	59 (23.4)
低カルシウム血症	0 (　0.0)	17 (　6.7)
高カリウム血症	5 (　1.9)	12 (　4.8)
水分過負荷	4 (　1.5)	7 (　2.8)
食欲減退	4 (　1.5)	6 (　2.4)
低血糖症	9 (　3.5)	6 (　2.4)
低リン酸血症	0 (　0.0)	5 (　2.0)
高血糖	2 (　0.8)	3 (　1.2)
高リン酸塩血症	4 (　1.5)	3 (　1.2)
代謝性アシドーシス	2 (　0.8)	3 (　1.2)
痛風	1 (　0.4)	2 (　0.8)
高カルシウム血症	8 (　3.1)	2 (　0.8)
低カリウム血症	3 (　1.2)	2 (　0.8)
低マグネシウム血症	0 (　0.0)	2 (　0.8)
低ナトリウム血症	0 (　0.0)	2 (　0.8)
アシドーシス	0 (　0.0)	1 (　0.4)
体液貯留	0 (　0.0)	1 (　0.4)
血液量増加症	0 (　0.0)	1 (　0.4)
肥満	1 (　0.4)	1 (　0.4)
異常体重減少	1 (　0.4)	0 (　0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 18）
解析対象集団：SAF

SOC	有害事象	
	プラセボ	ONO-5163
PT	n （%）	n （%）
N	259	252
糖尿病	1 (0.4)	0 (0.0)
低アルブミン血症	1 (0.4)	0 (0.0)
血液量減少症	2 (0.8)	0 (0.0)
食欲亢進	1 (0.4)	0 (0.0)
ビタミンD欠乏	1 (0.4)	0 (0.0)
筋骨格系および結合組織障害	59 (22.8)	71 (28.2)
筋痙縮	16 (6.2)	28 (11.1)
背部痛	11 (4.2)	14 (5.6)
関節痛	16 (6.2)	11 (4.4)
四肢痛	9 (3.5)	7 (2.8)
筋肉痛	0 (0.0)	4 (1.6)
頚部痛	4 (1.5)	4 (1.6)
筋力低下	2 (0.8)	3 (1.2)
筋骨格痛	7 (2.7)	3 (1.2)
骨痛	1 (0.4)	2 (0.8)
筋攣縮	1 (0.4)	2 (0.8)
筋骨格硬直	0 (0.0)	2 (0.8)
腱炎	0 (0.0)	2 (0.8)
関節炎	1 (0.4)	1 (0.4)
側腹部痛	1 (0.4)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 19）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
関節腫脹	0 (0.0)	1 (0.4)
腰部脊柱管狭窄症	0 (0.0)	1 (0.4)
脊椎痛	0 (0.0)	1 (0.4)
顎関節症候群	1 (0.4)	1 (0.4)
開口障害	0 (0.0)	1 (0.4)
骨折による偽関節	1 (0.4)	0 (0.0)
筋骨格系胸痛	2 (0.8)	0 (0.0)
筋骨格不快感	1 (0.4)	0 (0.0)
骨炎	1 (0.4)	0 (0.0)
変形性関節症	2 (0.8)	0 (0.0)
全身性エリテマトーデス	1 (0.4)	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）	3 (1.2)	3 (1.2)
良性腺腫	0 (0.0)	1 (0.4)
膀胱腺癌、病期不明	0 (0.0)	1 (0.4)
喉頭癌	0 (0.0)	1 (0.4)
食道腺癌	1 (0.4)	0 (0.0)
前立腺癌	1 (0.4)	0 (0.0)
遠隔転移を伴う腎癌	1 (0.4)	0 (0.0)
神経系障害	40 (15.4)	53 (21.0)
頭痛	11 (4.2)	20 (7.9)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 20）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
錯感覚	0 (0.0)	11 (4.4)
浮動性めまい	6 (2.3)	10 (4.0)
感覚鈍麻	1 (0.4)	6 (2.4)
痙攣	2 (0.8)	3 (1.2)
末梢性ニューロパチー	1 (0.4)	3 (1.2)
味覚異常	1 (0.4)	2 (0.8)
不全片麻痺	0 (0.0)	2 (0.8)
ミオクローヌス	0 (0.0)	2 (0.8)
失神	5 (1.9)	2 (0.8)
断端痛	0 (0.0)	1 (0.4)
脳損傷	0 (0.0)	1 (0.4)
灼熱感	1 (0.4)	1 (0.4)
手根管症候群	2 (0.8)	1 (0.4)
脳血管発作	1 (0.4)	1 (0.4)
体位性めまい	0 (0.0)	1 (0.4)
脳症	0 (0.0)	1 (0.4)
片頭痛	0 (0.0)	1 (0.4)
神経痛	1 (0.4)	1 (0.4)
下肢静止不能症候群	1 (0.4)	1 (0.4)
坐骨神経痛	0 (0.0)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 21）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
傾眠	1 (0.4)	1 (0.4)
振戦	0 (0.0)	1 (0.4)
尿毒症性脳症	0 (0.0)	1 (0.4)
第７脳神経麻痺	1 (0.4)	1 (0.4)
平衡障害	1 (0.4)	0 (0.0)
認知症	1 (0.4)	0 (0.0)
構語障害	1 (0.4)	0 (0.0)
出血性卒中	1 (0.4)	0 (0.0)
高血糖性痙攣	1 (0.4)	0 (0.0)
筋緊張低下	1 (0.4)	0 (0.0)
嗜眠	3 (1.2)	0 (0.0)
意識消失	2 (0.8)	0 (0.0)
失神寸前の状態	1 (0.4)	0 (0.0)
脊髄浮腫	1 (0.4)	0 (0.0)
刺激無反応	2 (0.8)	0 (0.0)
精神障害	15 (5.8)	14 (5.6)
不眠症	8 (3.1)	4 (1.6)
不安	3 (1.2)	3 (1.2)
精神状態変化	2 (0.8)	3 (1.2)
激越	0 (0.0)	2 (0.8)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 22）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
錯乱状態	1 (0.4)	2 (0.8)
うつ病	1 (0.4)	1 (0.4)
薬物乱用	0 (0.0)	1 (0.4)
幻覚	0 (0.0)	1 (0.4)
ストレス	0 (0.0)	1 (0.4)
不安障害	2 (0.8)	0 (0.0)
自殺念慮	1 (0.4)	0 (0.0)
腎および尿路障害	8 (3.1)	8 (3.2)
血尿	4 (1.5)	2 (0.8)
尿閉	0 (0.0)	2 (0.8)
腎結石症	0 (0.0)	1 (0.4)
腎嚢胞	0 (0.0)	1 (0.4)
腎嚢胞出血	0 (0.0)	1 (0.4)
尿道狭窄	0 (0.0)	1 (0.4)
尿路障害	0 (0.0)	1 (0.4)
排尿困難	1 (0.4)	0 (0.0)
夜間頻尿	1 (0.4)	0 (0.0)
腎嚢胞破裂	1 (0.4)	0 (0.0)
慢性腎不全	1 (0.4)	0 (0.0)
尿失禁	1 (0.4)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 23）
解析対象集団：SAF

SOC	有害事象	
	プラセボ	ONO-5163
PT	n　(%)	n　(%)
N	259	252
尿路の炎症	1 (　0.4)	0 (　0.0)
生殖系および乳房障害	3 (　1.2)	2 (　0.8)
骨盤痛	0 (　0.0)	1 (　0.4)
前立腺炎	0 (　0.0)	1 (　0.4)
性交出血	1 (　0.4)	0 (　0.0)
勃起不全	2 (　0.8)	0 (　0.0)
呼吸器、胸郭および縦隔障害	40 (15.4)	43 (17.1)
呼吸困難	12 (　4.6)	13 (　5.2)
咳嗽	15 (　5.8)	10 (　4.0)
口腔咽頭痛	6 (　2.3)	6 (　2.4)
鼻出血	1 (　0.4)	4 (　1.6)
肺水腫	3 (　1.2)	3 (　1.2)
呼吸窮迫	1 (　0.4)	3 (　1.2)
慢性閉塞性肺疾患	2 (　0.8)	2 (　0.8)
労作性呼吸困難	1 (　0.4)	2 (　0.8)
アレルギー性鼻炎	1 (　0.4)	2 (　0.8)
副鼻腔うっ血	1 (　0.4)	2 (　0.8)
睡眠時無呼吸症候群	0 (　0.0)	2 (　0.8)
喀血	1 (　0.4)	1 (　0.4)
低酸素症	0 (　0.0)	1 (　0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 24）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
間質性肺疾患	0 (0.0)	1 (0.4)
肺浸潤	1 (0.4)	1 (0.4)
鼻閉	1 (0.4)	1 (0.4)
非心原性肺水腫	0 (0.0)	1 (0.4)
呼吸時疼痛	0 (0.0)	1 (0.4)
湿性咳嗽	2 (0.8)	1 (0.4)
肺動脈性肺高血圧症	0 (0.0)	1 (0.4)
肺うっ血	1 (0.4)	1 (0.4)
肺高血圧症	2 (0.8)	1 (0.4)
呼吸不全	1 (0.4)	1 (0.4)
鼻漏	0 (0.0)	1 (0.4)
咽喉刺激感	0 (0.0)	1 (0.4)
喘鳴	0 (0.0)	1 (0.4)
急性肺水腫	1 (0.4)	0 (0.0)
急性呼吸不全	3 (1.2)	0 (0.0)
気管支拡張症	1 (0.4)	0 (0.0)
発声障害	1 (0.4)	0 (0.0)
起坐呼吸	1 (0.4)	0 (0.0)
咽頭腫瘤	1 (0.4)	0 (0.0)
胸膜痛	1 (0.4)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 25）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
肺臓炎	1 (0.4)	0 (0.0)
皮膚および皮下組織障害	28 (10.8)	25 (9.9)
そう痒症	6 (2.3)	4 (1.6)
全身性そう痒症	2 (0.8)	2 (0.8)
皮膚潰瘍	3 (1.2)	2 (0.8)
蕁麻疹	1 (0.4)	2 (0.8)
冷汗	0 (0.0)	1 (0.4)
褥瘡性潰瘍	0 (0.0)	1 (0.4)
接触性皮膚炎	1 (0.4)	1 (0.4)
糖尿病性足病変	1 (0.4)	1 (0.4)
斑状出血	1 (0.4)	1 (0.4)
紅斑	0 (0.0)	1 (0.4)
多汗症	3 (1.2)	1 (0.4)
嵌入爪	0 (0.0)	1 (0.4)
爪ジストロフィー	0 (0.0)	1 (0.4)
寝汗	0 (0.0)	1 (0.4)
爪甲離床症	0 (0.0)	1 (0.4)
触知可能紫斑病	0 (0.0)	1 (0.4)
点状出血	0 (0.0)	1 (0.4)
アレルギー性そう痒症	0 (0.0)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 26）
解析対象集団：SAF

SOC	有害事象	
	プラセボ	ONO-5163
PT	n （%）	n （%）
N	259	252
発疹	2 (0.8)	1 (0.4)
皮膚亀裂	1 (0.4)	1 (0.4)
皮膚病変	2 (0.8)	1 (0.4)
尿毒症性そう痒症	0 (0.0)	1 (0.4)
脱毛症	1 (0.4)	0 (0.0)
水疱	1 (0.4)	0 (0.0)
糖尿病性神経障害性潰瘍	1 (0.4)	0 (0.0)
糖尿病性潰瘍	1 (0.4)	0 (0.0)
湿疹	1 (0.4)	0 (0.0)
剥脱性発疹	1 (0.4)	0 (0.0)
間擦疹	1 (0.4)	0 (0.0)
爪痛	1 (0.4)	0 (0.0)
紅斑性皮疹	1 (0.4)	0 (0.0)
皮膚変色	1 (0.4)	0 (0.0)
皮膚色素過剰	1 (0.4)	0 (0.0)
社会環境	0 (0.0)	1 (0.4)
患者による治療拒否	0 (0.0)	1 (0.4)
外科および内科処置	2 (0.8)	1 (0.4)
カテーテル除去	0 (0.0)	1 (0.4)
中心静脈カテーテル留置	1 (0.4)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 27）
解析対象集団：SAF

SOC	有害事象	
	プラセボ	ONO-5163
PT	n （%）	n （%）
N	259	252
指切断	1 (0.4)	0 (0.0)
血管障害	45 (17.4)	40 (15.9)
高血圧	12 (4.6)	19 (7.5)
低血圧	16 (6.2)	14 (5.6)
静脈狭窄	3 (1.2)	3 (1.2)
出血性静脈瘤	0 (0.0)	1 (0.4)
塞栓症	0 (0.0)	1 (0.4)
血腫	1 (0.4)	1 (0.4)
出血	0 (0.0)	1 (0.4)
悪性高血圧	0 (0.0)	1 (0.4)
起立性低血圧	0 (0.0)	1 (0.4)
進行性高血圧	1 (0.4)	0 (0.0)
動静脈瘤	1 (0.4)	0 (0.0)
大動脈狭窄	1 (0.4)	0 (0.0)
動脈硬化症	1 (0.4)	0 (0.0)
高血圧クリーゼ	1 (0.4)	0 (0.0)
虚血性壊死	1 (0.4)	0 (0.0)
末梢動脈狭窄	1 (0.4)	0 (0.0)
末梢性虚血	1 (0.4)	0 (0.0)
末梢血管障害	1 (0.4)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-11　有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 28）
解析対象集団：SAF

SOC	有害事象	
	プラセボ	ONO-5163
PT	n （%）	n （%）
N	259	252
末梢循環不良	1 (0.4)	0 (0.0)
二次性高血圧	1 (0.4)	0 (0.0)
スチール症候群	1 (0.4)	0 (0.0)
血栓性静脈炎	1 (0.4)	0 (0.0)
血栓症	1 (0.4)	0 (0.0)
血管狭窄	1 (0.4)	0 (0.0)
静脈血栓症	1 (0.4)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．
出典［総括報告書 5.3.5.1-4（20120230 試験）Table 14-6.4 改変］

表 2.7.6.17-12　死亡した被験者の一覧表（20120230 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	20120230-23032002001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	BLEEDING FROM FISTULA [動静脈瘻部位出血]	20[redacted]-10-06T11:15	25	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-06T12:15	-
AMG 416	20120230-23032002001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	BLOOD CALCIUM DECREASED [血中カルシウム減少]	20[redacted]-11-14T07:20	64	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	RELATED	20[redacted]-11-21T07:15	-
AMG 416	20120230-23032002001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-11-28	78	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-12-03 *	-
AMG 416	20120230-23032002001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	BLOOD CALCIUM DECREASED [血中カルシウム減少]	20[redacted]-12-05T07:15	85	MODERATE	NO	-	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	RELATED	20[redacted]-01-23	-
AMG 416	20120230-23032002001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-12-08 *	88	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-12-08 *	-
AMG 416	20120230-23032002001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-01-19 *	130	MILD	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-01-19 *	-
AMG 416	20120230-23032002001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	BLOOD CALCIUM DECREASED [血中カルシウム減少]	20[redacted]-01-24 *	135	MILD	NO	-	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	RELATED	20[redacted]-02-23 *	-
AMG 416	20120230-23032002001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-02-18 *	160	MODERATE	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-02-23 *	-
AMG 416	20120230-23032002001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	LEG EDEMA [末梢性浮腫]	20[redacted]-02-20 *	162	MILD	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-02-23 *	-
AMG 416	20120230-23032002001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	SORE THROAT [口腔咽頭痛]	20[redacted]-02-20 *	162	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-02-20 *	-
AMG 416	20120230-23032002001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	SUDDEN DEATH, CAUSE UNKNOWN [突然死]	20[redacted]-02-23	165	LIFE THREATENING	YES	Results in Death	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-02-23	FATAL

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	20120230-23058006005	6[redacted]	F	WHITE	NOT HISPANIC OR LATINO	SEPSIS [敗血症]	20[redacted]-09-19	3	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-21	FATAL
AMG 416	20120230-23066022006	6[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	NON-ST-ELEVATION MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-09-04T00:00	15	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-15	RECOVERED/RESOLVED
AMG 416	20120230-23066022006	6[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	POST-OPERATIVE RESPIRATORY FAILURE [術後呼吸不全]	20[redacted]-09-13	24	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-15	FATAL
AMG 416	20120230-23066026008	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	TIBIA FRACTURE [脛骨骨折]	20[redacted]-07-22	42	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-25	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	20120230-23066026008	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	UPPER GASTROINTESTINAL HEMORRHAGE [上部消化管出血]	20[redacted]-11-13T06:06	156	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-20	FATAL
AMG 416	20120230-23066046002	4[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	RIGHT HAND THIRD DIGIT WOUND-SKIN SORE. [創合併症]	20[redacted]-06-11	22	MODERATE	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-08-24	-
AMG 416	20120230-23066046002	4[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	DECREASED BLOOD CALCIUM [血中カルシウム減少]	20[redacted]-07-02	43	MILD	NO	-	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	RELATED	20[redacted]-07-09	-
AMG 416	20120230-23066046002	4[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	PAIN IN RIGHT REMAINING LEG STUMP [断端痛]	20[redacted]-07-18T00:00	59	MODERATE	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-08-24	-
AMG 416	20120230-23066046002	4[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CELLULITIS RIGHT LEG STUMP [蜂巣炎]	20[redacted]-07-23T00:00	64	MODERATE	NO	-	DOSE NOT CHANGED	IV ANTIBIOTICS TAKEN, OTHER	NOT RELATED	20[redacted]-08-24	-

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	20120230-23066046002	4[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	GANGRENE OF RIGHT LEG STUMP [壊疽]	20[redacted]-08-05T00:00	77	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, UNKNOWN	NOT RELATED	20[redacted]-08-24	FATAL
AMG 416	20120230-23066046002	4[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-08-07T00:00	79	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, UNKNOWN	NOT RELATED	20[redacted]-08-24	RECOVERED/RESOLVED
PLACEBO	20120230-23013006005	7[redacted]	M	WHITE	NOT HISPANIC OR LATINO	LOW BACK PAIN [背部痛]	20[redacted]-07-24	34	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-07-26	-
PLACEBO	20120230-23013006005	7[redacted]	M	WHITE	NOT HISPANIC OR LATINO	WORSENING PAIN NECK [頚部痛]	20[redacted]-07-26	36	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-08-07	-
PLACEBO	20120230-23013006005	7[redacted]	M	WHITE	NOT HISPANIC OR LATINO	SEPSIS CATHETER [医療機器関連敗血症]	20[redacted]-08-05	46	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-07	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
＊　　：「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
PLACEBO	20120230-23013006005	7[redacted]	M	WHITE	NOT HISPANIC OR LATINO	FALL [転倒]	20[redacted]-08-06	47	MODERATE	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-08-06	-
PLACEBO	20120230-23013006005	7[redacted]	M	WHITE	NOT HISPANIC OR LATINO	PAIN LOW BACK [背部痛]	20[redacted]-08-06	47	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-08-07	-
PLACEBO	20120230-23013006005	7[redacted]	M	WHITE	NOT HISPANIC OR LATINO	WORSENING OF CHRONIC KIDNEY FAILURE [慢性腎不全]	20[redacted]-08-07	48	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-07	FATAL
PLACEBO	20120230-23048002008	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	SUDDEN DEATH [突然死]	20[redacted]-02-17	168	LIFE THREATENING	YES	Results in Death	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-02-17	FATAL
PLACEBO	20120230-23048004018	6[redacted]	F	WHITE	NOT HISPANIC OR LATINO	LOW PERFUSION OF THE LOWER LIMB [末梢循環不良]	20[redacted]-08-20	34	LIFE THREATENING	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23048004018	6[redacted]	F	WHITE	NOT HISPANIC OR LATINO	LOW PERFUSION OF THE LOWER LIMB - AGGRAVATION [末梢循環不良]	20[redacted]-11-05	111	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-10	FATAL

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
PLACEBO	20120230-23048006002	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	ABDOMINAL ABSCESSES [腹部膿瘍]	20[redacted]-01-16T08:00	151	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-14T18:00	RECOVERED/RESOLVED
PLACEBO	20120230-23048006002	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	PROTEUS MIRABILIS SEPSIS [細菌性敗血症]	20[redacted]-01-16T08:00	151	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-14	FATAL
PLACEBO	20120230-23066016006	5[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	INSOMNIA NOS [不眠症]	20[redacted]-07-31T00:00	50	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	ONGOING	-
PLACEBO	20120230-23066016006	5[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	RESTLESS LEG SYNDROME [下肢静止不能症候群]	20[redacted]-07-31T00:00	50	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-08-09T00:00	-

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
PLACEBO	20120230-23066016006	5[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	PULMONARY HYPERTENSION NOS [肺高血圧症]	20[redacted]-08-13T00:00	63	MODERATE	NO	-	DOSE NOT CHANGED	OTHER, OTHER	NOT RELATED	ONGOING	-
PLACEBO	20120230-23066016006	5[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	RIGHT HIP INFLAMMATION [関節炎]	20[redacted]-12-04	176	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN, EMERGENCY ROOM VISIT, OTHER	NOT RELATED	ONGOING	-
PLACEBO	20120230-23066016006	5[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ANXIETY [不安]	20[redacted]-12-09T00:00	181	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-09T00:00	-
PLACEBO	20120230-23066016006	5[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	PNEUMONITIS [肺臓炎]	20[redacted]-12-09T00:00	181	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN, OTHER	NOT RELATED	20[redacted]-12-22T00:00	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
PLACEBO	20120230-23066016006	5[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SEPSIS [敗血症]	20[redacted]-12-30T00:00	202	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN, OTHER	NOT RELATED	20[redacted]-12-31T00:00	FATAL
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CHEST PAIN [胸痛]	20[redacted]-09-02T00:00	76	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-09-06T00:00	-
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ABDOMINAL PAIN [腹痛]	20[redacted]-09-06T00:00	80	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-09-06T00:00	-
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	UPPER RESPIRATORY INFECTION [上気道感染]	20[redacted]-09-06T00:00	80	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-12-27	-
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	INTRAVASCULAR VOLUME DEPLETION [血液量減少症]	20[redacted]-09-06T12:30	80	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-09-06T15:55	-

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
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ACUTE ON CHRONIC RESPIRATORY FAILURE [急性呼吸不全]	20[redacted]-10-03T00:00	107	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-10-09	RECOVERED/RESOLVED
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	COUGH [咳嗽]	20[redacted]-10-04T00:00	108	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-27T01:00	-
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	INSOMNIA [不眠症]	20[redacted]-10-04T00:00	108	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-27T01:00	-
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CHEST PAIN [胸痛]	20[redacted]-10-05T00:00	109	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-10-09T00:00	-
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SUPRAVENTRICULAR TACHYCARDIA [上室性頻脈]	20[redacted]-10-14T06:00	118	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-25	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
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	RENAL CELL CARCINOMA WITH METASTASIS [遠隔転移を伴う腎癌]	20[redacted]-10-25T00:00	129	MODERATE	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-12-27	-
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-11-12T00:00	147	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-27	FATAL
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	GENERALIZED ITCHING [全身性そう痒症]	20[redacted]-11-12T00:00	147	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-27T01:00	-
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	POST-OP PAIN [処置による疼痛]	20[redacted]-11-12T00:00	147	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-27T01:00	-
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ATRIAL FIBRILLATION [心房細動]	20[redacted]-11-13T00:00	148	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-27T01:00	-

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
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ANXIETY [不安]	20[redacted]-11-14T00:00	149	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-27T01:00	-
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	HYPOALBUMINAEMIA [低アルブミン血症]	20[redacted]-11-15T00:00	150	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-27T01:00	-
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SORE THROAT [口腔咽頭痛]	20[redacted]-11-15T00:00	150	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-27T01:00	-
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	AGITATION POSTOPERATIVE [術後激越]	20[redacted]-11-16T00:00	151	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-27T01:00	-
PLACEBO	20120230-23066078004	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	WORSENING ANEMIA [貧血]	20[redacted]-11-21T00:00	156	MODERATE	NO	-	DOSE NOT CHANGED	TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-12-27T01:00	-
PLACEBO	20120230-23066088004	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	FLUID OVERLOAD [水分過負荷]	20[redacted]-10-21T00:00	21	MODERATE	NO	-	DOSE NOT CHANGED	OTHER, OTHER	NOT RELATED	20[redacted]-10-22T10:05	-

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
PLACEBO	20120230-23066088004	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ACID REFLUX (ESOPHAGEAL) [胃食道逆流性疾患]	20[redacted]-10-24T00:00	24	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-10-30T00:00	-
PLACEBO	20120230-23066088004	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN EXACERBATION [慢性閉塞性肺疾患]	20[redacted]-10-24T00:00	24	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-10-30T00:00	-
PLACEBO	20120230-23066088004	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN ACUTE EXACERBATION [慢性閉塞性肺疾患]	20[redacted]-11-05T00:00	36	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-06T00:00	RECOVERED/RESOLVED
PLACEBO	20120230-23066088004	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	HYPERKALEMIA [高カリウム血症]	20[redacted]-11-26T05:00	57	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-11-30T14:11	FATAL

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
PLACEBO	20120230-23066232008	4[redacted]	M	WHITE	HISPANIC OR LATINO	RIGHT TIBIA NONUNION FRACTURE [骨折による偽関節]	20[redacted]-11-04	35	MODERATE	NO	-	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-08 *	-
PLACEBO	20120230-23066232008	4[redacted]	M	WHITE	HISPANIC OR LATINO	HEMORRHAGIC CEREBROVASCULAR ACCIDENT WITH INTRAVENTRICULAR EXTENSION [出血性卒中]	20[redacted]-02-11T23:30 *	134	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-20T18:40 *	FATAL

*1:MedDRA Version 17.0J
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 2.7.6.17-13　重篤な有害事象の SOC・PT 別発現頻度（20120230 試験）
解析対象集団：SAF

SOC PT		有害事象 プラセボ n (%)	 ONO-5163 n (%)
	N	259	252
全体		71 (27.4)	62 (24.6)
血液およびリンパ系障害		2 (0.8)	1 (0.4)
貧血		1 (0.4)	1 (0.4)
骨髄機能不全		1 (0.4)	0 (0.0)
心臓障害		9 (3.5)	13 (5.2)
急性心筋梗塞		3 (1.2)	3 (1.2)
心房細動		1 (0.4)	2 (0.8)
うっ血性心不全		4 (1.5)	2 (0.8)
心筋梗塞		2 (0.8)	2 (0.8)
狭心症		2 (0.8)	1 (0.4)
不安定狭心症		1 (0.4)	1 (0.4)
完全房室ブロック		0 (0.0)	1 (0.4)
心不全		0 (0.0)	1 (0.4)
冠動脈疾患		0 (0.0)	1 (0.4)
冠動脈狭窄		0 (0.0)	1 (0.4)
心室性頻脈		0 (0.0)	1 (0.4)
不整脈		1 (0.4)	0 (0.0)
冠動脈硬化症		1 (0.4)	0 (0.0)
右脚ブロック		1 (0.4)	0 (0.0)
左室肥大		1 (0.4)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．
出典［総括報告書 5.3.5.1-4（20120230 試験）Table 14-6.5 改変］

表 2.7.6.17-13　重篤な有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 1）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
上室性頻脈	1 (0.4)	0 (0.0)
頻脈	1 (0.4)	0 (0.0)
耳および迷路障害	1 (0.4)	0 (0.0)
回転性めまい	1 (0.4)	0 (0.0)
内分泌障害	1 (0.4)	0 (0.0)
原発性アルドステロン症	1 (0.4)	0 (0.0)
胃腸障害	8 (3.1)	6 (2.4)
下部消化管出血	0 (0.0)	2 (0.8)
便秘	0 (0.0)	1 (0.4)
下痢	1 (0.4)	1 (0.4)
糞塊	0 (0.0)	1 (0.4)
胃前庭部毛細血管拡張症	0 (0.0)	1 (0.4)
吐血	0 (0.0)	1 (0.4)
腹痛	2 (0.8)	0 (0.0)
十二指腸潰瘍	2 (0.8)	0 (0.0)
悪心	2 (0.8)	0 (0.0)
食道炎	1 (0.4)	0 (0.0)
膵炎	1 (0.4)	0 (0.0)
一般・全身障害および投与部位の状態	7 (2.7)	7 (2.8)
発熱	0 (0.0)	3 (1.2)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-13　重篤な有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 2）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
カテーテル留置部位血腫	0 (0.0)	1 (0.4)
非心臓性胸痛	2 (0.8)	1 (0.4)
突然死	1 (0.4)	1 (0.4)
外科手術不成功	0 (0.0)	1 (0.4)
無力症	2 (0.8)	0 (0.0)
閉塞性ヘルニア	1 (0.4)	0 (0.0)
医療機器合併症	1 (0.4)	0 (0.0)
肝胆道系障害	3 (1.2)	2 (0.8)
胆管炎	0 (0.0)	1 (0.4)
胆石症	1 (0.4)	1 (0.4)
急性肝炎	0 (0.0)	1 (0.4)
胆嚢炎	1 (0.4)	0 (0.0)
急性胆嚢炎	1 (0.4)	0 (0.0)
感染症および寄生虫症	30 (11.6)	23 (9.1)
肺炎	10 (3.9)	4 (1.6)
蜂巣炎	1 (0.4)	2 (0.8)
敗血症	1 (0.4)	2 (0.8)
尿路感染	2 (0.8)	2 (0.8)
動静脈瘻部位感染	0 (0.0)	1 (0.4)
菌血症	0 (0.0)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-13　重篤な有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 3）
解析対象集団：SAF

SOC PT		有害事象 プラセボ n （%）	 ONO-5163 n （%）
	N	259	252
気管支炎		1 (0.4)	1 (0.4)
熱傷部感染		0 (0.0)	1 (0.4)
憩室炎		0 (0.0)	1 (0.4)
壊疽		1 (0.4)	1 (0.4)
胃腸炎		3 (1.2)	1 (0.4)
帯状疱疹性髄膜脳炎		0 (0.0)	1 (0.4)
インフルエンザ		0 (0.0)	1 (0.4)
無菌性髄膜炎		0 (0.0)	1 (0.4)
眼帯状疱疹		0 (0.0)	1 (0.4)
前立腺膿瘍		0 (0.0)	1 (0.4)
植皮感染		0 (0.0)	1 (0.4)
ブドウ球菌性菌血症		0 (0.0)	1 (0.4)
ブドウ球菌性敗血症		1 (0.4)	1 (0.4)
ウイルス性心筋炎		0 (0.0)	1 (0.4)
腹部膿瘍		1 (0.4)	0 (0.0)
四肢膿瘍		1 (0.4)	0 (0.0)
虫垂炎		1 (0.4)	0 (0.0)
細菌性敗血症		1 (0.4)	0 (0.0)
クロストリジウム・ディフィシレ大腸炎		1 (0.4)	0 (0.0)
クロストリジウム・ディフィシレ性敗血症		1 (0.4)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-13　重篤な有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 4）
解析対象集団：SAF

SOC	有害事象	
	プラセボ	ONO-5163
PT	n （%）	n （%）
N	259	252
医療機器関連敗血症	1 (0.4)	0 (0.0)
糖尿病性足感染	1 (0.4)	0 (0.0)
椎間板炎	1 (0.4)	0 (0.0)
メタニューモウイルス感染	1 (0.4)	0 (0.0)
骨髄炎	3 (1.2)	0 (0.0)
歯周炎	1 (0.4)	0 (0.0)
術後膿瘍	1 (0.4)	0 (0.0)
気道感染	1 (0.4)	0 (0.0)
敗血症症候群	1 (0.4)	0 (0.0)
上気道感染	1 (0.4)	0 (0.0)
細菌性尿路感染	1 (0.4)	0 (0.0)
腸球菌性尿路感染	1 (0.4)	0 (0.0)
真菌性尿路感染	1 (0.4)	0 (0.0)
ウイルス感染	1 (0.4)	0 (0.0)
傷害、中毒および処置合併症	16 (6.2)	15 (6.0)
動静脈瘻血栓症	2 (0.8)	2 (0.8)
脛骨骨折	1 (0.4)	2 (0.8)
血管グラフト血栓症	4 (1.5)	2 (0.8)
動静脈瘻瘤	0 (0.0)	1 (0.4)
顔面損傷	0 (0.0)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-13　重篤な有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 5）
解析対象集団：SAF

SOC	有害事象	
	プラセボ	ONO-5163
PT	n （%）	n （%）
N	259	252
転倒	0 (0.0)	1 (0.4)
大腿骨骨折	1 (0.4)	1 (0.4)
術後呼吸不全	0 (0.0)	1 (0.4)
処置による低血圧	0 (0.0)	1 (0.4)
処置による嘔吐	0 (0.0)	1 (0.4)
植皮生着不全	0 (0.0)	1 (0.4)
硬膜下血腫	0 (0.0)	1 (0.4)
各種物質毒性	0 (0.0)	1 (0.4)
動静脈瘻閉塞	1 (0.4)	0 (0.0)
動静脈瘻部位血腫	1 (0.4)	0 (0.0)
動静脈瘻部位出血	1 (0.4)	0 (0.0)
剥離骨折	1 (0.4)	0 (0.0)
第２度熱傷	1 (0.4)	0 (0.0)
鎖骨骨折	1 (0.4)	0 (0.0)
移植腎の合併症	1 (0.4)	0 (0.0)
移植片合併症	1 (0.4)	0 (0.0)
股関節部骨折	1 (0.4)	0 (0.0)
移植血管合併症	1 (0.4)	0 (0.0)
臨床検査	1 (0.4)	1 (0.4)
肝酵素上昇	0 (0.0)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-13　重篤な有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 6）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n （%）	 ONO-5163 n （%）
N	259	252
心電図T波逆転	1 (0.4)	0 (0.0)
代謝および栄養障害	8 (3.1)	10 (4.0)
高カリウム血症	1 (0.4)	6 (2.4)
水分過負荷	2 (0.8)	2 (0.8)
代謝性アシドーシス	0 (0.0)	2 (0.8)
高血糖	0 (0.0)	1 (0.4)
血液量増加症	0 (0.0)	1 (0.4)
低血糖症	1 (0.4)	1 (0.4)
肥満	1 (0.4)	1 (0.4)
異常体重減少	1 (0.4)	0 (0.0)
高カルシウム血症	1 (0.4)	0 (0.0)
低カリウム血症	1 (0.4)	0 (0.0)
筋骨格系および結合組織障害	6 (2.3)	0 (0.0)
関節痛	1 (0.4)	0 (0.0)
背部痛	2 (0.8)	0 (0.0)
筋攣縮	1 (0.4)	0 (0.0)
筋骨格系胸痛	1 (0.4)	0 (0.0)
骨炎	1 (0.4)	0 (0.0)
全身性エリテマトーデス	1 (0.4)	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）	2 (0.8)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-13　重篤な有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 7）
解析対象集団：SAF

SOC PT	有害事象 プラセボ n (%)	 ONO-5163 n (%)
N	259	252
食道腺癌	1 (0.4)	0 (0.0)
前立腺癌	1 (0.4)	0 (0.0)
神経系障害	9 (3.5)	5 (2.0)
脳損傷	0 (0.0)	1 (0.4)
脳血管発作	1 (0.4)	1 (0.4)
痙攣	2 (0.8)	1 (0.4)
振戦	0 (0.0)	1 (0.4)
尿毒症性脳症	0 (0.0)	1 (0.4)
平衡障害	1 (0.4)	0 (0.0)
認知症	1 (0.4)	0 (0.0)
出血性卒中	1 (0.4)	0 (0.0)
高血糖性痙攣	1 (0.4)	0 (0.0)
失神	1 (0.4)	0 (0.0)
刺激無反応	2 (0.8)	0 (0.0)
精神障害	3 (1.2)	3 (1.2)
精神状態変化	2 (0.8)	2 (0.8)
錯乱状態	0 (0.0)	1 (0.4)
不安障害	1 (0.4)	0 (0.0)
腎および尿路障害	1 (0.4)	5 (2.0)
血尿	0 (0.0)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-13　重篤な有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 8）
解析対象集団：SAF

SOC	有害事象	
	プラセボ	ONO-5163
PT	n （%）	n （%）
N	259	252
腎結石症	0 (0.0)	1 (0.4)
腎嚢胞出血	0 (0.0)	1 (0.4)
尿道狭窄	0 (0.0)	1 (0.4)
尿閉	0 (0.0)	1 (0.4)
慢性腎不全	1 (0.4)	0 (0.0)
呼吸器、胸郭および縦隔障害	13 (5.0)	7 (2.8)
慢性閉塞性肺疾患	2 (0.8)	2 (0.8)
呼吸困難	3 (1.2)	2 (0.8)
肺水腫	2 (0.8)	2 (0.8)
呼吸窮迫	1 (0.4)	2 (0.8)
低酸素症	0 (0.0)	1 (0.4)
非心原性肺水腫	0 (0.0)	1 (0.4)
呼吸不全	1 (0.4)	1 (0.4)
急性呼吸不全	3 (1.2)	0 (0.0)
胸膜痛	1 (0.4)	0 (0.0)
肺臓炎	1 (0.4)	0 (0.0)
肺うっ血	1 (0.4)	0 (0.0)
皮膚および皮下組織障害	4 (1.5)	2 (0.8)
触知可能紫斑病	0 (0.0)	1 (0.4)
皮膚潰瘍	1 (0.4)	1 (0.4)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．

表 2.7.6.17-13　重篤な有害事象の SOC・PT 別発現頻度（20120230 試験）（続き 9）
解析対象集団：SAF

SOC	有害事象	
	プラセボ	ONO-5163
PT	n （%）	n （%）
N	259	252
水疱	1 (0.4)	0 (0.0)
糖尿病性神経障害性潰瘍	1 (0.4)	0 (0.0)
糖尿病性潰瘍	1 (0.4)	0 (0.0)
外科および内科処置	1 (0.4)	0 (0.0)
指切断	1 (0.4)	0 (0.0)
血管障害	7 (2.7)	3 (1.2)
高血圧	0 (0.0)	1 (0.4)
悪性高血圧	0 (0.0)	1 (0.4)
静脈狭窄	0 (0.0)	1 (0.4)
進行性高血圧	1 (0.4)	0 (0.0)
高血圧クリーゼ	1 (0.4)	0 (0.0)
低血圧	1 (0.4)	0 (0.0)
末梢性虚血	1 (0.4)	0 (0.0)
末梢循環不良	1 (0.4)	0 (0.0)
血栓性静脈炎	1 (0.4)	0 (0.0)
血栓症	1 (0.4)	0 (0.0)

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．
出典［総括報告書 5.3.5.1-4（20120230 試験）Table 14-6.5 改変］

表 2.7.6.17-14　重篤な有害事象の一覧表（20120230 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	20120230-23011008001	HYPERKALAEMIA [高カリウム血症]	20[redacted]-02-10T14:50	153	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, OTHER	NOT RELATED	20[redacted]-02-10T20:20	RECOVERED/RESOLVED
AMG 416	20120230-23011008001	METABOLIC ACIDOSIS [代謝性アシドーシス]	20[redacted]-02-10T14:50	153	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-02-13T18:57	RECOVERED/RESOLVED
AMG 416	20120230-23011008001	URAEMIC ENCEPHALOPATHY [尿毒症性脳症]	20[redacted]-02-10T14:50	153	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-02-13T18:57	RECOVERED/RESOLVED
AMG 416	20120230-23011008001	FLUID OVERLOAD [水分過負荷]	20[redacted]-02-10T16:00	153	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, OTHER	NOT RELATED	20[redacted]-02-13T09:30	RECOVERED/RESOLVED
AMG 416	20120230-23011008007	THROMOBOSED VASCULAR HAEMODIALYSIS ACCESS [動静脈瘻血栓症]	20[redacted]-11-13	64	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-11-16T19:45	RECOVERED/RESOLVED
AMG 416	20120230-23011010001	HYPERKALAEMIA [高カリウム血症]	20[redacted]-03-10	195	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-03-12T18:00	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	20120230-23011010001	PULMONARY OEDEMA [肺水腫]	20[redacted]-03-10	195	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-03-12T18:00	RECOVERED/RESOLVED
AMG 416	20120230-23011012005	WORSENING OF ULCER ON LEFT LOWER LEG POSTERIA ASPECT [皮膚潰瘍]	20[redacted]-10-02T12:00	8	MODERATE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120230-23011012005	SPLIT SKIN GRAFT TO ULCER ON LEFT LOWER LEG POSTERIA ASPECT [植皮生着不全]	20[redacted]-10-21T12:00	27	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120230-23011012005	INFECTED SPLIT SKIN GRAFT TO ULCER ON LEFT LOWER LEG POSTERIA ASPECT [植皮感染]	20[redacted]-11-02T13:52	39	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120230-23011012005	NEW SPLIT SKIN GRAFT ON THE SAME AREA OF LEFT LOWER LEG POSTERIA ASPECT AS PREVIOUS EVENT [植皮生着不全]	20[redacted]-11-18T12:00	55	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120230-23011012005	ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RATE [心房細動]	20[redacted]-12-20T08:50	87	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-12-24T23:59	RECOVERED/RESOLVED
AMG 416	20120230-23011012006	RIGHT ARM CELLULITIS [蜂巣炎]	20[redacted]-03-11T00:05	168	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-24T23:00	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	20120230-23013006003	STENOSIS VEIN LEFT ARM [静脈狭窄]	20[redacted]-05-10	15	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-17 *	RECOVERED/RESOLVED
AMG 416	20120230-23013008001	PALPABLE PURPURA [触知可能紫斑病]	20[redacted]-09-04T11:45	87	MODERATE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-01-06	RECOVERED/RESOLVED
AMG 416	20120230-23013012004	HEMATOMA IN TH ECAROTID DURING THE PLACEMENT OF CATHETER [カテーテル留置部位血腫]	20[redacted]-09-25	108	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-26	RECOVERED/RESOLVED
AMG 416	20120230-23016002005	LOWER GASTROINTESTINAL BLEEDING [下部消化管出血]	20[redacted]-09-28T04:25	3	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-02T11:59	RECOVERED/RESOLVED
AMG 416	20120230-23016005010	URINARY TRACT INFECTION [尿路感染]	20[redacted]-10-25	33	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN	NOT RELATED	20[redacted]-10-30	RECOVERED/RESOLVED
AMG 416	20120230-23021002005	BRONCHITIS ACUTE [気管支炎]	20[redacted]-07-17	8	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-25	RECOVERED/RESOLVED
AMG 416	20120230-23021010007	PNEUMONIA [肺炎]	20[redacted]-01-25	123	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-03	RECOVERED/RESOLVED
AMG 416	20120230-23021012001	STENOSIS OF URETHRA [尿道狭窄]	20[redacted]-01-01T11:30	183	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-04T09:00 *	RECOVERED/RESOLVED
AMG 416	20120230-23021012003	TIBIA FRACTURE [脛骨骨折]	20[redacted]-09-03T05:30	41	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-21T14:00	RECOVERED/RESOLVED
AMG 416	20120230-23025008004	ARTERIOVENOUS FISTULA THROMBOSIS [動静脈瘻血栓症]	20[redacted]-09-25T06:45	92	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-29T13:00	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	20120230-23029004004	ANGINA AT REST [不安定狭心症]	20[redacted]-10-21	159	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-23	RECOVERED/RESOLVED
AMG 416	20120230-23032002001	SUDDEN DEATH, CAUSE UNKNOWN [突然死]	20[redacted]-02-23	165	LIFE THREATENING	YES	Results in Death	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-02-23	FATAL
AMG 416	20120230-23032002006	ARTERIO-VENOUS GRAFT THROMBOSIS [血管グラフト血栓症]	20[redacted]-04-03	183	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-04-04	RECOVERED/RESOLVED
AMG 416	20120230-23032002006	INTRADIALYTIC HYPOTENSION [処置による低血圧]	20[redacted]-04-07	187	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-04-10	RECOVERED/RESOLVED
AMG 416	20120230-23032008007	INFLUENZA B VIRUS INFECTION [インフルエンザ]	20[redacted]-01-16	106	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-20	RECOVERED/RESOLVED
AMG 416	20120230-23032008007	STAPHYLOCOCCUS BACTEREMIA [ブドウ球菌性菌血症]	20[redacted]-03-28	177	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN, OTHER	NOT RELATED	20[redacted]-04-12	RECOVERED/RESOLVED
AMG 416	20120230-23048002003	HEART FAILURE [心不全]	20[redacted]-11-08	54	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120230-23048002003	HYPERTENSION EXACERBATED [高血圧]	20[redacted]-02-13T23:00	151	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-27	RECOVERED/RESOLVED
AMG 416	20120230-23048014001	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-01-18	153	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-24	RECOVERED/RESOLVED

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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	20120230-23058002005	EVALUATION FOR PRIOR DAY FEVER [発熱]	20[redacted]-11-07T10:15	130	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-11-08T08:11	RECOVERED/RESOLVED
AMG 416	20120230-23058006005	SEPSIS [敗血症]	20[redacted]-09-19	3	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-21	FATAL
AMG 416	20120230-23058008013	HEMATEMESIS [吐血]	20[redacted]-04-14	-31	SEVERE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	-	20[redacted]-04-16	RECOVERED/RESOLVED
AMG 416	20120230-23058010002	VOLUME OVERLOAD [水分過負荷]	20[redacted]-09-07T08:00	115	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-26	RECOVERED/RESOLVED
AMG 416	20120230-23058010002	URINARY TRACT INFECTION [尿路感染]	20[redacted]-10-01	139	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-15T08:00	RECOVERED/RESOLVED
AMG 416	20120230-23058010002	TREMORS [振戦]	20[redacted]-10-01T08:00	139	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-10-15	RECOVERED/RESOLVED
AMG 416	20120230-23066004003	COMPLETE HEART BLOCK [完全房室ブロック]	20[redacted]-08-08	128	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-08-19	RECOVERED/RESOLVED
AMG 416	20120230-23066004017	PULMONARY EDEMA [肺水腫]	20[redacted]-03-12	-21	MODERATE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	-	20[redacted]-03-15	RECOVERED/RESOLVED
AMG 416	20120230-23066006003	CLOTTED RIGHT ARTERIOVENOUS GRAFT [血管グラフト血栓症]	20[redacted]-05-27	64	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-05-30	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
AMG 416	20120230-23066006003	CHOLANGITIS [胆管炎]	20[redacted]-06-20	88	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-06-25	RECOVERED/RESOLVED
AMG 416	20120230-23066006003	CHOLELITHIASIS [胆石症]	20[redacted]-06-20	88	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120230-23066006006	ATRIAL FIBRILLATION [心房細動]	20[redacted]-05-06	8	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-09	RECOVERED/RESOLVED
AMG 416	20120230-23066006006	MALIGNANT HYPERTENSION [悪性高血圧]	20[redacted]-05-06	8	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-09	RECOVERED/RESOLVED
AMG 416	20120230-23066006006	DIARRHEA [下痢]	20[redacted]-11-18	204	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-22	RECOVERED/RESOLVED
AMG 416	20120230-23066006006	FEVER [発熱]	20[redacted]-11-18	204	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-11-22	RECOVERED/RESOLVED
AMG 416	20120230-23066006017	ARTERIOVENOUS FISTULA SITE INFECTION [動静脈瘻部位感染]	20[redacted]-08-17	12	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN	NOT RELATED	ONGOING	UNKNOWN
AMG 416	20120230-23066006017	WORSENING OF ANEURYSMS OF RT. ARM AV FISTULA [動静脈瘻瘤]	20[redacted]-09-05	31	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, OTHER	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120230-23066006026	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-10-23	45	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-27	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	20120230-23066006026	HYPOGLYCEMIA [低血糖症]	20[redacted]-10-23	45	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-27	RECOVERED/RESOLVED
AMG 416	20120230-23066006028	ELEVATED LIVER ENZYMES [肝酵素上昇]	20[redacted]-09-24	29	SEVERE	YES	Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	OTHER	RELATED	20[redacted]-10-08	RECOVERED/RESOLVED
AMG 416	20120230-23066006029	WORSENING ANEMIA [貧血]	20[redacted]-11-19	85	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-11-28	RECOVERED/RESOLVED
AMG 416	20120230-23066006029	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-11-25	91	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-28	RECOVERED/RESOLVED
AMG 416	20120230-23066006029	CORONARY ARTERY STENOSIS, STATUS POST DRUG ELUTING STENT PLACEMENT [冠動脈狭窄]	20[redacted]-11-25	91	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-12-18	RECOVERED/RESOLVED
AMG 416	20120230-23066006029	CHEST PAIN - CARDIAC [狭心症]	20[redacted]-12-17	113	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-18	RECOVERED/RESOLVED

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AMG 416	20120230-23066006029	SHORTNESS OF BREATH - MULTIFACTORIAL [呼吸困難]	20[redacted]-01-26 *	153	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-31 *	RECOVERED/RESOLVED
AMG 416	20120230-23066006029	ACUTE VIRAL MYOCARDITIS [ウイルス性心筋炎]	20[redacted]-01-28 *	155	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-31 *	RECOVERED/RESOLVED
AMG 416	20120230-23066006029	CHEST PRESSURE CARDIAC [狭心症]	20[redacted]-01-28	155	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-31	RECOVERED/RESOLVED
AMG 416	20120230-23066008004	VARICELLA ZOSTER VIRUS OPTHALMICUS [眼帯状疱疹]	20[redacted]-08-12	102	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-20	RECOVERED/RESOLVED
AMG 416	20120230-23066008004	VARICELLA ZOSTER VIRUS ENCEPHALITIS [帯状疱疹性髄膜脳炎]	20[redacted]-08-17	107	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-20	RECOVERED/RESOLVED
AMG 416	20120230-23066008004	NON TRAUMATIC BRAIN INJURY [脳損傷]	20[redacted]-08-30	120	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-20	RECOVERED/RESOLVED
AMG 416	20120230-23066008008	CHEST PAIN (NON-CARDIAC) [非心臓性胸痛]	20[redacted]-08-17T10:00	53	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-08-19	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	20120230-23066010001	EXACERBATION OF MORBID OBESITY [肥満]	20[redacted]-10-21	42	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-23	RECOVERED/RESOLVED
AMG 416	20120230-23066010001	ASCEPTIC MENINGITIS [無菌性髄膜炎]	20[redacted]-11-19T12:23	71	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-11-23 *	RECOVERED/RESOLVED
AMG 416	20120230-23066010003	HEPATITIS, ACUTE, CAUSE UNKNOWN [急性肝炎]	20[redacted]-12-10	114	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-01-06	RECOVERED/RESOLVED
AMG 416	20120230-23066010003	PNEUMONIA [肺炎]	20[redacted]-12-18 *	122	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-12-29 *	RECOVERED/RESOLVED
AMG 416	20120230-23066010003	HEALTHCARE ASSOCIATED PNEUMONIA [肺炎]	20[redacted]-01-10	145	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-23	RECOVERED/RESOLVED
AMG 416	20120230-23066014018	DIVERTICULITIS INTESTINAL [憩室炎]	20[redacted]-12-16T08:00	97	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-18	RECOVERED/RESOLVED
AMG 416	20120230-23066016005	SYNCOPE [失神]	20[redacted]-05-29T12:06	-91	SEVERE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	-	20[redacted]-05-29T13:07	RECOVERED/RESOLVED
AMG 416	20120230-23066016005	CHOLELITHIASIS [胆石症]	20[redacted]-08-23T00:00	-5	SEVERE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-08-26	RECOVERED/RESOLVED

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AMG 416	20120230-23066016005	CALCULUS KIDNEY [腎結石症]	20[redacted]-09-22T00:00	26	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN, OTHER	NOT RELATED	20[redacted]-09-24T00:00	RECOVERED/RESOLVED
AMG 416	20120230-23066022006	NON-ST-ELEVATION MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-09-04T00:00	15	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-15	RECOVERED/RESOLVED
AMG 416	20120230-23066022006	POST-OPERATIVE RESPIRATORY FAILURE [術後呼吸不全]	20[redacted]-09-13	24	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-15	FATAL
AMG 416	20120230-23066026005	PROSTATIC ABCESS [前立腺膿瘍]	20[redacted]-07-19	89	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-25	RECOVERED/RESOLVED
AMG 416	20120230-23066026005	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-08-30	131	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-09-03	RECOVERED/RESOLVED
AMG 416	20120230-23066026005	FACIAL TRAUMA [顔面損傷]	20[redacted]-09-01	133	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-03	RECOVERED/RESOLVED
AMG 416	20120230-23066026008	TIBIA FRACTURE [脛骨骨折]	20[redacted]-07-22	42	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-25	RECOVERED/RESOLVED

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AMG 416	20120230-23066026008	UPPER GASTROINTESTINAL HEMORRHAGE [上部消化管出血]	20[redacted]-11-13T06:06	156	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-20	FATAL
AMG 416	20120230-23066026022	ACUTE LOWER GASTROINTESTINAL BLEED [下部消化管出血]	20[redacted]-07-07	34	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-10	RECOVERED/RESOLVED
AMG 416	20120230-23066028006	NON ST SEGMENT ELEVATION MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-10-06T05:44	17	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-11	RECOVERED/RESOLVED
AMG 416	20120230-23066028006	PNEUMONIA [肺炎]	20[redacted]-10-06T05:44	17	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-08	RECOVERED/RESOLVED
AMG 416	20120230-23066028006	RESPIRATORY DISTRESS [呼吸窮迫]	20[redacted]-10-06T05:44	17	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-11	RECOVERED/RESOLVED
AMG 416	20120230-23066028006	COPD EXACERBATION [慢性閉塞性肺疾患]	20[redacted]-11-24T12:00	66	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-28	RECOVERED/RESOLVED
AMG 416	20120230-23066028006	CORONARY ARTERY DISEASE [冠動脈疾患]	20[redacted]-12-27T07:00	99	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-04T07:00	RECOVERED/RESOLVED
AMG 416	20120230-23066034002	DISTAL FEMUR FRACTURE [大腿骨骨折]	20[redacted]-12-01	68	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-03	RECOVERED/RESOLVED

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AMG 416	20120230-23066034002	HYPOXIA [低酸素症]	20[redacted]-12-01	68	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-03	RECOVERED/RESOLVED
AMG 416	20120230-23066034009	CVA [脳血管発作]	20[redacted]-02-05T11:00	132	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-25	RECOVERED/RESOLVED
AMG 416	20120230-23066036019	DIVERTICULITIS [憩室炎]	20[redacted]-05-01	-70	SEVERE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION, HOSPITALIZED / PROLONGED HOSPITALIZATION, UNKNOWN, UNKNOWN	-	20[redacted]-05-05	RECOVERED/RESOLVED
AMG 416	20120230-23066042002	HYPERGLYCEMIA [高血糖]	20[redacted]-08-05	70	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-09	RECOVERED/RESOLVED
AMG 416	20120230-23066042002	VOMITING BLOOD [吐血]	20[redacted]-08-18	83	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-25	RECOVERED/RESOLVED
AMG 416	20120230-23066042002	HYPERGLYCEMIA [高血糖]	20[redacted]-09-30	126	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-20	RECOVERED/RESOLVED
AMG 416	20120230-23066046002	GANGRENE OF RIGHT LEG STUMP [壊疽]	20[redacted]-08-05T00:00	77	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, UNKNOWN	NOT RELATED	20[redacted]-08-24	FATAL

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AMG 416	20120230-23066046002	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-08-07T00:00	79	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, UNKNOWN	NOT RELATED	20[redacted]-08-24	RECOVERED/RESOLVED
AMG 416	20120230-23066056008	ALTERED MENTAL STATE [精神状態変化]	20[redacted]-10-07	110	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-10	RECOVERED/RESOLVED
AMG 416	20120230-23066078010	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-01-03T00:00	122	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-07T00:00	RECOVERED/RESOLVED
AMG 416	20120230-23066078014	GASTROENTERITIS [胃腸炎]	20[redacted]-02-25T11:33	170	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-26	RECOVERED/RESOLVED
AMG 416	20120230-23066080004	BACTEREMIA [菌血症]	20[redacted]-09-20T15:00	3	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-28	RECOVERED/RESOLVED
AMG 416	20120230-23066080004	SEPSIS [敗血症]	20[redacted]-10-08T17:00	21	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	UNKNOWN
AMG 416	20120230-23066080004	HEMORRHAGIC RIGTH INFERIOR RENAL CYST, POLYCYSTIC KIDNEY DISEASE [腎嚢胞出血]	20[redacted]-11-05T10:00	49	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-06	RECOVERED/RESOLVED
AMG 416	20120230-23066084004	CELLULITIS OF ARM [蜂巣炎]	20[redacted]-07-29T05:00	13	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-08-03T20:00	RECOVERED/RESOLVED
AMG 416	20120230-23066084010	HYPERKALEMIA [高カリウム血症]	20[redacted]-10-07T10:15	21	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-13T11:30	RECOVERED/RESOLVED
AMG 416	20120230-23066102005	TRANSIENT ISCHAEMIC ATTACK [一過性脳虚血発作]	20[redacted]-09-09	-9	MODERATE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-09-12	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	20120230-23066102005	RESPIRATORY DISTRESS [呼吸窮迫]	20[redacted]-10-07	20	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-15	RECOVERED/RESOLVED
AMG 416	20120230-23066102005	HYPERKALEMIA [高カリウム血症]	20[redacted]-12-26 *	100	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-27 *	RECOVERED/RESOLVED
AMG 416	20120230-23066102005	COPD EXACERBATION [慢性閉塞性肺疾患]	20[redacted]-02-08 *	144	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-13 *	RECOVERED/RESOLVED
AMG 416	20120230-23066102005	HEALTHCARE ASSOCIATED PNEUMONIA [肺炎]	20[redacted]-02-08 *	144	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-02-13 *	RECOVERED/RESOLVED
AMG 416	20120230-23066102005	HYPERVOLEMIA [血液量増加症]	20[redacted]-02-08 *	144	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-13 *	RECOVERED/RESOLVED
AMG 416	20120230-23066102005	HYPERCAPNIC RESPIRATORY FAILURE [呼吸不全]	20[redacted]-02-16 *	152	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-18 *	RECOVERED/RESOLVED
AMG 416	20120230-23066102005	METABOLIC ACIDOSIS [代謝性アシドーシス]	20[redacted]-02-16	152	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-18	RECOVERED/RESOLVED
AMG 416	20120230-23066104004	GASTRIC ANTRAL VASCULAR ECTASIA [胃前庭部毛細血管拡張症]	20[redacted]-01-07	170	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-12	RECOVERED/RESOLVED
AMG 416	20120230-23066130004	GROSS HEMATURIA [血尿]	20[redacted]-01-05	153	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-08	RECOVERED/RESOLVED
AMG 416	20120230-23066150005	ACUTE ACYLOCVIR TOXICITY [各種物質毒性]	20[redacted]-01-27T06:30	125	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER, OTHER	NOT RELATED	20[redacted]-01-30T00:00	RECOVERED/RESOLVED

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AMG 416	20120230-23066152012	ACUTE MYOCARDIAL INFARCTION TYPE 1 [急性心筋梗塞]	20[redacted]-01-27	173	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-01-29	RECOVERED/RESOLVED
AMG 416	20120230-23066152013	NONCARDIOGENIC PULMONARY EDEMA [非心原性肺水腫]	20[redacted]-08-14T15:08 *	28	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-08-16 *	RECOVERED/RESOLVED
AMG 416	20120230-23066152013	PULMONARY EDEMA [肺水腫]	20[redacted]-01-05 *	172	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-09 *	RECOVERED/RESOLVED
AMG 416	20120230-23066152013	WORSENED HYPERKALEMIA [高カリウム血症]	20[redacted]-01-05	172	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-06 *	RECOVERED/RESOLVED
AMG 416	20120230-23066152021	METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS SEPSIS [ブドウ球菌性敗血症]	20[redacted]-12-31 *	97	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-10 *	RECOVERED/RESOLVED
AMG 416	20120230-23066152021	HYPERKALEMIA [高カリウム血症]	20[redacted]-01-21 *	118	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION, OTHER	NOT RELATED	20[redacted]-01-22 *	RECOVERED/RESOLVED
AMG 416	20120230-23066152021	VENTRICULAR TACHYCARDIA [心室性頻脈]	20[redacted]-01-24 *	121	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-24 *	RECOVERED/RESOLVED
AMG 416	20120230-23066152021	SUBDURAL HEMATOMOA [硬膜下血腫]	20[redacted]-02-27	155	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-03	RECOVERED/RESOLVED

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AMG 416	20120230-23066152021	SEIZURES [痙攣]	20[redacted]-03-04 *	160	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120230-23066152021	SEIZURES [痙攣]	20[redacted]-03-13 *	169	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120230-23066152021	WORSENED HYPERKALEMIA [高カリウム血症]	20[redacted]-03-13 *	169	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING *	NOT RECOVERED/NOT RESOLVED
AMG 416	20120230-23066152021	WORSENING OF SUBDURAL HEMATOMA [硬膜下血腫]	20[redacted]-03-13 *	169	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-03-21 *	RECOVERED/RESOLVED
AMG 416	20120230-23066152021	SEIZURES, WORSENED [痙攣]	20[redacted]-03-16 *	172	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-21 *	RECOVERED/RESOLVED
AMG 416	20120230-23066152021	CONFUSION [錯乱状態]	20[redacted]-03-22 *	178	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-24 *	RECOVERED/RESOLVED
AMG 416	20120230-23066152021	FEVER [発熱]	20[redacted]-03-22	178	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-24	RECOVERED/RESOLVED
AMG 416	20120230-23066166002	FALLS [転倒]	20[redacted]-11-12	135	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER	NOT RELATED	20[redacted]-12-01T12:00	RECOVERED/RESOLVED
AMG 416	20120230-23066166002	URINARY RETENTION [尿閉]	20[redacted]-11-29T20:00	152	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-12-06T13:00	RECOVERED/RESOLVED

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AMG 416	20120230-23066166002	BURN TO BACK WITH MODERATE SIGNS OF INFECTION [熱傷部感染]	20[redacted]-12-01T11:15	154	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-12-12	RECOVERED/RESOLVED
AMG 416	20120230-23066166003	CONSTIPATION [便秘]	20[redacted]-08-15T01:00	32	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-18T12:00	RECOVERED/RESOLVED
AMG 416	20120230-23066166003	FECAL IMPACTION NOS [糞塊]	20[redacted]-08-17	34	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-18	RECOVERED/RESOLVED
AMG 416	20120230-23066202003	LAP BAND FAILURE [外科手術不成功]	20[redacted]-02-04T08:00	174	MILD	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-02-08T14:53	RECOVERED/RESOLVED
AMG 416	20120230-23066202003	VOMITING FOLLOWING GASTROINTESTINAL SURGERY [処置による嘔吐]	20[redacted]-02-13T08:00	183	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-16	RECOVERED/RESOLVED
NOT TREATED	20120230-23066104008	PULMONARY EDEMA [肺水腫]	20[redacted]-01-18	115	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-25	RECOVERED/RESOLVED
PLACEBO	20120230-23011006002	CHEST PAIN (NON-CARDIAC) [非心臓性胸痛]	20[redacted]-08-20T22:50	-10	MODERATE	YES	Requires or Prolongs Hospitalization	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER, OTHER	-	20[redacted]-08-20T22:55	RECOVERED/RESOLVED
PLACEBO	20120230-23011006003	GASTROENTERITIS [胃腸炎]	20[redacted]-02-26	160	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-03-02	RECOVERED/RESOLVED

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PLACEBO	20120230-23011006005	INFECTED 2ND,3RD AND 4TH TOES OF LEFT FOOT [限局性感染]	20[redacted]-09-10T09:30	-14	MODERATE	YES	Requires or Prolongs Hospitalization	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	-	20[redacted]-09-23T13:01	RECOVERED/RESOLVED
PLACEBO	20120230-23011006005	LEFT FOREFOOT INFECTION [限局性感染]	20[redacted]-09-23	-1	MODERATE	YES	Requires or Prolongs Hospitalization	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	-	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23011006005	LEFT PLEURITIC CHEST PAIN [胸膜痛]	20[redacted]-10-04T20:00	11	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-06T09:30	RECOVERED/RESOLVED
PLACEBO	20120230-23011006005	BONE MARROW SUPPRESSION [骨髄機能不全]	20[redacted]-11-18	56	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, OTHER	NOT RELATED	20[redacted]-11-25	RECOVERED/RESOLVED
PLACEBO	20120230-23011006005	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-12-12T19:35	80	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-13T16:15	RECOVERED/RESOLVED
PLACEBO	20120230-23011008002	THROMBOSED RIGHT PTFE GRAFT [血管グラフト血栓症]	20[redacted]-01-02T17:00	100	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-11T09:38	RECOVERED/RESOLVED
PLACEBO	20120230-23011008002	UNRESPONSIVE ON DIALYSIS [刺激無反応]	20[redacted]-01-03T17:46	101	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, OTHER	NOT RELATED	20[redacted]-01-03T18:20	RECOVERED/RESOLVED

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PLACEBO	20120230-23013002001	MUSCULOSKELETAL THORACAL PAIN [筋骨格系胸痛]	20[redacted]-10-26T08:00	46	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-28T08:00	RECOVERED/RESOLVED
PLACEBO	20120230-23013002003	VERTIGO [回転性めまい]	20[redacted]-02-03T02:00	132	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-04	RECOVERED/RESOLVED
PLACEBO	20120230-23013004001	PNEUMONIA [肺炎]	20[redacted]-01-02T10:00	116	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-08	RECOVERED/RESOLVED
PLACEBO	20120230-23013006005	SEPSIS CATHETER [医療機器関連敗血症]	20[redacted]-08-05	46	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-07	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23013006005	WORSENING OF CHRONIC KIDNEY FAILURE [慢性腎不全]	20[redacted]-08-07	48	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-07	FATAL
PLACEBO	20120230-23013008002	BILIARY CHOLECYSTITIS [胆嚢炎]	20[redacted]-01-13T20:00	148	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, OTHER	NOT RELATED	20[redacted]-01-20 *	RECOVERED/RESOLVED
PLACEBO	20120230-23013008003	ENLARGED ISCMAEMIC LESION ON TWO FINGERS OF THE RIGHT HAND [末梢性虚血]	20[redacted]-12-11T14:30	87	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-02 *	RECOVERED/RESOLVED
PLACEBO	20120230-23013008003	CELLULITIS OF RIGHT HAND [蜂巣炎]	20[redacted]-12-22T14:30	98	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER, OTHER	NOT RELATED	20[redacted]-01-02	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
PLACEBO	20120230-23013008003	AMPUTATION TWO FINGERS OF THE RIGHT HAND [指切断]	20[redacted]-01-02	109	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-01-10	RECOVERED/RESOLVED
PLACEBO	20120230-23013012001	WORSENING OF LEFT FOOT 4TH RAY OSTEITIS [骨炎]	20[redacted]-05-30	23	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-27	RECOVERED/RESOLVED
PLACEBO	20120230-23013012001	ABSCESS IN THE AMPUTATION ZONE (LEFT FOOT) [術後膿瘍]	20[redacted]-07-11	65	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN, OTHER	NOT RELATED	20[redacted]-12-19	RECOVERED/RESOLVED
PLACEBO	20120230-23016001001	HOSPITALISATION DU TO AN FLUIDE OVERLOAD POST PTCA [水分過負荷]	20[redacted]-12-06	101	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-07	RECOVERED/RESOLVED
PLACEBO	20120230-23016001001	PULMONARY EDEMA [肺水腫]	20[redacted]-12-27T07:18	122	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-12-28T11:40	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
PLACEBO	20120230-23016001001	NSTMI [急性心筋梗塞]	20[redacted]-02-03 *	160	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-07 *	RECOVERED/RESOLVED
PLACEBO	20120230-23016001001	PULMONARY OVERLOAD [肺うっ血]	20[redacted]-02-03 *	160	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-07 *	RECOVERED/RESOLVED
PLACEBO	20120230-23016001001	NSTMI [急性心筋梗塞]	20[redacted]-02-08 *	165	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-08 *	RECOVERED/RESOLVED
PLACEBO	20120230-23016001001	PULOMANARY OEDEMA [肺水腫]	20[redacted]-02-08 *	165	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-14 *	RECOVERED/RESOLVED
PLACEBO	20120230-23016001001	RAPID ATRIAL FIBRILLATION [心房細動]	20[redacted]-02-26 *	183	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-28 *	RECOVERED/RESOLVED
PLACEBO	20120230-23016001001	PNEUMONIA [肺炎]	20[redacted]-03-03 *	188	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-08	RECOVERED/RESOLVED
PLACEBO	20120230-23016001001	FEMUR FRACTURE [大腿骨骨折]	20[redacted]-03-22	207	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23016002001	DELAYED GRAFT FUNCTION [移植腎の合併症]	20[redacted]-01-12	117	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, OTHER	NOT RELATED	20[redacted]-01-29T07:00	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
PLACEBO	20120230-23021012005	HEMODIALYSIS FISTULA THROMBOSIS [動静脈瘻血栓症]	20[redacted]-09-10T06:45	27	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-14T06:30	RECOVERED/RESOLVED
PLACEBO	20120230-23021012005	HEMODIALYSIS FISTULA THROMBOSIS [動静脈瘻血栓症]	20[redacted]-09-19T06:00	36	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-20T12:00	RECOVERED/RESOLVED
PLACEBO	20120230-23021012005	HYPERGLYCAEMIC SEIZURE [高血糖性痙攣]	20[redacted]-10-13T20:00	60	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-22 *	RECOVERED/RESOLVED
PLACEBO	20120230-23021012005	URINARY INFECTION [尿路感染]	20[redacted]-12-31T09:30	139	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-09T06:00	RECOVERED/RESOLVED
PLACEBO	20120230-23025004001	SEPSIS SYNDROME [敗血症症候群]	20[redacted]-07-06T15:00	11	MODERATE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-07-13	RECOVERED/RESOLVED
PLACEBO	20120230-23025004002	ARTERIOVENOUS FISTULA OCCLUSION [動静脈瘻閉塞]	20[redacted]-08-13T13:00	48	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-08-15T13:00	RECOVERED/RESOLVED
PLACEBO	20120230-23025004002	CONVULSION [痙攣]	20[redacted]-09-10T16:45	76	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-10T16:50	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
PLACEBO	20120230-23032004001	THROMBOSIS OF AVG [血管グラフト血栓症]	20[redacted]-12-02	83	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-12-09	RECOVERED/RESOLVED
PLACEBO	20120230-23033002002	CRONIC PERIODONTITIS [歯周炎]	20[redacted]-09-17T08:00	7	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-18T13:30	RECOVERED/RESOLVED
PLACEBO	20120230-23033002003	GRAFT COMPLICATION [移植片合併症]	20[redacted]-10-17T13:00	36	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-10-26T15:00	RECOVERED/RESOLVED
PLACEBO	20120230-23033002003	VASCULAR GRAFT COMPLICATION [移植血管合併症]	20[redacted]-12-26	106	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-12-28 *	RECOVERED/RESOLVED
PLACEBO	20120230-23033002003	VASCOLAR GRAFT COMPLICATION [移植血管合併症]	20[redacted]-02-13	155	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-02-15	RECOVERED/RESOLVED
PLACEBO	20120230-23042002001	PNEUMONIA [肺炎]	20[redacted]-10-14T08:30	41	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-10-21	RECOVERED/RESOLVED
PLACEBO	20120230-23048002008	SUDDEN DEATH [突然死]	20[redacted]-02-17	168	LIFE THREATENING	YES	Results in Death	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-02-17	FATAL
PLACEBO	20120230-23048004002	CONGESTIVE CARDIAC FAILURE AGGRAVATED [うっ血性心不全]	20[redacted]-05-22T23:00	8	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-05-31T13:46	RECOVERED/RESOLVED
PLACEBO	20120230-23048004017	DIABETIC FOOT INFECTION [糖尿病性足感染]	20[redacted]-01-31	191	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-06	RECOVERED/RESOLVED

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PLACEBO	20120230-23048004018	LOW PERFUSION OF THE LOWER LIMB [末梢循環不良]	20[redacted]-08-20	34	LIFE THREATENING	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23048004018	LOW PERFUSION OF THE LOWER LIMB - AGGRAVATION [末梢循環不良]	20[redacted]-11-05	111	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-10	FATAL
PLACEBO	20120230-23048006002	ABDOMINAL ABSCESSES [腹部膿瘍]	20[redacted]-01-16T08:00	151	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-14T18:00	RECOVERED/RESOLVED
PLACEBO	20120230-23048006002	PROTEUS MIRABILIS SEPSIS [細菌性敗血症]	20[redacted]-01-16T08:00	151	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-14	FATAL
PLACEBO	20120230-23048008001	THROMBOSIS HEMODIALYSIS FISTULA [動静脈瘻血栓症]	20[redacted]-02-15T07:00	157	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-03-20	RECOVERED/RESOLVED
PLACEBO	20120230-23048008001	HEMATOMA NEAR FISTULA [動静脈瘻部位血腫]	20[redacted]-03-14	184	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-20	RECOVERED/RESOLVED
PLACEBO	20120230-23051002008	PRIMARY ALDOSTERONIZM [原発性アルドステロン症]	20[redacted]-08-02	25	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-27	RECOVERED/RESOLVED

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PLACEBO	20120230-23058004004	RESPIRATORY INFECTION [気道感染]	20[redacted]-08-25T12:00	109	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-28T13:00	RECOVERED/RESOLVED
PLACEBO	20120230-23058004005	SEIZURE CEREBRAL [痙攣]	20[redacted]-09-02T21:50	111	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-04T12:00	RECOVERED/RESOLVED
PLACEBO	20120230-23058008002	THROMBOPHLEBITIS ARM [血栓性静脈炎]	20[redacted]-11-15T16:11	201	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-11-20	RECOVERED/RESOLVED
PLACEBO	20120230-23058008011	DIABETIC ULCER [糖尿病性潰瘍]	20[redacted]-03-23	180	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-11	RECOVERED/RESOLVED
PLACEBO	20120230-23059002001	NAUSEA [悪心]	20[redacted]-12-16T14:00	71	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-12-18T07:30	RECOVERED/RESOLVED
PLACEBO	20120230-23059004002	FAINTING FIT DUE TO HYPOTENSION [失神]	20[redacted]-12-19	79	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-24 *	RECOVERED/RESOLVED
PLACEBO	20120230-23059004002	FRACTURE OF CLAVICLE [鎖骨骨折]	20[redacted]-12-19 *	79	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-08 *	RECOVERED/RESOLVED
PLACEBO	20120230-23059004002	GASTROENTERITIS [胃腸炎]	20[redacted]-03-15	165	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-03-19	RECOVERED/RESOLVED
PLACEBO	20120230-23066004013	VOLUME OVERLOAD [水分過負荷]	20[redacted]-05-14	55	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-15	RECOVERED/RESOLVED

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PLACEBO	20120230-23066004024	WORSENING OBESITY [肥満]	20[redacted]-06-24	70	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-06-28	RECOVERED/RESOLVED
PLACEBO	20120230-23066004024	HIP FRACTURE [股関節部骨折]	20[redacted]-09-01	139	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-08	RECOVERED/RESOLVED
PLACEBO	20120230-23066004024	ORTHOPEDIC APPLIANCE COMPLICATION [医療機器合併症]	20[redacted]-09-21	159	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-25	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23066004024	OSTEOMYELITIS OF SECOND DIGIT LEFT HAND [骨髄炎]	20[redacted]-10-31	199	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-11-03	RECOVERED/RESOLVED
PLACEBO	20120230-23066006018	PULMONARY EDEMA [肺水腫]	20[redacted]-12-08	147	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-12	RECOVERED/RESOLVED
PLACEBO	20120230-23066006018	ANXIETY DISORDER [不安障害]	20[redacted]-12-09	148	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-12	RECOVERED/RESOLVED
PLACEBO	20120230-23066006018	LOW BACK PAIN RADIATING TO RIGHT LEG [背部痛]	20[redacted]-12-24	163	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING *	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23066006018	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-12-24	163	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-01	RECOVERED/RESOLVED

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PLACEBO	20120230-23066006018	PULMONARY EDEMA [肺水腫]	20[redacted]-12-24	163	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-01*	RECOVERED/RESOLVED
PLACEBO	20120230-23066006018	WORSENING OF KNEE PAIN [関節痛]	20[redacted]-12-24*	163	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING*	UNKNOWN
PLACEBO	20120230-23066006018	ACCELERATED HYPERTENSION [進行性高血圧]	20[redacted]-01-24*	194	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-27*	RECOVERED/RESOLVED
PLACEBO	20120230-23066006018	LEFT VENTRICULAR HYPERTROPHY [左室肥大]	20[redacted]-01-24*	194	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING*	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23066006018	WORSENING OF CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-01-24*	194	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-27*	RECOVERED/RESOLVED
PLACEBO	20120230-23066008003	PROSTATE CANCER [前立腺癌]	20[redacted]-08-16	50	SEVERE	YES	Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-11	RECOVERED/RESOLVED
PLACEBO	20120230-23066010004	HEALTHCARE ASSOCIATED PNEUMONIA [肺炎]	20[redacted]-02-02	175	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-02-17	RECOVERED/RESOLVED
PLACEBO	20120230-23066012004	UNINTENTIONAL WEIGHT LOSS [異常体重減少]	20[redacted]-10-16	71	MODERATE	YES	Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	OTHER	RELATED	20[redacted]-12-09	RECOVERED/RESOLVED
PLACEBO	20120230-23066012006	SEVERE MULTIPLE CORONARY ARTERY DISEASE DUE TO ATHEROSCLEROSIS [冠動脈硬化症]	20[redacted]-01-02T08:48	134	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-01-14	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
PLACEBO	20120230-23066012006	UPPER RESPIRATORY INFECTION [上気道感染]	20[redacted]-01-02T09:48	134	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-07	RECOVERED/RESOLVED
PLACEBO	20120230-23066016006	PNEUMONITIS [肺臓炎]	20[redacted]-12-09T00:00	181	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN, OTHER	NOT RELATED	20[redacted]-12-22T00:00	RECOVERED/RESOLVED
PLACEBO	20120230-23066016006	SEPSIS [敗血症]	20[redacted]-12-30T00:00	202	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN, OTHER	NOT RELATED	20[redacted]-12-31T00:00	FATAL
PLACEBO	20120230-23066022009	CALCULUS OF GALLBLADDER WITH ACUTE CHOLECYSTITIS, WITH OBSTRUCTION [急性胆嚢炎]	20[redacted]-10-24	37	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-02	RECOVERED/RESOLVED
PLACEBO	20120230-23066022009	INCARCERATED HERNIA [閉塞性ヘルニア]	20[redacted]-10-24	37	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-11-02	RECOVERED/RESOLVED
PLACEBO	20120230-23066022009	PANCREATITIS DUE TO BILIARY OBSTRUCTION [膵炎]	20[redacted]-10-24	37	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-11-02	RECOVERED/RESOLVED
PLACEBO	20120230-23066024007	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-10-07	48	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-10-08	RECOVERED/RESOLVED
PLACEBO	20120230-23066032001	SHORT OF BREATH [呼吸困難]	20[redacted]-08-15T08:00	116	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-17T09:00	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
PLACEBO	20120230-23066032002	VIRAL INFECTION [ウイルス感染]	20[redacted]-09-24	135	SEVERE	YES	Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-16	RECOVERED/RESOLVED
PLACEBO	20120230-23066032002	BILATERAL PNEUMONIA [肺炎]	20[redacted]-11-15	187	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER	NOT RELATED	20[redacted]-11-22	RECOVERED/RESOLVED
PLACEBO	20120230-23066032005	EXACERBATION OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE [慢性閉塞性肺疾患]	20[redacted]-11-29	180	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-12-06	RECOVERED/RESOLVED
PLACEBO	20120230-23066032006	EXACERBATION OF SHORTNESS OF BREATH [呼吸困難]	20[redacted]-09-13T13:28	89	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-27	RECOVERED/RESOLVED
PLACEBO	20120230-23066032006	CHRONIC THORACIC DISKITIS [椎間板炎]	20[redacted]-09-15	91	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-27	RECOVERED/RESOLVED
PLACEBO	20120230-23066032006	CHEST PAIN (NON-CARDIAC) [非心臓性胸痛]	20[redacted]-10-11	117	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-10-18	RECOVERED/RESOLVED
PLACEBO	20120230-23066032006	CEREBROVASCULAR ACCIDENT [脳血管発作]	20[redacted]-12-04	171	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	ONGOING *	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23066032006	BILATERAL PNEUMONIA [肺炎]	20[redacted]-12-26	193	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-01-06	RECOVERED/RESOLVED

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PLACEBO	20120230-23066036004	BRONCHITIS ACUTE [気管支炎]	20[redacted]-06-26	59	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, CULTURE TAKEN	NOT RELATED	20[redacted]-07-02	RECOVERED/RESOLVED
PLACEBO	20120230-23066036004	RESPIRATORY DISTRESS [呼吸窮迫]	20[redacted]-09-09	134	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, CULTURE TAKEN	NOT RELATED	20[redacted]-09-12	RECOVERED/RESOLVED
PLACEBO	20120230-23066036004	ABDOMINAL PAIN [腹痛]	20[redacted]-09-18	143	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-20	RECOVERED/RESOLVED
PLACEBO	20120230-23066036004	AGGRAVATED SYSTEMIC LUPUS ERYTHEMATOSIS [全身性エリテマトーデス]	20[redacted]-09-18	143	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-20	RECOVERED/RESOLVED
PLACEBO	20120230-23066036004	CHEST DISCOMFORT, NON CARDIAC [非心臓性胸痛]	20[redacted]-10-16	171	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-23	RECOVERED/RESOLVED
PLACEBO	20120230-23066036004	PERICARDITIS RELATED TO LUPUS [ループス心膜炎]	20[redacted]-11-26	212	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-11	RECOVERED/RESOLVED
PLACEBO	20120230-23066036016	DUODENAL ULCER [十二指腸潰瘍]	20[redacted]-06-20	36	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-26	RECOVERED/RESOLVED
PLACEBO	20120230-23066042001	CHEST PAIN - CARDIAC [狭心症]	20[redacted]-09-16T15:56	63	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-09-17	RECOVERED/RESOLVED

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PLACEBO	20120230-23066042001	TACHYCARDIA [頻脈]	20[redacted]-09-16T15:56	63	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-09-17	RECOVERED/RESOLVED
PLACEBO	20120230-23066042008	DIARRHEA [下痢]	20[redacted]-07-05	32	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-08	RECOVERED/RESOLVED
PLACEBO	20120230-23066042008	BILATERAL BACK PAIN [背部痛]	20[redacted]-07-15	42	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, REMOVED FROM STUDY	NOT RELATED	20[redacted]-07-30	RECOVERED/RESOLVED
PLACEBO	20120230-23066042008	ESOPHAGEAL ADENOCARCINOMA [食道腺癌]	20[redacted]-07-15	42	SEVERE	YES	Other Medically Important Serious Event	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23066046008	SEVERE ABDOMINAL PAIN [腹痛]	20[redacted]-10-18	137	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-29	RECOVERED/RESOLVED
PLACEBO	20120230-23066046011	NAUSEA AGGRAVATED [悪心]	20[redacted]-09-08	35	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-09-23	RECOVERED/RESOLVED
PLACEBO	20120230-23066046011	UNRESPONSIVENESS [刺激無反応]	20[redacted]-09-15	42	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-17	RECOVERED/RESOLVED
PLACEBO	20120230-23066046011	BLISTERS ON RIGHT LOWER EXTREMITY [水疱]	20[redacted]-12-13	131	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-17	RECOVERED/RESOLVED

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PLACEBO	20120230-23066046011	GANGRENE OF THE RIGHT FOOT [壊疽]	20[redacted]-01-19 *	168	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-29 *	RECOVERED/RESOLVED
PLACEBO	20120230-23066046011	RIGHT FOOT ABSCESS [四肢膿瘍]	20[redacted]-01-19 *	168	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-29 *	RECOVERED/RESOLVED
PLACEBO	20120230-23066046011	RIGHT FOOT OSTEOMYELITIS [骨髄炎]	20[redacted]-01-19 *	168	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-29 *	RECOVERED/RESOLVED
PLACEBO	20120230-23066046011	BALANCE DIFFICULTY [平衡障害]	20[redacted]-02-17	197	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-18	RECOVERED/RESOLVED
PLACEBO	20120230-23066048001	MUSCLE TWITCHING [筋攣縮]	20[redacted]-09-16T19:30	35	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-20	RECOVERED/RESOLVED
PLACEBO	20120230-23066048001	AVULSION FRACTURE [剥離骨折]	20[redacted]-11-12T00:00 *	92	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-11-14T00:00 *	RECOVERED/RESOLVED
PLACEBO	20120230-23066048001	CALCANEAL OSTEOMYELITIS [骨髄炎]	20[redacted]-01-10T00:00	151	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-17T00:00	RECOVERED/RESOLVED

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PLACEBO	20120230-23066048001	DIABETIC NEUROPATHIC ULCER [糖尿病性神経障害性潰瘍]	20[redacted]-01-10T00:00	151	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-17T00:00	RECOVERED/RESOLVED
PLACEBO	20120230-23066048004	AXILLARY THROMBOSIS [血栓症]	20[redacted]-10-24T14:00	92	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-01	RECOVERED/RESOLVED
PLACEBO	20120230-23066052001	WORSENING LEFT FOOT ULCER [皮膚潰瘍]	20[redacted]-10-31T00:00	199	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-08	RECOVERED/RESOLVED
PLACEBO	20120230-23066052008	APPENDICITIS [虫垂炎]	20[redacted]-12-28	167	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-29	RECOVERED/RESOLVED
PLACEBO	20120230-23066068006	PNEUMONIA [肺炎]	20[redacted]-07-27T15:30	52	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-07T00:00	RECOVERED/RESOLVED
PLACEBO	20120230-23066078001	INTRACRANIAL HEMORRHAGE SECONDARY TO TRAUMA [頭蓋内出血]	20[redacted]-05-02T15:24 *	-88	MODERATE	YES	Requires or Prolongs Hospitalization	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-05-03T15:40 *	RECOVERED/RESOLVED
PLACEBO	20120230-23066078001	ACUTE RESPIRATORY FAILURE [急性呼吸不全]	20[redacted]-01-03T00:00	159	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-05T00:00	RECOVERED/RESOLVED
PLACEBO	20120230-23066078004	ACUTE ON CHRONIC RESPIRATORY FAILURE [急性呼吸不全]	20[redacted]-10-03T00:00	107	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-10-09	RECOVERED/RESOLVED
PLACEBO	20120230-23066078004	SUPRAVENTRICULAR TACHYCARDIA [上室性頻脈]	20[redacted]-10-14T06:00	118	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-25	RECOVERED/RESOLVED

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PLACEBO	20120230-23066078004	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-11-12T00:00	147	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-27	FATAL
PLACEBO	20120230-23066084002	RIGHT TIBIA FRACTURE [脛骨骨折]	20[redacted]-08-22	57	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23066084002	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-09-02	68	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-09-09	RECOVERED/RESOLVED
PLACEBO	20120230-23066084002	RESPIRATORY DISTRESS/FAILURE [呼吸不全]	20[redacted]-09-03	69	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, OTHER	NOT RELATED	20[redacted]-09-09	RECOVERED/RESOLVED
PLACEBO	20120230-23066088003	GANGRENE, 2ND TOE, LEFT FOOT [壊疽]	20[redacted]-03-27T00:00	214	MODERATE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23066088004	CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN ACUTE EXACERBATION [慢性閉塞性肺疾患]	20[redacted]-11-05T00:00	36	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-06T00:00	RECOVERED/RESOLVED
PLACEBO	20120230-23066088004	HYPERKALEMIA [高カリウム血症]	20[redacted]-11-26T05:00	57	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-11-30T14:11	FATAL

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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
PLACEBO	20120230-23066102014	HYPERCALCEMIA [高カルシウム血症]	20[redacted]-12-02T10:52	74	MODERATE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-09T09:50	RECOVERED/RESOLVED
PLACEBO	20120230-23066104012	CHOLELITHIASIS WITH ACUTE NECROTIZING CHOLECYSTITIS [胆石症]	20[redacted]-02-24	148	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23066104012	BILATERAL SECOND DEGREE BURN OF FEET [第２度熱傷]	20[redacted]-04-23	206	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-05-09	RECOVERED/RESOLVED
PLACEBO	20120230-23066132005	ARTERIOVENOUS FISTULA RUPTURE/HEMORRHAGE RISK [動静脈瘻部位出血]	20[redacted]-09-18	1	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-21	RECOVERED/RESOLVED
PLACEBO	20120230-23066132007	CLOTTED ARTERIOVENOUS GRAFT [血管グラフト血栓症]	20[redacted]-10-25	38	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23066152008	PALPITATIONS [動悸]	20[redacted]-07-30T11:50	-2	SEVERE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER	-	20[redacted]-07-30T15:50	RECOVERED/RESOLVED
PLACEBO	20120230-23066152011	ACUTE RESPIRATORY FAILURE [急性呼吸不全]	20[redacted]-12-26	113	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN	NOT RELATED	20[redacted]-01-01 *	RECOVERED/RESOLVED
PLACEBO	20120230-23066152011	HUMAN METAPNEUOVIRUS INFECTION [メタニューモウイルス感染]	20[redacted]-12-27	114	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-01	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
PLACEBO	20120230-23066152011	PNEUMONIA RIGHT LOWER LOBE [肺炎]	20[redacted]-12-29 *	116	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-01 *	RECOVERED/RESOLVED
PLACEBO	20120230-23066152011	HYPOGLYCEMIA [低血糖症]	20[redacted]-01-02 *	120	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-02 *	RECOVERED/RESOLVED
PLACEBO	20120230-23066152011	DUODENAL ULCERS [十二指腸潰瘍]	20[redacted]-01-06 *	124	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-07 *	RECOVERED/RESOLVED
PLACEBO	20120230-23066152011	ESOPHAGITIS [食道炎]	20[redacted]-01-06	124	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-07	RECOVERED/RESOLVED
PLACEBO	20120230-23066152022	STAPHYLOCOCCUS AUREUS SEPSIS [ブドウ球菌性敗血症]	20[redacted]-10-01T02:00	19	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-04	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	CLOTTED AV GRAFT - LEFT UPPER ARM [血管グラフト血栓症]	20[redacted]-07-13	20	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-17	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	NON ST SEGMENT ELEVATION MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-07-13	20	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-07-15	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	URINARY TRACT INFECTION [尿路感染]	20[redacted]-07-13	20	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-07-17	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	PNEUMONIA [肺炎]	20[redacted]-07-13T00:00	20	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-30	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
PLACEBO	20120230-23066166004	CLOSTRIDIUM DIFFICILE COLITIS [クロストリジウム・ディフィシレ大腸炎]	20[redacted]-08-04	42	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-18	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	URINARY TRACT INFECTION FUNGAL [真菌性尿路感染]	20[redacted]-08-04	42	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-09-17	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	RECURRENT C-DIFF COLITIS [クロストリジウム・ディフィシレ大腸炎]	20[redacted]-09-02	71	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-03	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	C-DIFF SEPSIS [クロストリジウム・ディフィシレ性敗血症]	20[redacted]-09-02T02:00	71	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-09-13	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	INFEROLATERAL T-WAVE INVERSION [心電図T波逆転]	20[redacted]-09-02T03:04	71	MILD	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-09T07:32	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	RIGHT BUNDLE BRANCH BLOCK [右脚ブロック]	20[redacted]-09-02T03:04	71	MILD	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-11-09T07:32	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	ARRYTHMIAS [不整脈]	20[redacted]-09-03T09:00	72	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-07T13:00	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	HYPOTENSION [低血圧]	20[redacted]-09-05T07:41	74	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-06T17:00	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	DEMENTIA/ COGNITIVE DEFICITS [認知症]	20[redacted]-09-10T17:26	79	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	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
PLACEBO	20120230-23066166004	URINARY TRACT INFECTION [尿路感染]	20[redacted]-11-09T06:00	139	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-12-12T08:00 *	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	SEPSIS RELATED TO C-DIFF [クロストリジウム・ディフィシレ性敗血症]	20[redacted]-12-21T00:00	181	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-08 *	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	WEAKNESS [無力症]	20[redacted]-12-21T05:00	181	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-01-01	RECOVERED/RESOLVED
PLACEBO	20120230-23066166004	URINARY TRACT INFECTION ENTEROCOCCAL [腸球菌性尿路感染]	20[redacted]-12-21T16:15	181	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-26	RECOVERED/RESOLVED
PLACEBO	20120230-23066166005	TRANSMURAL MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-07-19	26	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER	NOT RELATED	20[redacted]-07-20	RECOVERED/RESOLVED
PLACEBO	20120230-23066166005	CHEST PAIN - CARDIAC [狭心症]	20[redacted]-08-23	61	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-25	RECOVERED/RESOLVED
PLACEBO	20120230-23066166005	ALTERED MENTAL STATUS, UNSPECIFIED R41.82 [精神状態変化]	20[redacted]-09-03T08:00	72	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, OTHER	NOT RELATED	20[redacted]-09-05T12:00	RECOVERED/RESOLVED
PLACEBO	20120230-23066166005	ANEMIA [貧血]	20[redacted]-09-03T10:00	72	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-09-05T14:00	RECOVERED/RESOLVED
PLACEBO	20120230-23066166005	HYPOKALAEMIA [低カリウム血症]	20[redacted]-09-03T10:00	72	MILD	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-05T14:00	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
PLACEBO	20120230-23066166005	URINARY TRACT INFECTION BACTERIAL [細菌性尿路感染]	20[redacted]-09-03T10:00	72	MILD	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-12T18:00	RECOVERED/RESOLVED
PLACEBO	20120230-23066166005	WEAKNESS GENERALIZED [無力症]	20[redacted]-09-03T10:00	72	MILD	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-05T14:00	RECOVERED/RESOLVED
PLACEBO	20120230-23066166005	PNEUMONIA [肺炎]	20[redacted]-09-20T18:00 *	89	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-22T11:00 *	RECOVERED/RESOLVED
PLACEBO	20120230-23066166005	NONSTEMI [急性心筋梗塞]	20[redacted]-01-10T22:00 *	201	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-01-11T11:00 *	RECOVERED/RESOLVED
PLACEBO	20120230-23066166005	UNSTABLE ANGINA/ CHEST PAIN [不安定狭心症]	20[redacted]-01-10T22:00 *	201	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-01-11T11:57 *	RECOVERED/RESOLVED
PLACEBO	20120230-23066166005	HYPERTENSIVE URGENCY [高血圧クリーゼ]	20[redacted]-01-11	202	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-01-14	RECOVERED/RESOLVED
PLACEBO	20120230-23066232001	ACUTE GASTROENTERITIS [胃腸炎]	20[redacted]-11-22T12:00	75	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-24T11:35	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
PLACEBO	20120230-23066232008	HEMORRHAGIC CEREBROVASCULAR ACCIDENT WITH INTRAVENTRICULAR EXTENSION [出血性卒中]	20[redacted]-02-11T23:30	134	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-20T18:40	FATAL

*1:MedDRA Version 17.0J
AMG 416 = ONO-5163

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表 2.7.6.17-15　投与中止に至った有害事象の一覧表（20120230 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	20120230-23051002004	LOW SERUM CALCIUM [血中カルシウム減少]	20[redacted]-07-24	22	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	ONGOING	-
AMG 416	20120230-23066036015	BLOOD CA DECREASED INTERMITTENTLY [血中カルシウム減少]	20[redacted]-08-01	6	MILD	NO	-	DRUG WITHDRAWN	OTHER	RELATED	20[redacted]-11-19	-
AMG 416	20120230-23066036017	LOW BLOOD CA [血中カルシウム減少]	20[redacted]-08-13	15	MODERATE	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN, OTHER	RELATED	20[redacted]-10-01	-
AMG 416	20120230-23066152007	CHEST DISCOMFORT [胸部不快感]	20[redacted]-09-19	86	MILD	NO	-	DRUG WITHDRAWN	OTHER	RELATED	20[redacted]-09-29	-
AMG 416	20120230-23066152007	LEFT SIDED WEAKNESS [不全片麻痺]	20[redacted]-09-19	86	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-09-29	-
PLACEBO	20120230-23029002003	HYPOTENSION [低血圧]	20[redacted]-10-11	24	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	ONGOING	-
PLACEBO	20120230-23029002003	WEAKNESS [無力症]	20[redacted]-10-11	24	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	ONGOING	-
PLACEBO	20120230-23066022005	HEADACHE [頭痛]	20[redacted]-07-22T00:00	27	MODERATE	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	ONGOING	-
PLACEBO	20120230-23066042005	WORSENING HYPERPHOSPHATEMIA [高リン酸塩血症]	20[redacted]-06-09	12	MODERATE	NO	-	DRUG WITHDRAWN	OTHER	NOT RELATED	20[redacted]-07-21	-
PLACEBO	20120230-23066042008	BILATERAL BACK PAIN [背部痛]	20[redacted]-07-15	42	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, REMOVED FROM STUDY	NOT RELATED	20[redacted]-07-30	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
PLACEBO	20120230-23066042008	ESOPHAGEAL ADENOCARCINOMA [食道腺癌]	20[redacted]-07-15	42	SEVERE	YES	Other Medically Important Serious Event	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120230-23066078004	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-11-12T00:00	147	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-27	FATAL
PLACEBO	20120230-23066232008	HEMORRHAGIC CEREBROVASCULAR ACCIDENT WITH INTRAVENTRICULAR EXTENSION [出血性卒中]	20[redacted]-02-11T23:30	134	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-20T18:40	FATAL

*1:MedDRA Version 17.0J
AMG 416 = ONO-5163

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表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）
解析対象集団：SAF

SOC PT		有害事象 シナカルセト n （%）	 ONO-5163 n （%）
	N	341	338
全体		307 (90.0)	314 (92.9)
血液およびリンパ系障害		22 (6.5)	22 (6.5)
貧血		15 (4.4)	17 (5.0)
腎性貧血		5 (1.5)	2 (0.6)
慢性疾患の貧血		0 (0.0)	1 (0.3)
抗リン脂質抗体症候群		0 (0.0)	1 (0.3)
好酸球増加症		0 (0.0)	1 (0.3)
リンパ節症		1 (0.3)	1 (0.3)
脾臓梗塞		0 (0.0)	1 (0.3)
鉄欠乏性貧血		1 (0.3)	0 (0.0)
心臓障害		24 (7.0)	26 (7.7)
心不全		1 (0.3)	3 (0.9)
頻脈		2 (0.6)	3 (0.9)
心停止		3 (0.9)	2 (0.6)
急性心不全		0 (0.0)	2 (0.6)
冠動脈疾患		1 (0.3)	2 (0.6)
動悸		2 (0.6)	2 (0.6)
発作性頻脈		0 (0.0)	2 (0.6)
急性心筋梗塞		2 (0.6)	1 (0.3)
狭心症		4 (1.2)	1 (0.3)

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．
出典［総括報告書 5.3.5.1-5（20120360 試験）Table 14-6.4 改変］

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 1）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n (%)	 ONO-5163 n (%)
N	341	338
心房細動	5 (1.5)	1 (0.3)
徐脈	0 (0.0)	1 (0.3)
左脚ブロック	0 (0.0)	1 (0.3)
右脚ブロック	0 (0.0)	1 (0.3)
心臓性喘息	0 (0.0)	1 (0.3)
うっ血性心不全	1 (0.3)	1 (0.3)
心タンポナーデ	0 (0.0)	1 (0.3)
心肺停止	0 (0.0)	1 (0.3)
心筋虚血	1 (0.3)	1 (0.3)
洞性頻脈	0 (0.0)	1 (0.3)
上室性頻脈	0 (0.0)	1 (0.3)
急性冠動脈症候群	1 (0.3)	0 (0.0)
不安定狭心症	2 (0.6)	0 (0.0)
上室性不整脈	1 (0.3)	0 (0.0)
心房頻脈	1 (0.3)	0 (0.0)
冠動脈狭窄	1 (0.3)	0 (0.0)
僧帽弁疾患	1 (0.3)	0 (0.0)
洞性不整脈	1 (0.3)	0 (0.0)
洞性徐脈	1 (0.3)	0 (0.0)
先天性、家族性および遺伝性障害	1 (0.3)	2 (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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 2）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
先天性嚢胞性腎疾患	0 (0.0)	1 (0.3)
先天性心臓疾患	0 (0.0)	1 (0.3)
脳血管動静脈奇形	1 (0.3)	0 (0.0)
耳および迷路障害	6 (1.8)	6 (1.8)
回転性めまい	1 (0.3)	5 (1.5)
耳痛	0 (0.0)	2 (0.6)
内耳障害	0 (0.0)	1 (0.3)
耳不快感	2 (0.6)	0 (0.0)
耳管機能障害	1 (0.3)	0 (0.0)
聴力低下	1 (0.3)	0 (0.0)
突発難聴	1 (0.3)	0 (0.0)
耳鳴	1 (0.3)	0 (0.0)
内分泌障害	0 (0.0)	1 (0.3)
甲状腺機能低下症	0 (0.0)	1 (0.3)
眼障害	9 (2.6)	13 (3.8)
結膜出血	0 (0.0)	2 (0.6)
眼乾燥	0 (0.0)	2 (0.6)
乱視	0 (0.0)	1 (0.3)
白内障	2 (0.6)	1 (0.3)
脈絡網膜障害	0 (0.0)	1 (0.3)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 3）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
アレルギー性結膜炎	0 (0.0)	1 (0.3)
眼刺激	0 (0.0)	1 (0.3)
眼瞼浮腫	0 (0.0)	1 (0.3)
緑内障	0 (0.0)	1 (0.3)
眼充血	2 (0.6)	1 (0.3)
虚血性視神経症	0 (0.0)	1 (0.3)
潰瘍性角膜炎	0 (0.0)	1 (0.3)
霧視	1 (0.3)	1 (0.3)
視力低下	0 (0.0)	1 (0.3)
皮質白内障	1 (0.3)	0 (0.0)
核性白内障	1 (0.3)	0 (0.0)
糖尿病網膜症	2 (0.6)	0 (0.0)
眼部腫脹	1 (0.3)	0 (0.0)
眼窩嚢胞	1 (0.3)	0 (0.0)
網膜剥離	1 (0.3)	0 (0.0)
視力障害	1 (0.3)	0 (0.0)
硝子体出血	1 (0.3)	0 (0.0)
胃腸障害	140 (41.1)	123 (36.4)
悪心	77 (22.6)	62 (18.3)
嘔吐	47 (13.8)	45 (13.3)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 4）
解析対象集団：SAF

SOC		有害事象	
		シナカルセト	ONO-5163
PT		n （%）	n （%）
	N	341	338
下痢		35 (10.3)	21 (6.2)
腹痛		13 (3.8)	13 (3.8)
消化不良		5 (1.5)	7 (2.1)
便秘		8 (2.3)	5 (1.5)
上腹部痛		8 (2.3)	4 (1.2)
腹部不快感		2 (0.6)	3 (0.9)
胃炎		2 (0.6)	2 (0.6)
胃腸出血		0 (0.0)	2 (0.6)
胃食道逆流性疾患		1 (0.3)	2 (0.6)
吐血		0 (0.0)	2 (0.6)
痔核		1 (0.3)	2 (0.6)
急性膵炎		0 (0.0)	2 (0.6)
直腸出血		0 (0.0)	2 (0.6)
歯痛		6 (1.8)	2 (0.6)
腹部ヘルニア		0 (0.0)	1 (0.3)
下腹部痛		0 (0.0)	1 (0.3)
慢性胃炎		0 (0.0)	1 (0.3)
齲歯		3 (0.9)	1 (0.3)
糖尿病性胃不全麻痺		0 (0.0)	1 (0.3)
憩室		0 (0.0)	1 (0.3)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 5）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
口内乾燥	0 (0.0)	1 (0.3)
十二指腸潰瘍	1 (0.3)	1 (0.3)
出血性十二指腸炎	0 (0.0)	1 (0.3)
十二指腸胃逆流	0 (0.0)	1 (0.3)
便失禁	0 (0.0)	1 (0.3)
放屁	2 (0.6)	1 (0.3)
胃腸の炎症	0 (0.0)	1 (0.3)
血便排泄	1 (0.3)	1 (0.3)
痔出血	1 (0.3)	1 (0.3)
過敏性腸症候群	0 (0.0)	1 (0.3)
出血性食道炎	0 (0.0)	1 (0.3)
膵嚢胞	0 (0.0)	1 (0.3)
慢性膵炎	0 (0.0)	1 (0.3)
歯周病	0 (0.0)	1 (0.3)
逆流性胃炎	0 (0.0)	1 (0.3)
鉄欠乏性嚥下障害	0 (0.0)	1 (0.3)
停滞症候群	0 (0.0)	1 (0.3)
臍ヘルニア	0 (0.0)	1 (0.3)
腹部膨満	1 (0.3)	0 (0.0)
腹水	1 (0.3)	0 (0.0)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 6）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n (%)	 ONO-5163 n (%)
N	341	338
十二指腸炎	1 (0.3)	0 (0.0)
びらん性食道炎	1 (0.3)	0 (0.0)
胃障害	1 (0.3)	0 (0.0)
出血性胃潰瘍	1 (0.3)	0 (0.0)
胃十二指腸炎	2 (0.6)	0 (0.0)
胃腸障害	1 (0.3)	0 (0.0)
消化管壊死	1 (0.3)	0 (0.0)
歯肉痛	1 (0.3)	0 (0.0)
口の感覚鈍麻	1 (0.3)	0 (0.0)
イレウス	1 (0.3)	0 (0.0)
胃排出不全	1 (0.3)	0 (0.0)
鼠径ヘルニア	1 (0.3)	0 (0.0)
大腸穿孔	1 (0.3)	0 (0.0)
メレナ	1 (0.3)	0 (0.0)
食道拡張	1 (0.3)	0 (0.0)
膵炎	1 (0.3)	0 (0.0)
後腹膜出血	1 (0.3)	0 (0.0)
口内炎	1 (0.3)	0 (0.0)
上部消化管出血	1 (0.3)	0 (0.0)
一般・全身障害および投与部位の状態	47 (13.8)	60 (17.8)

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.

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 7）
解析対象集団：SAF

SOC		有害事象	
		シナカルセト	ONO-5163
PT		n （%）	n （%）
	N	341	338
発熱		8 (2.3)	12 (3.6)
末梢性浮腫		3 (0.9)	7 (2.1)
無力症		6 (1.8)	6 (1.8)
疲労		3 (0.9)	5 (1.5)
悪寒		3 (0.9)	4 (1.2)
倦怠感		2 (0.6)	4 (1.2)
顔面浮腫		0 (0.0)	3 (0.9)
カテーテル留置部位炎症		0 (0.0)	2 (0.6)
インフルエンザ様疾患		1 (0.3)	2 (0.6)
医療機器合併症		1 (0.3)	2 (0.6)
浮腫		2 (0.6)	2 (0.6)
口渇		1 (0.3)	2 (0.6)
医療機器関連の血栓症		2 (0.6)	2 (0.6)
カテーテル留置部位内出血		0 (0.0)	1 (0.3)
カテーテル留置部位分泌物		3 (0.9)	1 (0.3)
カテーテル留置部位びらん		0 (0.0)	1 (0.3)
カテーテル留置部位紅斑		0 (0.0)	1 (0.3)
カテーテル留置部位漏出		0 (0.0)	1 (0.3)
カテーテル留置部位腫脹		0 (0.0)	1 (0.3)
胸部不快感		0 (0.0)	1 (0.3)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 8）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
胸痛	3 (0.9)	1 (0.3)
医療機器機能不良	0 (0.0)	1 (0.3)
医療機器閉塞	1 (0.3)	1 (0.3)
不快感	1 (0.3)	1 (0.3)
異常感	0 (0.0)	1 (0.3)
熱感	0 (0.0)	1 (0.3)
治癒不良	1 (0.3)	1 (0.3)
炎症	0 (0.0)	1 (0.3)
限局性浮腫	0 (0.0)	1 (0.3)
非心臓性胸痛	3 (0.9)	1 (0.3)
疼痛	3 (0.9)	1 (0.3)
末梢腫脹	4 (1.2)	1 (0.3)
突然死	0 (0.0)	1 (0.3)
腫脹	1 (0.3)	1 (0.3)
医薬品副作用	1 (0.3)	0 (0.0)
適用部位過敏反応	1 (0.3)	0 (0.0)
カテーテル留置部位出血	1 (0.3)	0 (0.0)
医療機器位置異常	2 (0.6)	0 (0.0)
医療機器リーク	1 (0.3)	0 (0.0)
びくびく感	1 (0.3)	0 (0.0)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 9）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n (%)	 ONO-5163 n (%)
N	341	338
注入部位血管外漏出	2 (0.6)	0 (0.0)
血管穿刺部位反応	1 (0.3)	0 (0.0)
肝胆道系障害	6 (1.8)	2 (0.6)
胆管結石	0 (0.0)	1 (0.3)
肝脾腫大	0 (0.0)	1 (0.3)
胆道仙痛	2 (0.6)	0 (0.0)
急性胆嚢炎	1 (0.3)	0 (0.0)
胆石症	1 (0.3)	0 (0.0)
胆嚢障害	1 (0.3)	0 (0.0)
血性胆汁	1 (0.3)	0 (0.0)
肝硬変	1 (0.3)	0 (0.0)
脂肪肝	1 (0.3)	0 (0.0)
免疫系障害	6 (1.8)	4 (1.2)
薬物過敏症	1 (0.3)	1 (0.3)
過敏症	1 (0.3)	1 (0.3)
腎移植拒絶反応	0 (0.0)	1 (0.3)
季節性アレルギー	1 (0.3)	1 (0.3)
節足動物刺傷アレルギー	1 (0.3)	0 (0.0)
アナフィラキシー反応	1 (0.3)	0 (0.0)
初回透析症候群	1 (0.3)	0 (0.0)

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．

表 2.7.6.17-16 有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 10）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
感染症および寄生虫症	82 (24.0)	76 (22.5)
上気道感染	15 (4.4)	10 (3.0)
肺炎	3 (0.9)	6 (1.8)
気管支炎	17 (5.0)	5 (1.5)
胃腸炎	7 (2.1)	5 (1.5)
カテーテル留置部位感染	2 (0.6)	4 (1.2)
医療機器関連感染	6 (1.8)	4 (1.2)
壊疽	0 (0.0)	4 (1.2)
限局性感染	1 (0.3)	4 (1.2)
敗血症	5 (1.5)	4 (1.2)
蜂巣炎	4 (1.2)	3 (0.9)
鼻咽頭炎	6 (1.8)	3 (0.9)
歯感染	2 (0.6)	3 (0.9)
細菌感染	0 (0.0)	2 (0.6)
糖尿病性足感染	0 (0.0)	2 (0.6)
感染	0 (0.0)	2 (0.6)
大葉性肺炎	0 (0.0)	2 (0.6)
慢性腎盂腎炎	1 (0.3)	2 (0.6)
ブドウ球菌性菌血症	0 (0.0)	2 (0.6)
ブドウ球菌感染	0 (0.0)	2 (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．

表 2.7.6.17-16 有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 11）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
動静脈瘻部位感染	1 (0.3)	1 (0.3)
動静脈グラフト部位膿瘍	0 (0.0)	1 (0.3)
動静脈グラフト部位感染	0 (0.0)	1 (0.3)
菌血症	1 (0.3)	1 (0.3)
細菌性気管支炎	0 (0.0)	1 (0.3)
膀胱炎	2 (0.6)	1 (0.3)
細菌性膀胱炎	0 (0.0)	1 (0.3)
赤痢	0 (0.0)	1 (0.3)
耳感染	0 (0.0)	1 (0.3)
細菌性心内膜炎	0 (0.0)	1 (0.3)
丹毒	0 (0.0)	1 (0.3)
皮膚真菌感染	1 (0.3)	1 (0.3)
せつ	0 (0.0)	1 (0.3)
消化管感染	0 (0.0)	1 (0.3)
鼠径部膿瘍	0 (0.0)	1 (0.3)
麦粒腫	0 (0.0)	1 (0.3)
感染性瘻孔	0 (0.0)	1 (0.3)
インフルエンザ	1 (0.3)	1 (0.3)
肝膿瘍	0 (0.0)	1 (0.3)
下気道感染	0 (0.0)	1 (0.3)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 12）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n (%)	 ONO-5163 n (%)
N	341	338
肺感染	0 (0.0)	1 (0.3)
口腔カンジダ症	2 (0.6)	1 (0.3)
口腔ヘルペス	1 (0.3)	1 (0.3)
骨髄炎	1 (0.3)	1 (0.3)
歯周炎	1 (0.3)	1 (0.3)
咽頭炎	0 (0.0)	1 (0.3)
咽喉頭膿瘍	0 (0.0)	1 (0.3)
細菌性肺炎	0 (0.0)	1 (0.3)
クレブシエラ菌性肺炎	0 (0.0)	1 (0.3)
腎嚢胞感染	0 (0.0)	1 (0.3)
ウイルス性気道感染	0 (0.0)	1 (0.3)
鼻炎	0 (0.0)	1 (0.3)
皮膚感染	0 (0.0)	1 (0.3)
ブドウ球菌性敗血症	0 (0.0)	1 (0.3)
気管気管支炎	0 (0.0)	1 (0.3)
尿路感染	8 (2.3)	1 (0.3)
ウイルス性上気道感染	0 (0.0)	1 (0.3)
創傷感染	1 (0.3)	1 (0.3)
腹部膿瘍	1 (0.3)	0 (0.0)
急性副鼻腔炎	1 (0.3)	0 (0.0)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 13）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
虫垂炎	1 (0.3)	0 (0.0)
回虫症	1 (0.3)	0 (0.0)
細菌性敗血症	1 (0.3)	0 (0.0)
気管支肺炎	2 (0.6)	0 (0.0)
感染性胆嚢炎	1 (0.3)	0 (0.0)
結膜炎	2 (0.6)	0 (0.0)
ウイルス性結膜炎	1 (0.3)	0 (0.0)
医療機器関連敗血症	1 (0.3)	0 (0.0)
心内膜炎	1 (0.3)	0 (0.0)
精巣上体炎	1 (0.3)	0 (0.0)
毛包炎	1 (0.3)	0 (0.0)
ウイルス性胃腸炎	2 (0.6)	0 (0.0)
ヘルペス性皮膚炎	1 (0.3)	0 (0.0)
帯状疱疹	1 (0.3)	0 (0.0)
感染性皮膚潰瘍	1 (0.3)	0 (0.0)
注入部位感染	1 (0.3)	0 (0.0)
爪真菌症	1 (0.3)	0 (0.0)
外耳炎	1 (0.3)	0 (0.0)
腹膜炎	1 (0.3)	0 (0.0)
術後創感染	1 (0.3)	0 (0.0)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 14）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
腎盂腎炎	1 (0.3)	0 (0.0)
急性腎盂腎炎	1 (0.3)	0 (0.0)
気道感染	1 (0.3)	0 (0.0)
唾液腺炎	1 (0.3)	0 (0.0)
副鼻腔炎	2 (0.6)	0 (0.0)
ストーマ部感染	1 (0.3)	0 (0.0)
歯膿瘍	1 (0.3)	0 (0.0)
結核	1 (0.3)	0 (0.0)
細菌性尿路感染	1 (0.3)	0 (0.0)
膣膿瘍	1 (0.3)	0 (0.0)
前庭炎	1 (0.3)	0 (0.0)
ウイルス感染	1 (0.3)	0 (0.0)
外陰膣真菌感染	1 (0.3)	0 (0.0)
ブドウ球菌性創感染	1 (0.3)	0 (0.0)
傷害、中毒および処置合併症	65 (19.1)	58 (17.2)
動静脈瘻部位合併症	6 (1.8)	9 (2.7)
処置による低血圧	10 (2.9)	8 (2.4)
移植血管合併症	3 (0.9)	5 (1.5)
動静脈瘻血栓症	3 (0.9)	4 (1.2)
創傷	3 (0.9)	4 (1.2)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 15）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
動静脈瘻部位出血	2 (0.6)	3 (0.9)
転倒	8 (2.3)	3 (0.9)
血管グラフト血栓症	6 (1.8)	3 (0.9)
動静脈瘻瘤	2 (0.6)	2 (0.6)
挫傷	3 (0.9)	2 (0.6)
処置による疼痛	0 (0.0)	2 (0.6)
血管確保合併症	7 (2.1)	2 (0.6)
動物咬傷	0 (0.0)	1 (0.3)
動静脈瘻部位血腫	0 (0.0)	1 (0.3)
動静脈グラフト瘤	0 (0.0)	1 (0.3)
脳振盪	0 (0.0)	1 (0.3)
造影剤反応	0 (0.0)	1 (0.3)
足骨折	1 (0.3)	1 (0.3)
骨折	0 (0.0)	1 (0.3)
移植片血栓症	0 (0.0)	1 (0.3)
腎臓破裂	0 (0.0)	1 (0.3)
靭帯捻挫	2 (0.6)	1 (0.3)
四肢損傷	1 (0.3)	1 (0.3)
腰椎骨折	1 (0.3)	1 (0.3)
肉離れ	1 (0.3)	1 (0.3)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 16）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
過量投与	0 (0.0)	1 (0.3)
外傷性気胸	0 (0.0)	1 (0.3)
処置後出血	1 (0.3)	1 (0.3)
処置後浮腫	0 (0.0)	1 (0.3)
処置によるめまい	0 (0.0)	1 (0.3)
処置による高血圧	1 (0.3)	1 (0.3)
処置による悪心	0 (0.0)	1 (0.3)
処置による嘔吐	0 (0.0)	1 (0.3)
橈骨骨折	0 (0.0)	1 (0.3)
肋骨骨折	1 (0.3)	1 (0.3)
交通事故	1 (0.3)	1 (0.3)
皮膚損傷	0 (0.0)	1 (0.3)
脊椎骨折	0 (0.0)	1 (0.3)
移植血管閉塞	1 (0.3)	1 (0.3)
血管損傷	0 (0.0)	1 (0.3)
創離開	0 (0.0)	1 (0.3)
創部分泌	0 (0.0)	1 (0.3)
吻合部瘻孔	1 (0.3)	0 (0.0)
動静脈グラフト部位出血	3 (0.9)	0 (0.0)
大腿骨骨折	3 (0.9)	0 (0.0)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 17）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
血液透析合併症	1 (0.3)	0 (0.0)
関節損傷	1 (0.3)	0 (0.0)
裂傷	1 (0.3)	0 (0.0)
靭帯断裂	1 (0.3)	0 (0.0)
骨盤骨折	1 (0.3)	0 (0.0)
処置後瘻孔	1 (0.3)	0 (0.0)
外傷後疼痛	1 (0.3)	0 (0.0)
処置による頭痛	1 (0.3)	0 (0.0)
骨格損傷	2 (0.6)	0 (0.0)
皮膚擦過傷	1 (0.3)	0 (0.0)
腱損傷	1 (0.3)	0 (0.0)
腱断裂	1 (0.3)	0 (0.0)
胸椎骨折	1 (0.3)	0 (0.0)
血管偽動脈瘤	1 (0.3)	0 (0.0)
臨床検査	212 (62.2)	239 (70.7)
血中カルシウム減少	204 (59.8)	233 (68.9)
血中副甲状腺ホルモン減少	6 (1.8)	6 (1.8)
血圧上昇	3 (0.9)	5 (1.5)
血中カルシウム増加	4 (1.2)	4 (1.2)
ヘモグロビン減少	1 (0.3)	4 (1.2)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 18）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n (%)	 ONO-5163 n (%)
N	341	338
血中リン減少	0 (0.0)	3 (0.9)
血中カリウム減少	1 (0.3)	3 (0.9)
補正カルシウム減少	0 (0.0)	2 (0.6)
体重減少	0 (0.0)	2 (0.6)
冠血管造影	0 (0.0)	1 (0.3)
血中カルシトニン減少	0 (0.0)	1 (0.3)
血中ブドウ糖増加	0 (0.0)	1 (0.3)
血圧異常	1 (0.3)	1 (0.3)
骨密度減少	0 (0.0)	1 (0.3)
Ｃ－反応性蛋白増加	0 (0.0)	1 (0.3)
心電図ＱＴ延長	0 (0.0)	1 (0.3)
瘻造影	0 (0.0)	1 (0.3)
心拍数増加	0 (0.0)	1 (0.3)
肝酵素上昇	1 (0.3)	1 (0.3)
国際標準比増加	0 (0.0)	1 (0.3)
便潜血陽性	0 (0.0)	1 (0.3)
体重増加	2 (0.6)	1 (0.3)
血中アルブミン減少	1 (0.3)	0 (0.0)
血中副甲状腺ホルモン異常	2 (0.6)	0 (0.0)
血中リン増加	4 (1.2)	0 (0.0)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 19）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
血中カリウム増加	3 (0.9)	0 (0.0)
呼吸音異常	1 (0.3)	0 (0.0)
結腸内視鏡検査	1 (0.3)	0 (0.0)
ヘモグロビン増加	1 (0.3)	0 (0.0)
総蛋白減少	1 (0.3)	0 (0.0)
血清フェリチン減少	1 (0.3)	0 (0.0)
代謝および栄養障害	59 (17.3)	63 (18.6)
低カルシウム血症	8 (2.3)	17 (5.0)
高カリウム血症	15 (4.4)	13 (3.8)
高リン酸塩血症	10 (2.9)	10 (3.0)
食欲減退	6 (1.8)	8 (2.4)
水分過負荷	7 (2.1)	7 (2.1)
鉄欠乏	0 (0.0)	5 (1.5)
低血糖症	3 (0.9)	3 (0.9)
高カルシウム血症	3 (0.9)	2 (0.6)
低リン酸血症	3 (0.9)	2 (0.6)
食欲亢進	1 (0.3)	2 (0.6)
カルシフィラキシス	1 (0.3)	1 (0.3)
高浸透圧をともなう糖尿病	0 (0.0)	1 (0.3)
糖尿病性ケトアシドーシス	0 (0.0)	1 (0.3)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 20）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
脂質異常症	1 (0.3)	1 (0.3)
体液貯留	1 (0.3)	1 (0.3)
高血糖	2 (0.6)	1 (0.3)
高脂血症	0 (0.0)	1 (0.3)
血液量増加症	0 (0.0)	1 (0.3)
低ナトリウム血症	1 (0.3)	1 (0.3)
低鉄血症	1 (0.3)	1 (0.3)
多飲症	0 (0.0)	1 (0.3)
ビタミンD欠乏	2 (0.6)	1 (0.3)
クボステック徴候	1 (0.3)	0 (0.0)
高コレステロール血症	1 (0.3)	0 (0.0)
低アルブミン血症	2 (0.6)	0 (0.0)
低カリウム血症	1 (0.3)	0 (0.0)
血液量減少症	1 (0.3)	0 (0.0)
筋骨格系および結合組織障害	71 (20.8)	75 (22.2)
筋痙縮	20 (5.9)	22 (6.5)
四肢痛	14 (4.1)	17 (5.0)
背部痛	10 (2.9)	9 (2.7)
筋骨格痛	7 (2.1)	8 (2.4)
関節痛	7 (2.1)	7 (2.1)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 21）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n (%)	n (%)
N	341	338
筋肉痛	2 (0.6)	5 (1.5)
滑液包炎	0 (0.0)	3 (0.9)
筋力低下	3 (0.9)	3 (0.9)
頚部痛	5 (1.5)	3 (0.9)
関節炎	1 (0.3)	2 (0.6)
骨痛	1 (0.3)	2 (0.6)
骨壊死	1 (0.3)	2 (0.6)
褐色腫	0 (0.0)	1 (0.3)
足変形	3 (0.9)	1 (0.3)
椎間板変性症	0 (0.0)	1 (0.3)
椎間板偏位	0 (0.0)	1 (0.3)
関節強直	0 (0.0)	1 (0.3)
腰部脊柱管狭窄症	0 (0.0)	1 (0.3)
筋拘縮	0 (0.0)	1 (0.3)
筋骨格系胸痛	1 (0.3)	1 (0.3)
変形性関節症	3 (0.9)	1 (0.3)
骨端症	0 (0.0)	1 (0.3)
病的骨折	1 (0.3)	1 (0.3)
変形性脊椎症	0 (0.0)	1 (0.3)
腱炎	0 (0.0)	1 (0.3)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 22）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
側腹部痛	3 (0.9)	0 (0.0)
痛風性関節炎	1 (0.3)	0 (0.0)
単径部痛	2 (0.6)	0 (0.0)
関節硬直	1 (0.3)	0 (0.0)
関節腫脹	1 (0.3)	0 (0.0)
膝関節変形	1 (0.3)	0 (0.0)
筋炎	1 (0.3)	0 (0.0)
骨粗鬆症	2 (0.6)	0 (0.0)
足底筋膜炎	1 (0.3)	0 (0.0)
リウマトイド結節	1 (0.3)	0 (0.0)
腱石灰化	1 (0.3)	0 (0.0)
腱障害	1 (0.3)	0 (0.0)
腱鞘炎	1 (0.3)	0 (0.0)
弾発指	2 (0.6)	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）	5 (1.5)	5 (1.5)
乳房の良性新生物	0 (0.0)	1 (0.3)
肺の悪性新生物	0 (0.0)	1 (0.3)
メラノサイト性母斑	0 (0.0)	1 (0.3)
膵新生物	0 (0.0)	1 (0.3)
子宮平滑筋腫	1 (0.3)	1 (0.3)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 23）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n (%)	 ONO-5163 n (%)
N	341	338
膀胱新生物	1 (0.3)	0 (0.0)
肝転移	1 (0.3)	0 (0.0)
卵巣新生物	1 (0.3)	0 (0.0)
咽頭癌	1 (0.3)	0 (0.0)
神経系障害	70 (20.5)	65 (19.2)
頭痛	24 (7.0)	22 (6.5)
浮動性めまい	9 (2.6)	15 (4.4)
錯感覚	6 (1.8)	7 (2.1)
感覚鈍麻	3 (0.9)	4 (1.2)
失神	2 (0.6)	4 (1.2)
振戦	0 (0.0)	3 (0.9)
重症筋無力症	0 (0.0)	2 (0.6)
末梢性ニューロパチー	1 (0.3)	2 (0.6)
一過性脳虚血発作	1 (0.3)	2 (0.6)
断端痛	0 (0.0)	1 (0.3)
失語症	0 (0.0)	1 (0.3)
頚動脈硬化症	0 (0.0)	1 (0.3)
手根管症候群	2 (0.6)	1 (0.3)
脳梗塞	1 (0.3)	1 (0.3)
昏睡	0 (0.0)	1 (0.3)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 24）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
痙攣	2 (0.6)	1 (0.3)
異常感覚	0 (0.0)	1 (0.3)
味覚異常	1 (0.3)	1 (0.3)
全身性強直性間代性発作	0 (0.0)	1 (0.3)
不全片麻痺	1 (0.3)	1 (0.3)
筋緊張低下	2 (0.6)	1 (0.3)
虚血性脳卒中	1 (0.3)	1 (0.3)
腰髄神経根障害	0 (0.0)	1 (0.3)
片頭痛	2 (0.6)	1 (0.3)
神経痛	0 (0.0)	1 (0.3)
神経学的症状	0 (0.0)	1 (0.3)
多発ニューロパチー	1 (0.3)	1 (0.3)
失神寸前の状態	0 (0.0)	1 (0.3)
下肢静止不能症候群	4 (1.2)	1 (0.3)
坐骨神経痛	1 (0.3)	1 (0.3)
感覚障害	0 (0.0)	1 (0.3)
傾眠	1 (0.3)	1 (0.3)
強直性痙攣	0 (0.0)	1 (0.3)
血管性脳症	0 (0.0)	1 (0.3)
意識変容状態	2 (0.6)	0 (0.0)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 25）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
無感覚	1 (0.3)	0 (0.0)
頚動脈疾患	1 (0.3)	0 (0.0)
脳出血	1 (0.3)	0 (0.0)
脳血管発作	1 (0.3)	0 (0.0)
脳血管不全	1 (0.3)	0 (0.0)
体位性めまい	1 (0.3)	0 (0.0)
脳症	1 (0.3)	0 (0.0)
ラクナ梗塞	1 (0.3)	0 (0.0)
視神経炎	1 (0.3)	0 (0.0)
パーキンソン病	1 (0.3)	0 (0.0)
末梢性感覚運動ニューロパチー	1 (0.3)	0 (0.0)
神経根障害	1 (0.3)	0 (0.0)
尿毒症性脳症	1 (0.3)	0 (0.0)
声帯麻痺	1 (0.3)	0 (0.0)
妊娠、産褥および周産期の状態	1 (0.3)	0 (0.0)
妊娠	1 (0.3)	0 (0.0)
精神障害	19 (5.6)	21 (6.2)
不眠症	5 (1.5)	6 (1.8)
不安	6 (1.8)	5 (1.5)
うつ病	2 (0.6)	4 (1.2)

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．

表 2.7.6.17-16 有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 26）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
激越	0 (0.0)	1 (0.3)
錯乱状態	0 (0.0)	1 (0.3)
希死念慮を有するうつ病	0 (0.0)	1 (0.3)
精神状態変化	0 (0.0)	1 (0.3)
神経過敏	0 (0.0)	1 (0.3)
睡眠障害	1 (0.3)	1 (0.3)
自殺念慮	0 (0.0)	1 (0.3)
急性ストレス反応	1 (0.3)	0 (0.0)
抑うつ気分	1 (0.3)	0 (0.0)
幻覚	1 (0.3)	0 (0.0)
易刺激性	1 (0.3)	0 (0.0)
精神病性障害	1 (0.3)	0 (0.0)
昏眠	1 (0.3)	0 (0.0)
ストレス	1 (0.3)	0 (0.0)
腎および尿路障害	5 (1.5)	3 (0.9)
尿路出血	0 (0.0)	1 (0.3)
水腎症	1 (0.3)	1 (0.3)
乏尿	0 (0.0)	1 (0.3)
尿管拡張	0 (0.0)	1 (0.3)
血尿	2 (0.6)	0 (0.0)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 27）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
腎結石症	1 (0.3)	0 (0.0)
腎嚢胞破裂	1 (0.3)	0 (0.0)
尿細管間質性腎炎	1 (0.3)	0 (0.0)
生殖系および乳房障害	5 (1.5)	6 (1.8)
腟出血	0 (0.0)	2 (0.6)
良性前立腺肥大症	0 (0.0)	1 (0.3)
乳房痛	0 (0.0)	1 (0.3)
勃起不全	1 (0.3)	1 (0.3)
腟分泌物	0 (0.0)	1 (0.3)
月経困難症	1 (0.3)	0 (0.0)
不正子宮出血	1 (0.3)	0 (0.0)
前立腺炎	1 (0.3)	0 (0.0)
外陰腟そう痒症	1 (0.3)	0 (0.0)
呼吸器、胸郭および縦隔障害	43 (12.6)	43 (12.7)
呼吸困難	14 (4.1)	14 (4.1)
咳嗽	9 (2.6)	10 (3.0)
口腔咽頭痛	3 (0.9)	4 (1.2)
喘息	1 (0.3)	3 (0.9)
鼻出血	10 (2.9)	3 (0.9)
慢性閉塞性肺疾患	1 (0.3)	2 (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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 28）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
胸水	1 (0.3)	2 (0.6)
肺水腫	0 (0.0)	2 (0.6)
睡眠時無呼吸症候群	0 (0.0)	2 (0.6)
急性肺水腫	0 (0.0)	1 (0.3)
急性呼吸不全	0 (0.0)	1 (0.3)
慢性気管支炎	1 (0.3)	1 (0.3)
気管支痙攣	1 (0.3)	1 (0.3)
発声障害	1 (0.3)	1 (0.3)
しゃっくり	0 (0.0)	1 (0.3)
胸水症	0 (0.0)	1 (0.3)
肺過膨脹	0 (0.0)	1 (0.3)
夜間呼吸困難	1 (0.3)	1 (0.3)
胸膜炎	1 (0.3)	1 (0.3)
肺塞栓症	0 (0.0)	1 (0.3)
肺高血圧症	0 (0.0)	1 (0.3)
呼吸停止	0 (0.0)	1 (0.3)
呼吸不全	1 (0.3)	1 (0.3)
アレルギー性鼻炎	2 (0.6)	1 (0.3)
副鼻腔うっ血	0 (0.0)	1 (0.3)
喀血	1 (0.3)	0 (0.0)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 29）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
低酸素症	1 (0.3)	0 (0.0)
鼻閉	1 (0.3)	0 (0.0)
湿性咳嗽	1 (0.3)	0 (0.0)
鼻漏	1 (0.3)	0 (0.0)
咽喉刺激感	1 (0.3)	0 (0.0)
上気道咳症候群	1 (0.3)	0 (0.0)
喘鳴	1 (0.3)	0 (0.0)
皮膚および皮下組織障害	26 (7.6)	37 (10.9)
そう痒症	5 (1.5)	15 (4.4)
皮膚潰瘍	2 (0.6)	6 (1.8)
皮膚炎	0 (0.0)	3 (0.9)
糖尿病性足病変	0 (0.0)	3 (0.9)
全身性そう痒症	0 (0.0)	3 (0.9)
発疹	3 (0.9)	3 (0.9)
皮膚乾燥	1 (0.3)	2 (0.6)
湿疹	1 (0.3)	2 (0.6)
皮膚病変	0 (0.0)	2 (0.6)
光線過敏性反応	0 (0.0)	1 (0.3)
皮膚障害	0 (0.0)	1 (0.3)
脱毛症	1 (0.3)	0 (0.0)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 30）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
皮脂欠乏症	1 (0.3)	0 (0.0)
水疱	2 (0.6)	0 (0.0)
褥瘡性潰瘍	2 (0.6)	0 (0.0)
アレルギー性皮膚炎	2 (0.6)	0 (0.0)
斑状出血	3 (0.9)	0 (0.0)
多汗症	1 (0.3)	0 (0.0)
寝汗	1 (0.3)	0 (0.0)
小葉性脂肪織炎	1 (0.3)	0 (0.0)
アレルギー性そう痒症	1 (0.3)	0 (0.0)
そう痒性皮疹	1 (0.3)	0 (0.0)
血管障害	44 (12.9)	57 (16.9)
低血圧	10 (2.9)	23 (6.8)
高血圧	23 (6.7)	21 (6.2)
血腫	1 (0.3)	3 (0.9)
潮紅	0 (0.0)	2 (0.6)
起立性低血圧	1 (0.3)	2 (0.6)
末梢動脈閉塞性疾患	1 (0.3)	2 (0.6)
鎖骨下静脈血栓症	0 (0.0)	2 (0.6)
大動脈狭窄	0 (0.0)	1 (0.3)
循環虚脱	0 (0.0)	1 (0.3)

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．

表 2.7.6.17-16　有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 31）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
四肢壊死	1 (0.3)	1 (0.3)
末梢動脈狭窄	1 (0.3)	1 (0.3)
末梢血管障害	1 (0.3)	1 (0.3)
二次性高血圧	0 (0.0)	1 (0.3)
上大静脈症候群	0 (0.0)	1 (0.3)
血栓症	1 (0.3)	1 (0.3)
血管収縮	0 (0.0)	1 (0.3)
静脈狭窄	2 (0.6)	1 (0.3)
大動脈硬化症	1 (0.3)	0 (0.0)
動脈血栓症	1 (0.3)	0 (0.0)
動静脈瘻	1 (0.3)	0 (0.0)
腕頭静脈狭窄	2 (0.6)	0 (0.0)
ほてり	1 (0.3)	0 (0.0)
高血圧クリーゼ	2 (0.6)	0 (0.0)
スチール症候群	2 (0.6)	0 (0.0)
血栓性静脈炎	1 (0.3)	0 (0.0)
表在性血栓性静脈炎	1 (0.3)	0 (0.0)
血管狭窄	1 (0.3)	0 (0.0)
静脈障害	1 (0.3)	0 (0.0)

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．
出典［総括報告書 5.3.5.1-5（20120360 試験）Table 14-6.4 改変］

表 2.7.6.17-17　死亡した被験者の一覧表（20120360 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 + CINACALCET PLACEBO	20120360-36016001005	5[redacted]	M	WHITE	NOT HISPANIC OR LATINO	BLOOD CALCIUM DECREASED [血中カルシウム減少]	20[redacted]-05-26	22	MODERATE	NO	-	DRUG INTERRUPTED	NO ACTION TAKEN	RELATED	20[redacted]-06-04	-
AMG 416 + CINACALCET PLACEBO	20120360-36016001005	5[redacted]	M	WHITE	NOT HISPANIC OR LATINO	CARDIAC ARREST [心停止]	20[redacted]-06-09	36	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-06-09	FATAL
AMG 416 + CINACALCET PLACEBO	20120360-36016005002	5[redacted]	M	GUYANESE - EAST INDIAN / BLACK MIX	HISPANIC OR LATINO	FEELING UNWELL [倦怠感]	20[redacted]-06-09	69	MILD	NO	-	DRUG INTERRUPTED	UNKNOWN	NOT RELATED	20[redacted]-06-09	-
AMG 416 + CINACALCET PLACEBO	20120360-36016005002	5[redacted]	M	GUYANESE - EAST INDIAN / BLACK MIX	HISPANIC OR LATINO	CARDIORESPIRATORY ARREST [心肺停止]	20[redacted]-06-10	70	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-06-11	FATAL
AMG 416 + CINACALCET PLACEBO	20120360-36033006003	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	PLEURAL EFFUSION [胸水]	20[redacted]-02-13	1	MODERATE	NO	-	DOSE NOT CHANGED	IV ANTIBIOTICS TAKEN, OTHER	NOT RELATED	20[redacted]-04-12	-
AMG 416 + CINACALCET PLACEBO	20120360-36033006003	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	ANEMIA WORSENING [貧血]	20[redacted]-03-04	20	MODERATE	NO	-	DOSE NOT CHANGED	TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-04-12	-

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 + CINACALCET PLACEBO	20120360-36033006003	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	RETTORRAGIA [直腸出血]	20[redacted]-04-09	56	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-04-12	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36033006003	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	ACUTE CARDIAC FAILURE [急性心不全]	20[redacted]-04-12	59	LIFE THREATENING	YES	Results in Death	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-04-12	FATAL
AMG 416 + CINACALCET PLACEBO	20120360-36036004003	3[redacted]	F	WHITE	NOT HISPANIC OR LATINO	VOMITING [嘔吐]	20[redacted]-03-25	42	MILD	NO	-	DOSE NOT CHANGED	-	NOT RELATED	20[redacted]-03-26	-
AMG 416 + CINACALCET PLACEBO	20120360-36036004003	3[redacted]	F	WHITE	NOT HISPANIC OR LATINO	SEPSIS [敗血症]	20[redacted]-03-31	48	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-04-19	FATAL

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 + CINACALCET PLACEBO	20120360-36036004003	3[redacted]	F	WHITE	NOT HISPANIC OR LATINO	DRY DERMATITIS [皮膚炎]	20[redacted]-04-16	64	MODERATE	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-04-19	-
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	4[redacted]	M	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-05-21	45	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-13	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	4[redacted]	M	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	UPPER RESPIRATORY TRACT INFECTION [上気道感染]	20[redacted]-05-28	52	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-06-13	-
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	4[redacted]	M	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	RIGHT LOWER LEG INFECTION [限局性感染]	20[redacted]-06-26	81	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-08-29	-
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	4[redacted]	M	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	ANXIETY [不安]	20[redacted]-07-09	94	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	-	-

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 + CINACALCET PLACEBO	20120360-36043003005	4[redacted]	M	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	RIGHT LOWER LOBE PNUEMONIA. [大葉性肺炎]	20[redacted]-08-11	127	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-08-22	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	4[redacted]	M	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	PULMONARY EMBOLISM [肺塞栓症]	20[redacted]-08-27	143	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	4[redacted]	M	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	RIGHT PLEURAL EFFUSION [胸水]	20[redacted]-08-27	143	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN, IV ANTIBIOTICS TAKEN	NOT RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	4[redacted]	M	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	RIGHT LEG ULCER [皮膚潰瘍]	20[redacted]-08-29	145	MILD	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-09-24	-

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 + CINACALCET PLACEBO	20120360-36043003005	4[redacted]	M	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	GENERALISED TONIC SEIZURES [強直性痙攣]	20[redacted]-09-02	149	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	4[redacted]	M	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	BILATERAL LEG ULCERS [皮膚潰瘍]	20[redacted]-09-24	171	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	4[redacted]	M	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	ACUTE HYPOTENSION [低血圧]	20[redacted]-10-07	184	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-14	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	4[redacted]	M	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	PERIPHERAL LEG PAIN [四肢痛]	20[redacted]-10-08	185	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-10-18	-
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	4[redacted]	M	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	ACUTE CARDIAC INSUFFICIENCY [急性心不全]	20[redacted]-10-18	195	LIFE THREATENING	YES	Results in Death	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-18	FATAL
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	WEAKNESS [無力症]	20[redacted]-12-23	6	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-23	-

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	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 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	PROLONGED BLEEDING AFTER HD [処置後出血]	20[redacted]-12-25	8	MILD	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-12-25	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPOGLYCAEMIA [低血糖症]	20[redacted]-12-27 *	10	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-27 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	UPPER RESPIRATORY TRACT INFECTION [上気道感染]	20[redacted]-01-01 *	15	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-01-03 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPOTONIA [筋緊張低下]	20[redacted]-02-03 *	48	MILD	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-02-03 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	UPPER RESPIRATORY TRACT INFECTION [上気道感染]	20[redacted]-02-26 *	71	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-03-02 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPERTENSION ARTERIAL [高血圧]	20[redacted]-02-28 *	73	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-02-28 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	BRONCHITIS BACTERIAL [細菌性気管支炎]	20[redacted]-03-03 *	76	MODERATE	NO	-	DOSE NOT CHANGED	IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-03-10 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPOGLYCEMIA, UNSPECIFIED [低血糖症]	20[redacted]-03-21	94	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-03-21	-

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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 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	WEAKNESS GENERALISED [無力症]	20[redacted]-03-26 *	99	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-03-26 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	WEAKNESS GENERALISED [無力症]	20[redacted]-03-31 *	104	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-03-31 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPERTENSION [高血圧]	20[redacted]-04-25 *	129	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-04-25 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	VOMITING [嘔吐]	20[redacted]-05-01 *	135	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	RELATED	20[redacted]-05-01 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	VOMITING [嘔吐]	20[redacted]-05-03 *	137	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	RELATED	20[redacted]-05-03 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPERTENSION [高血圧]	20[redacted]-05-05 *	139	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-05-05 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPERTENSION [高血圧]	20[redacted]-05-09 *	143	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-05-09 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPERTENSION [高血圧]	20[redacted]-05-19 *	153	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-05-19 *	-

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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 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	WEAKNESS [無力症]	20[redacted]-05-26 *	160	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-05-26 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPERTENSION [高血圧]	20[redacted]-05-28 *	162	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-05-28 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPERTENSION [高血圧]	20[redacted]-06-04 *	169	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-06-04 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HARD, PAINFUL THIGH SKIN CHANGE [皮膚障害]	20[redacted]-06-12 *	177	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-27 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	PATHOLOGICAL FRACTURE OF HIP [病的骨折]	20[redacted]-06-18 *	183	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-27 *	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	ANXIETY [不安]	20[redacted]-06-23	188	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-06-23	-

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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 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	UNCONSCIOUS DEFECATION [便失禁]	20[redacted]-06-23 *	188	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-06-23 *	-
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	SUDDEN DEATH-PATIENT DIED DURING SLEEP [突然死]	20[redacted]-06-27	192	LIFE THREATENING	YES	Results in Death	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-06-27	FATAL
AMG 416 + CINACALCET PLACEBO	20120360-36066001010	3[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SEVERE MUSCLE WEAKNESS [筋力低下]	20[redacted]-05-05	13	MODERATE	NO	-	DRUG INTERRUPTED	NO ACTION TAKEN	RELATED	20[redacted]-05-19	-
AMG 416 + CINACALCET PLACEBO	20120360-36066001010	3[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	BLOOD CALCIUM DECREASED [血中カルシウム減少]	20[redacted]-05-28	36	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-06-11	-
AMG 416 + CINACALCET PLACEBO	20120360-36066001010	3[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SEVERE MUSCLE WEAKNESS [筋力低下]	20[redacted]-06-16	55	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-06-18	-
AMG 416 + CINACALCET PLACEBO	20120360-36066001010	3[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	DIALYSIS CATHETER MALFUNCTION [医療機器機能不良]	20[redacted]-07-02	71	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-05	RECOVERED/RESOLVED

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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 + CINACALCET PLACEBO	20120360-36066001010	3[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CARDIAC TAMONADE [心タンポナーデ]	20[redacted]-07-03	72	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-05	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066001010	3[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	INNOMINATE VEIN LACERATION [血管損傷]	20[redacted]-07-03	72	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-05	FATAL
AMG 416 + CINACALCET PLACEBO	20120360-36066001010	3[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SEIZURE [痙攣]	20[redacted]-07-03	72	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-03	RECOVERED/RESOLVED

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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 + CINACALCET PLACEBO	20120360-36066001010	3[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	BLOOD LOSS INTO CHEST SECONDARY TO INOMINATE VEIN LACERATION [血管損傷]	20[redacted]-07-04	73	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-07-05	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	HYPOGLYCEMIA [低血糖症]	20[redacted]-05-02	19	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-05-02	-
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	WORSENING RIGHT-SIDED NECK PAIN [頚部痛]	20[redacted]-05-07	24	SEVERE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN, EMERGENCY ROOM VISIT	NOT RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	ACUTE RESPIRATORY FAILURE [急性呼吸不全]	20[redacted]-05-08	25	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-08	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	INTERMITTENT DRY EYES [眼乾燥]	20[redacted]-05-08	25	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	INTERMITTENT HYPOTENSION [低血圧]	20[redacted]-05-08	25	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-07-09	-
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	LOW BLOOD CALCIUM [血中カルシウム減少]	20[redacted]-05-08	25	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	PROBABLE MYASTHENIA GRAVIS [重症筋無力症]	20[redacted]-05-08	25	SEVERE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	RESPIRATORY ARREST [呼吸停止]	20[redacted]-05-08	25	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-06-26	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	CARDIAC ARREST TRANSIENT [心停止]	20[redacted]-05-09	26	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-05-09	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	COMA (NON-DIABETIC) [昏睡]	20[redacted]-05-09	26	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-05-13	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	KLIEBSIELLA PNEUMONIA [クレブシエラ菌性肺炎]	20[redacted]-05-12	29	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-24	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-05-13	30	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-07-01	-
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	INTERMITTENT AGITATION [激越]	20[redacted]-05-13	30	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	-	-

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AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-05-13	30	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	SINUS CONGESTION [副鼻腔うっ血]	20[redacted]-05-13	30	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	VENTILATOR-ASSOCIATED PNEUMONIA [肺炎]	20[redacted]-05-26	43	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-06-26	-
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	HYPERLIPIDEMIA [高脂血症]	20[redacted]-05-29	46	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	INTERMITTENT FLATULENCE [放屁]	20[redacted]-05-29	46	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	HYPOTENSION [低血圧]	20[redacted]-07-10	88	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-12	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	INTERMITTENT HYPOTENSION [低血圧]	20[redacted]-07-13	91	MODERATE	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	-	-

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AMG 416 + CINACALCET PLACEBO	20120360-36066083004	5[redacted]	M	WHITE	HISPANIC OR LATINO	END STAGE RENAL DISEASE [慢性腎不全]	20[redacted]-07-28	106	LIFE THREATENING	YES	Results in Death	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-07-28	FATAL
CINACALCET + AMG 416 PLACEBO	20120360-36035004001	3[redacted]	M	WHITE	NOT HISPANIC OR LATINO	SPONTAN INTRACEREBRAL HAEMORRHAGIA [脳出血]	20[redacted]-02-25	9	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-25	FATAL
CINACALCET + AMG 416 PLACEBO	20120360-36049001002	7[redacted]	M	WHITE	HISPANIC OR LATINO	CALCIUM BLOOD DECREASED [血中カルシウム減少]	20[redacted]-03-12	36	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN, OTHER	RELATED	20[redacted]-04-09	-
CINACALCET + AMG 416 PLACEBO	20120360-36049001002	7[redacted]	M	WHITE	HISPANIC OR LATINO	HYPERKALEMIA [高カリウム血症]	20[redacted]-03-30	54	SEVERE	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-04-01	-
CINACALCET + AMG 416 PLACEBO	20120360-36049001002	7[redacted]	M	WHITE	HISPANIC OR LATINO	DYSPNEA [呼吸困難]	20[redacted]-06-13	129	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-06-13	-
CINACALCET + AMG 416 PLACEBO	20120360-36049001002	7[redacted]	M	WHITE	HISPANIC OR LATINO	PARESTHESIA LEFT HAND [錯感覚]	20[redacted]-06-20	136	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-06-25	-
CINACALCET + AMG 416 PLACEBO	20120360-36049001002	7[redacted]	M	WHITE	HISPANIC OR LATINO	BRADYCARDIA SINUS [洞性徐脈]	20[redacted]-07-14	160	MILD	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-07-22	-
CINACALCET + AMG 416 PLACEBO	20120360-36049001002	7[redacted]	M	WHITE	HISPANIC OR LATINO	CALCIUM BLOOD DECREASED [血中カルシウム減少]	20[redacted]-07-16	162	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	RELATED	20[redacted]-08-01	-

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
CINACALCET + AMG 416 PLACEBO	20120360-36049001002	7[redacted]	M	WHITE	HISPANIC OR LATINO	CARDIAC ARREST [心停止]	20[redacted]-08-21	198	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-06	FATAL
CINACALCET + AMG 416 PLACEBO	20120360-36051012007	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	ACUTE CORONARY SYNDROME [急性冠動脈症候群]	20[redacted]-05-02	75	LIFE THREATENING	YES	Results in Death	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-05-02	FATAL
CINACALCET + AMG 416 PLACEBO	20120360-36060009005	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	LOW BLOOD CALCIUM [血中カルシウム減少]	20[redacted]-06-14	82	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	RELATED	20[redacted]-09-02	-
CINACALCET + AMG 416 PLACEBO	20120360-36060009005	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	BRONCHITIS [気管支炎]	20[redacted]-08-14	143	MODERATE	NO	-	DOSE NOT CHANGED	NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-08-15	-
CINACALCET + AMG 416 PLACEBO	20120360-36060009005	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	BRONCHOPNEUMONIA [気管支肺炎]	20[redacted]-08-16	145	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-08-23	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
CINACALCET + AMG 416 PLACEBO	20120360-36060009005	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	STEMI [急性心筋梗塞]	20[redacted]-10-23	213	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-23	FATAL
CINACALCET + AMG 416 PLACEBO	20120360-36063001003	5[redacted]	F	WHITE	NOT HISPANIC OR LATINO	COUGH [咳嗽]	20[redacted]-05-05	1	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	-	20[redacted]-05-06	-
CINACALCET + AMG 416 PLACEBO	20120360-36063001003	5[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HEMATOMA [血腫]	20[redacted]-06-21	48	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-07-03	-
CINACALCET + AMG 416 PLACEBO	20120360-36063001003	5[redacted]	F	WHITE	NOT HISPANIC OR LATINO	FOOT DEFORMITY [足変形]	20[redacted]-07-08	65	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36063001003	5[redacted]	F	WHITE	NOT HISPANIC OR LATINO	PERIPHERAL ARTERIAL DISEASE [末梢動脈閉塞性疾患]	20[redacted]-07-08	65	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-10	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
CINACALCET + AMG 416 PLACEBO	20120360-36063001003	5[redacted]	F	WHITE	NOT HISPANIC OR LATINO	CALCIPHYLAXIS [カルシフィラキシス]	20[redacted]-08-06	94	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-10	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36063001003	5[redacted]	F	WHITE	NOT HISPANIC OR LATINO	NECROTIC LESIONS ON FOOT [四肢壊死]	20[redacted]-08-06	94	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-08-10	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36063001003	5[redacted]	F	WHITE	NOT HISPANIC OR LATINO	SEPSIS [敗血症]	20[redacted]-08-08	96	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]-08-10	FATAL
CINACALCET + AMG 416 PLACEBO	20120360-36063001003	5[redacted]	F	WHITE	NOT HISPANIC OR LATINO	ECCHYMOSIS [斑状出血]	20[redacted]-08-10	98	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-08-10	-
CINACALCET + AMG 416 PLACEBO	20120360-36066001009	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	AV GRAFT THROMBOSIS [血管グラフト血栓症]	20[redacted]-06-23	48	MODERATE	NO	-	DRUG INTERRUPTED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-24	-

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
CINACALCET + AMG 416 PLACEBO	20120360-36066001009	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	HYPERKALAEMIA [高カリウム血症]	20[redacted]-06-23	48	MODERATE	NO	-	DRUG INTERRUPTED	MEDICATION TAKEN	NOT RELATED	20[redacted]-06-24	-
CINACALCET + AMG 416 PLACEBO	20120360-36066001009	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	AV GRAFT THROMBOSIS [血管グラフト血栓症]	20[redacted]-08-27	113	MODERATE	NO	-	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-08-28	-
CINACALCET + AMG 416 PLACEBO	20120360-36066001009	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	HEMORRHAGE FROM AV GRAFT [動静脈グラフト部位出血]	20[redacted]-10-27	174	LIFE THREATENING	YES	Results in Death	DRUG INTERRUPTED	MEDICATION TAKEN, EMERGENCY ROOM VISIT, OTHER	NOT RELATED	20[redacted]-10-27	FATAL
UNPLANNED TREATMENT	20120360-36035002002	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	PERIPHERAL ARTERIAL OCCLUSIVE DISEASE AGGRAVATED [末梢動脈閉塞性疾患]	20[redacted]-03-29	12	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-26	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
UNPLANNED TREATMENT	20120360-36035002002	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	DECOMPENSATED HEART FAILURE [心不全]	20[redacted]-04-30	44	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-03	FATAL
UNPLANNED TREATMENT	20120360-36049005002	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	ISCHEMIA CORONARY ARTERY ORIGIN [心筋虚血]	20[redacted]-01-02	24	LIFE THREATENING	YES	Results in Death	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-01-02	FATAL
UNPLANNED TREATMENT	20120360-36051002009	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	PAIN IN THE SECOND FINGER OF THE RIGHT LOWER EXTREMITY [四肢痛]	20[redacted]-03-25	1	MILD	NO	-	DOSE NOT CHANGED	OTHER	-	20[redacted]-03-27	-
UNPLANNED TREATMENT	20120360-36051002009	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	ISCHEMIC STROKE [虚血性脳卒中]	20[redacted]-03-28	4	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-02	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
UNPLANNED TREATMENT	20120360-36051002009	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	OSTEOARTHRITIS OF THE SECOND METATARSOPHALANGEAL JOINT [変形性関節症]	20[redacted]-03-28	4	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-02	RECOVERED/RESOLVED
UNPLANNED TREATMENT	20120360-36051002009	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	OSTEOMYELITIS NAIL PHALANX OF THE SECOND FINGER OF THE RIGHT FOOT [骨髄炎]	20[redacted]-03-28	4	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-02	RECOVERED/RESOLVED
UNPLANNED TREATMENT	20120360-36051002009	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	PHLEGMON OF PLANTAR SURFACE OF THE RIGHT FOOT [蜂巣炎]	20[redacted]-03-28	4	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-02	RECOVERED/RESOLVED
UNPLANNED TREATMENT	20120360-36051002009	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	SEPSIS [敗血症]	20[redacted]-03-28	4	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-02	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
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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
UNPLANNED TREATMENT	20120360-36051002009	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-04-01	8	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG INTERRUPTED	NO ACTION TAKEN	NOT RELATED	20[redacted]-04-02	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 2.7.6.17-18　重篤な有害事象の SOC・PT 別発現頻度（20120360 試験）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
全体	93 (27.3)	85 (25.1)
血液およびリンパ系障害	4 (1.2)	1 (0.3)
抗リン脂質抗体症候群	0 (0.0)	1 (0.3)
貧血	4 (1.2)	0 (0.0)
心臓障害	12 (3.5)	10 (3.0)
心停止	3 (0.9)	2 (0.6)
急性心不全	0 (0.0)	2 (0.6)
急性心筋梗塞	2 (0.6)	1 (0.3)
狭心症	1 (0.3)	1 (0.3)
心不全	0 (0.0)	1 (0.3)
心タンポナーデ	0 (0.0)	1 (0.3)
心肺停止	0 (0.0)	1 (0.3)
心筋虚血	0 (0.0)	1 (0.3)
急性冠動脈症候群	1 (0.3)	0 (0.0)
不安定狭心症	2 (0.6)	0 (0.0)
心房細動	2 (0.6)	0 (0.0)
うっ血性心不全	1 (0.3)	0 (0.0)
冠動脈疾患	1 (0.3)	0 (0.0)
僧帽弁疾患	1 (0.3)	0 (0.0)
先天性、家族性および遺伝性障害	1 (0.3)	0 (0.0)

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．
出典［総括報告書 5.3.5.1-5（20120360 試験）Table 14-6.5 改変］

表 2.7.6.17-18　重篤な有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 1）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
脳血管動静脈奇形	1 (0.3)	0 (0.0)
耳および迷路障害	1 (0.3)	1 (0.3)
回転性めまい	1 (0.3)	1 (0.3)
内分泌障害	0 (0.0)	1 (0.3)
甲状腺機能低下症	0 (0.0)	1 (0.3)
眼障害	0 (0.0)	1 (0.3)
緑内障	0 (0.0)	1 (0.3)
胃腸障害	10 (2.9)	15 (4.4)
胃腸出血	0 (0.0)	2 (0.6)
直腸出血	0 (0.0)	2 (0.6)
腹部ヘルニア	0 (0.0)	1 (0.3)
腹痛	0 (0.0)	1 (0.3)
糖尿病性胃不全麻痺	0 (0.0)	1 (0.3)
憩室	0 (0.0)	1 (0.3)
出血性十二指腸炎	0 (0.0)	1 (0.3)
吐血	0 (0.0)	1 (0.3)
痔出血	0 (0.0)	1 (0.3)
痔核	1 (0.3)	1 (0.3)
出血性食道炎	0 (0.0)	1 (0.3)
急性膵炎	0 (0.0)	1 (0.3)

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．

表 2.7.6.17-18　重篤な有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 2）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
慢性膵炎	0 (0.0)	1 (0.3)
臍ヘルニア	0 (0.0)	1 (0.3)
嘔吐	1 (0.3)	1 (0.3)
上腹部痛	1 (0.3)	0 (0.0)
腹水	1 (0.3)	0 (0.0)
下痢	1 (0.3)	0 (0.0)
消化管壊死	1 (0.3)	0 (0.0)
イレウス	1 (0.3)	0 (0.0)
胃排出不全	1 (0.3)	0 (0.0)
鼠径ヘルニア	1 (0.3)	0 (0.0)
大腸穿孔	1 (0.3)	0 (0.0)
後腹膜出血	1 (0.3)	0 (0.0)
上部消化管出血	1 (0.3)	0 (0.0)
一般・全身障害および投与部位の状態	4 (1.2)	6 (1.8)
無力症	1 (0.3)	1 (0.3)
医療機器機能不良	0 (0.0)	1 (0.3)
治癒不良	0 (0.0)	1 (0.3)
末梢性浮腫	0 (0.0)	1 (0.3)
発熱	0 (0.0)	1 (0.3)
突然死	0 (0.0)	1 (0.3)

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．

表 2.7.6.17-18　重篤な有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 3）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
医療機器閉塞	1 (0.3)	0 (0.0)
医療機器合併症	1 (0.3)	0 (0.0)
非心臓性胸痛	1 (0.3)	0 (0.0)
肝胆道系障害	1 (0.3)	1 (0.3)
胆管結石	0 (0.0)	1 (0.3)
胆道仙痛	1 (0.3)	0 (0.0)
急性胆嚢炎	1 (0.3)	0 (0.0)
感染症および寄生虫症	22 (6.5)	27 (8.0)
壊疽	0 (0.0)	4 (1.2)
敗血症	4 (1.2)	3 (0.9)
胃腸炎	1 (0.3)	2 (0.6)
慢性腎盂腎炎	1 (0.3)	2 (0.6)
動静脈グラフト部位膿瘍	0 (0.0)	1 (0.3)
細菌感染	0 (0.0)	1 (0.3)
膀胱炎	1 (0.3)	1 (0.3)
医療機器関連感染	2 (0.6)	1 (0.3)
糖尿病性足感染	0 (0.0)	1 (0.3)
細菌性心内膜炎	0 (0.0)	1 (0.3)
丹毒	0 (0.0)	1 (0.3)
感染性瘻孔	0 (0.0)	1 (0.3)

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．

表 2.7.6.17-18　重篤な有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 4）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
肝膿瘍	0 (0.0)	1 (0.3)
大葉性肺炎	0 (0.0)	1 (0.3)
骨髄炎	1 (0.3)	1 (0.3)
咽喉頭膿瘍	0 (0.0)	1 (0.3)
肺炎	1 (0.3)	1 (0.3)
クレブシエラ菌性肺炎	0 (0.0)	1 (0.3)
腎嚢胞感染	0 (0.0)	1 (0.3)
ブドウ球菌性菌血症	0 (0.0)	1 (0.3)
ブドウ球菌感染	0 (0.0)	1 (0.3)
ブドウ球菌性敗血症	0 (0.0)	1 (0.3)
腹部膿瘍	1 (0.3)	0 (0.0)
虫垂炎	1 (0.3)	0 (0.0)
細菌性敗血症	1 (0.3)	0 (0.0)
気管支炎	3 (0.9)	0 (0.0)
気管支肺炎	1 (0.3)	0 (0.0)
蜂巣炎	3 (0.9)	0 (0.0)
感染性胆嚢炎	1 (0.3)	0 (0.0)
医療機器関連敗血症	1 (0.3)	0 (0.0)
腹膜炎	1 (0.3)	0 (0.0)
術後創感染	1 (0.3)	0 (0.0)

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．

表 2.7.6.17-18　重篤な有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 5）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
腎盂腎炎	1 (0.3)	0 (0.0)
急性腎盂腎炎	1 (0.3)	0 (0.0)
尿路感染	2 (0.6)	0 (0.0)
創傷感染	1 (0.3)	0 (0.0)
傷害、中毒および処置合併症	18 (5.3)	14 (4.1)
動静脈瘻部位合併症	2 (0.6)	2 (0.6)
動静脈瘻部位出血	0 (0.0)	2 (0.6)
動静脈瘻瘤	0 (0.0)	1 (0.3)
動静脈瘻血栓症	1 (0.3)	1 (0.3)
脳振盪	0 (0.0)	1 (0.3)
腎臓破裂	0 (0.0)	1 (0.3)
過量投与	0 (0.0)	1 (0.3)
外傷性気胸	0 (0.0)	1 (0.3)
処置による低血圧	0 (0.0)	1 (0.3)
肋骨骨折	0 (0.0)	1 (0.3)
脊椎骨折	0 (0.0)	1 (0.3)
移植血管閉塞	0 (0.0)	1 (0.3)
血管損傷	0 (0.0)	1 (0.3)
創離開	0 (0.0)	1 (0.3)
動静脈グラフト部位出血	2 (0.6)	0 (0.0)

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．

表 2.7.6.17-18　重篤な有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 6）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n (%)	 ONO-5163 n (%)
N	341	338
大腿骨骨折	3 (0.9)	0 (0.0)
血液透析合併症	1 (0.3)	0 (0.0)
靭帯断裂	1 (0.3)	0 (0.0)
処置後瘻孔	1 (0.3)	0 (0.0)
処置後出血	1 (0.3)	0 (0.0)
血管確保合併症	3 (0.9)	0 (0.0)
血管グラフト血栓症	3 (0.9)	0 (0.0)
臨床検査	2 (0.6)	3 (0.9)
血中カルシウム減少	1 (0.3)	1 (0.3)
肝酵素上昇	0 (0.0)	1 (0.3)
国際標準比増加	0 (0.0)	1 (0.3)
結腸内視鏡検査	1 (0.3)	0 (0.0)
代謝および栄養障害	8 (2.3)	7 (2.1)
水分過負荷	1 (0.3)	2 (0.6)
カルシフィラキシス	1 (0.3)	1 (0.3)
高浸透圧をともなう糖尿病	0 (0.0)	1 (0.3)
糖尿病性ケトアシドーシス	0 (0.0)	1 (0.3)
高血糖	0 (0.0)	1 (0.3)
高カリウム血症	5 (1.5)	1 (0.3)
低リン酸血症	1 (0.3)	0 (0.0)

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．

表 2.7.6.17-18　重篤な有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 7）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
筋骨格系および結合組織障害	9 (2.6)	2 (0.6)
褐色腫	0 (0.0)	1 (0.3)
病的骨折	1 (0.3)	1 (0.3)
足変形	2 (0.6)	0 (0.0)
筋力低下	1 (0.3)	0 (0.0)
変形性関節症	2 (0.6)	0 (0.0)
骨壊死	1 (0.3)	0 (0.0)
四肢痛	2 (0.6)	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）	3 (0.9)	2 (0.6)
肺の悪性新生物	0 (0.0)	1 (0.3)
子宮平滑筋腫	1 (0.3)	1 (0.3)
膀胱新生物	1 (0.3)	0 (0.0)
咽頭癌	1 (0.3)	0 (0.0)
神経系障害	12 (3.5)	13 (3.8)
断端痛	0 (0.0)	1 (0.3)
失語症	0 (0.0)	1 (0.3)
手根管症候群	0 (0.0)	1 (0.3)
脳梗塞	1 (0.3)	1 (0.3)
昏睡	0 (0.0)	1 (0.3)
痙攣	1 (0.3)	1 (0.3)

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．

表 2.7.6.17-18　重篤な有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 8）
解析対象集団：SAF

SOC	有害事象	
	シナカルセト	ONO-5163
PT	n （%）	n （%）
N	341	338
浮動性めまい	0 (0.0)	1 (0.3)
頭痛	0 (0.0)	1 (0.3)
感覚鈍麻	0 (0.0)	1 (0.3)
虚血性脳卒中	1 (0.3)	1 (0.3)
重症筋無力症	0 (0.0)	1 (0.3)
神経学的症状	0 (0.0)	1 (0.3)
多発ニューロパチー	0 (0.0)	1 (0.3)
一過性脳虚血発作	0 (0.0)	1 (0.3)
意識変容状態	2 (0.6)	0 (0.0)
脳出血	1 (0.3)	0 (0.0)
脳血管発作	1 (0.3)	0 (0.0)
脳症	1 (0.3)	0 (0.0)
不全片麻痺	1 (0.3)	0 (0.0)
ラクナ梗塞	1 (0.3)	0 (0.0)
視神経炎	1 (0.3)	0 (0.0)
末梢性感覚運動ニューロパチー	1 (0.3)	0 (0.0)
傾眠	1 (0.3)	0 (0.0)
精神障害	3 (0.9)	2 (0.6)
錯乱状態	0 (0.0)	1 (0.3)
希死念慮を有するうつ病	0 (0.0)	1 (0.3)

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．

表 2.7.6.17-18　重篤な有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 9）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
うつ病	1 (0.3)	0 (0.0)
精神病性障害	1 (0.3)	0 (0.0)
昏眠	1 (0.3)	0 (0.0)
腎および尿路障害	3 (0.9)	0 (0.0)
水腎症	1 (0.3)	0 (0.0)
腎結石症	1 (0.3)	0 (0.0)
尿細管間質性腎炎	1 (0.3)	0 (0.0)
呼吸器、胸郭および縦隔障害	5 (1.5)	8 (2.4)
呼吸困難	1 (0.3)	2 (0.6)
急性肺水腫	0 (0.0)	1 (0.3)
急性呼吸不全	0 (0.0)	1 (0.3)
鼻出血	1 (0.3)	1 (0.3)
胸水症	0 (0.0)	1 (0.3)
肺塞栓症	0 (0.0)	1 (0.3)
肺高血圧症	0 (0.0)	1 (0.3)
肺水腫	0 (0.0)	1 (0.3)
呼吸停止	0 (0.0)	1 (0.3)
呼吸不全	1 (0.3)	1 (0.3)
慢性閉塞性肺疾患	1 (0.3)	0 (0.0)
胸膜炎	1 (0.3)	0 (0.0)

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．

表 2.7.6.17-18　重篤な有害事象の SOC・PT 別発現頻度（20120360 試験）（続き 10）
解析対象集団：SAF

SOC PT	有害事象 シナカルセト n （%）	 ONO-5163 n （%）
N	341	338
皮膚および皮下組織障害	1 (0.3)	2 (0.6)
皮膚潰瘍	0 (0.0)	2 (0.6)
斑状出血	1 (0.3)	0 (0.0)
血管障害	8 (2.3)	10 (3.0)
高血圧	1 (0.3)	2 (0.6)
低血圧	0 (0.0)	2 (0.6)
末梢動脈閉塞性疾患	1 (0.3)	2 (0.6)
四肢壊死	1 (0.3)	1 (0.3)
末梢動脈狭窄	0 (0.0)	1 (0.3)
鎖骨下静脈血栓症	0 (0.0)	1 (0.3)
上大静脈症候群	0 (0.0)	1 (0.3)
静脈狭窄	2 (0.6)	1 (0.3)
大動脈硬化症	1 (0.3)	0 (0.0)
動脈血栓症	1 (0.3)	0 (0.0)
腕頭静脈狭窄	2 (0.6)	0 (0.0)
高血圧クリーゼ	1 (0.3)	0 (0.0)

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．
出典［総括報告書 5.3.5.1-5（20120360 試験）Table 14-6.5 改変］

表 2.7.6.17-19　重篤な有害事象の一覧表（20120360 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 + CINACALCET PLACEBO	20120360-36012007002	STAPHYLOCOCCUS AUREUS SEPSIS [ブドウ球菌性敗血症]	20[redacted]-09-16	140	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-26	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36013003001	ULCER TOE 1 RIGHT [皮膚潰瘍]	20[redacted]-03-28	108	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36013003001	ERYSIPELAS [丹毒]	20[redacted]-04-21	132	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36016001005	CARDIAC ARREST [心停止]	20[redacted]-06-09	36	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-06-09	FATAL
AMG 416 + CINACALCET PLACEBO	20120360-36016002006	ARTERIOVENOUS FISTULA THROMBOSIS, RIGHT UPPER LIMB [動静脈瘻血栓症]	20[redacted]-05-09	24	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-05-09	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36016002006	SEVERE INTRASTENT RESTENOSIS OF THE ARCH OF THE RIGHT CEPHALIC VEIN [静脈狭窄]	20[redacted]-05-09	24	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-05-20	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 + CINACALCET PLACEBO	20120360-36016002008	HYPERGLYCAEMIA [高血糖]	20[redacted]-09-19	150	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-09-20	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36016005002	CARDIORESPIRATORY ARREST [心肺停止]	20[redacted]-06-10	70	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-06-11	FATAL
AMG 416 + CINACALCET PLACEBO	20120360-36016005006	MYASTHENIA GRAVIS [重症筋無力症]	20[redacted]-08-31	139	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-15	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36021003001	FRACTURE OFF RIBS [肋骨骨折]	20[redacted]-03-09	11	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-12	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36021003001	COMMOTIO CEREBRI [脳振盪]	20[redacted]-08-02	157	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-04	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36021006001	PNEUMOTHORAX IATROGENIC ON THE RIGHT SIDE [外傷性気胸]	20[redacted]-08-18	166	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36021007002	TIA [一過性脳虚血発作]	20[redacted]-09-19	179	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-24	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 + CINACALCET PLACEBO	20120360-36022002004	INFECTION BLADDER [膀胱炎]	20[redacted]-03-22	31	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-29	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36022004002	BURSTED ARTERIOVENOUS FISTULA [動静脈瘻部位合併症]	20[redacted]-04-21	71	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-05-02	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36022004002	INFECTION BACTERIAL IN FISTULA AREA [感染性瘻孔]	20[redacted]-04-21	71	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-10	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36022007007	SEPTICAEMIA [敗血症]	20[redacted]-06-08	34	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-06-24	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36022007007	ENDOCARDITIS BACTERIAL [細菌性心内膜炎]	20[redacted]-06-12	38	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-06-24	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36022007007	CALCIPHYLAXIS [カルシフィラキシス]	20[redacted]-06-18	44	SEVERE	YES	Persist or Signif Disability/Incapacity	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	20[redacted]-06-24	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 + CINACALCET PLACEBO	20120360-36023003001	PULMONARY OEDEMA [肺水腫]	20[redacted]-08-24	138	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-01	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36025006001	BROWN TUMOR [褐色腫]	20[redacted]-03-20	37	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36025012001	TUBERCULOSIS PULMONARY SUSPICION [肺結核]	20[redacted]-08-29	163	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36026001004	ATHEROOCCLUSIVE DISEASE OF LEFT LOWER LEG WITH PAIN AT REST (FONAINE III) [末梢動脈閉塞性疾患]	20[redacted]-06-04	36	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-06-06	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36026001006	SPONTANEOUS FRACTURE LUMBAR SPINE AND OS SACRUM [脊椎骨折]	20[redacted]-07-05	59	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36026001006	LOW SERUM CALCIUM [血中カルシウム減少]	20[redacted]-08-17	102	MODERATE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36026007001	ABDOMINAL HERNIA [腹部ヘルニア]	20[redacted]-04-30	22	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-09	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 + CINACALCET PLACEBO	20120360-36026009001	CARPAL-TUNNEL-SYNDROME [手根管症候群]	20[redacted]-09-04	135	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-05	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36026014001	UMBILICAL HERNIA [臍ヘルニア]	20[redacted]-04-03	10	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-23	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36027001001	STAPH AUREUS INFECTION [ブドウ球菌感染]	20[redacted]-07-07	152	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-09	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36027006002	ACUTE CONFUSION STATE [錯乱状態]	20[redacted]-03-11	63	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER, OTHER	NOT RELATED	20[redacted]-03-12	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36027006002	DYSPNEA [呼吸困難]	20[redacted]-03-11	63	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER, OTHER	NOT RELATED	20[redacted]-03-12	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36027006002	HEADACHE [頭痛]	20[redacted]-03-11	63	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER, OTHER	NOT RELATED	20[redacted]-03-12	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36027007004	STAPHYLOCOCCAL BACTEREMIA [ブドウ球菌性菌血症]	20[redacted]-10-25 *	3	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-10-29 *	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36027007004	FEVER OF UNKNOWN ORIGIN [発熱]	20[redacted]-02-03 *	104	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-02-06 *	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36027007004	KIDNEY RUPTURE [腎臓破裂]	20[redacted]-03-04	133	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-03-17	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36029006004	SEVERE HYPERKALEMIA [高カリウム血症]	20[redacted]-07-28	74	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-08	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36029006004	SEVERE HYPERKALEMIE [高カリウム血症]	20[redacted]-08-18	95	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-27	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36029006004	PNEUMONIA [肺炎]	20[redacted]-09-11	119	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-22	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36029006004	HYPOTENSION DURING DIALYSIS [処置による低血圧]	20[redacted]-10-27	165	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-11-05	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36029012007	RENAL CYST INFECTION [腎嚢胞感染]	20[redacted]-04-07	27	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-28	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36033002002	SEPSIS [敗血症]	20[redacted]-05-01	36	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-05-06	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36033005004	STENOSIS OF LEFT ILIAC ARTERIA [末梢動脈狭窄]	20[redacted]-05-27	43	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-10-01	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36033006003	RETTORRAGIA [直腸出血]	20[redacted]-04-09	56	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-04-12	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36033006003	ACUTE CARDIAC FAILURE [急性心不全]	20[redacted]-04-12	59	LIFE THREATENING	YES	Results in Death	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-04-12	FATAL

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AMG 416 + CINACALCET PLACEBO	20120360-36036001004	EPIGLOTTIS ABSCESS [咽喉頭膿瘍]	20[redacted]-06-01	158	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-06-14	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36036003002	ANTIPHOSPHOLIPID SYNDROM [抗リン脂質抗体症候群]	20[redacted]-04-07	48	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-18	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36036003003	ABSCESS OF AVF DISTAL AREA [動静脈グラフト部位膿瘍]	20[redacted]-04-01	36	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-12	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36036004003	SEPSIS [敗血症]	20[redacted]-03-31	48	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-04-19	FATAL
AMG 416 + CINACALCET PLACEBO	20120360-36036004005	STENOCARDIA [狭心症]	20[redacted]-04-23	45	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-28	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36036004005	HYDROTORAX SINISTRA [胸水症]	20[redacted]-06-18	101	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36043001006	EPISTAXIS [鼻出血]	20[redacted]-07-24	88	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-25	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36043003001	BLOCKED LEFT LOOP GRAFT. [移植血管閉塞]	20[redacted]-07-11	164	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-14	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-05-21	45	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-13	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	RIGHT LOWER LOBE PNUEMONIA. [大葉性肺炎]	20[redacted]-08-11	127	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-08-22	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	PULMONARY EMBOLISM [肺塞栓症]	20[redacted]-08-27	143	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36043003005	BILATERAL LEG ULCERS [皮膚潰瘍]	20[redacted]-09-24	171	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	ACUTE HYPOTENSION [低血圧]	20[redacted]-10-07	184	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-14	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36043003005	ACUTE CARDIAC INSUFFICIENCY [急性心不全]	20[redacted]-10-18	195	LIFE THREATENING	YES	Results in Death	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-18	FATAL
AMG 416 + CINACALCET PLACEBO	20120360-36043003006	RIGHT ARM AND LEG NUMBNESS [感覚鈍麻]	20[redacted]-09-22	146	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION, OTHER	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36048001002	NECROSIS OF THE RIGHT FOOT [四肢壊死]	20[redacted]-08-19	148	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-20	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36048004001	OEDEMA OF THE RIGHT UPPER EXTREMITY - PROBABLY DUE TO PROBLEMS WITH A-V FISTULA [末梢性浮腫]	20[redacted]-04-17	44	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-28	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36048004001	STHENOSIS OF A-V FISTULA [動静脈瘻部位合併症]	20[redacted]-05-07	64	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-28	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36048004001	SIGNIFICANT INCREASE INR LEVEL (8,74) [国際標準比増加]	20[redacted]-07-21	139	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-07-31	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36048004001	METOCLOPRAMIDUM OVER DOSE [過量投与]	20[redacted]-07-24	142	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-07-31	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36048004001	NEUROLOGICAL SYMPTOMS NOS [神経学的症状]	20[redacted]-07-24	142	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-07-31	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36048004001	POLINEUROPATIA [多発ニューロパチー]	20[redacted]-07-24	142	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-07-31	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	PATHOLOGICAL FRACTURE OF HIP [病的骨折]	20[redacted]-06-18	183	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-27	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36048007001	SUDDEN DEATH- PATIENT DIED DURING SLEEP [突然死]	20[redacted]-06-27	192	LIFE THREATENING	YES	Results in Death	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-06-27	FATAL

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AMG 416 + CINACALCET PLACEBO	20120360-36048011004	GASTROINTESTINAL BLEEDING- DUODENITIS [出血性十二指腸炎]	20[redacted]-06-04	22	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-11	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36048011004	GASTROINTESTINAL BLEEDING- EROSIVE ESOPHAGITIS [出血性食道炎]	20[redacted]-06-04	22	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-11	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36048011004	HEMATOMA (LEFT ORBIT) [眼窩周囲血腫]	20[redacted]-07-14	62	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-21	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36049004003	ISCHEMIC STROKE [虚血性脳卒中]	20[redacted]-02-03	97	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-02-25	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36049004003	ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-03-02	124	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-03-10	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36049004003	ACUTE PULMONARY EDEMA [急性肺水腫]	20[redacted]-03-02	124	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER, OTHER	NOT RELATED	20[redacted]-03-10	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36051001007	GLAUCOMA SINGLE EYE [緑内障]	20[redacted]-04-08	41	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-15	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36051011009	PYELONEPHRITIS CHRONIC [慢性腎盂腎炎]	20[redacted]-07-10	136	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-08	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36051011013	EXACERBATION OF CHRONIC PANCREATITIS [慢性膵炎]	20[redacted]-09-03	127	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-06	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36051013003	CHRONIC PYELONEPHRITIS, WORSENING [慢性腎盂腎炎]	20[redacted]-07-03	135	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-07-17	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36051013008	GASTRO-INTESTINAL BLEEDING [胃腸出血]	20[redacted]-08-27	163	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-09-02	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36058004001	EXTERNAL HEMORRHOIDS WITHOUT MENTION OF COMPLICATION [痔核]	20[redacted]-07-13	118	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-15	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36058005003	AFASIA [失語症]	20[redacted]-05-05	118	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-13	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36058005003	HYPERTENSION AGGRAVATED [高血圧]	20[redacted]-05-05	118	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-13	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36058008001	AMIGDALAR INFECTION-PERITONSILLAR ABSCESS [扁桃周囲膿瘍]	20[redacted]-12-03	-24	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-12-08	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36058008002	ACUTE PANCREATITIS [急性膵炎]	20[redacted]-02-12	44	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-20	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36058008004	ACUTE GASTROENTERITIS [胃腸炎]	20[redacted]-06-04	133	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-06	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36058010002	REFRACTORY HYPERTENSION [高血圧]	20[redacted]-02-11	77	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-02-13	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36058012003	CHOLEDOCOLYTHIASIS [胆管結石]	20[redacted]-09-18	125	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-26	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36058012003	GASTRO INTESTINAL BLEEDING [胃腸出血]	20[redacted]-10-02	139	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-07	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36059004001	ABSCESS HEPATIC [肝膿瘍]	20[redacted]-02-13	28	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-04-14	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36059004001	INFECTION BACTERIAL [細菌感染]	20[redacted]-02-14	29	MODERATE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN, NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-02-19	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36059004001	AV FISTULA PUNCTURE SITE BLEEDING [動静脈瘻部位出血]	20[redacted]-05-16	120	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-05-19	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36059004001	AV FISTULA BLEEDING [動静脈瘻部位出血]	20[redacted]-06-15	150	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-06-16	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36059004002	FISTULA BLEEDING [動静脈瘻部位出血]	20[redacted]-10-01	184	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-06	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36060004001	PERM-A-CATH DISLOCATION [医療機器位置異常]	20[redacted]-03-24	-8	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	-	20[redacted]-03-29	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36060004001	THROMBOSIS OF V.GIUGULARIS INTERNA DESTRA [頚静脈血栓症]	20[redacted]-04-01	1	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	-	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36060004005	VERTIGINOUS SYNDROM [回転性めまい]	20[redacted]-07-14	77	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-16	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36060005001	ABDOMINAL PAIN NOS [腹痛]	20[redacted]-02-12	64	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, EMERGENCY ROOM VISIT	RELATED	20[redacted]-02-13	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36063011002	CATHETER INFECTION (BACTERIAL) [医療機器関連感染]	20[redacted]-08-06	90	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-15	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066001010	DIALYSIS CATHETER MALFUNCTION [医療機器機能不良]	20[redacted]-07-02	71	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-05	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36066001010	CARDIAC TAMONADE [心タンポナーデ]	20[redacted]-07-03	72	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-05	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066001010	INNOMINATE VEIN LACERATION [血管損傷]	20[redacted]-07-03	72	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-05	FATAL
AMG 416 + CINACALCET PLACEBO	20120360-36066001010	SEIZURE [痙攣]	20[redacted]-07-03	72	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-03	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066001010	BLOOD LOSS INTO CHEST SECONDARY TO INOMINATE VEIN LACERATION [血管損傷]	20[redacted]-07-04	73	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-07-05	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066010003	GASTROENTERITIS [胃腸炎]	20[redacted]-05-05	12	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-08	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36066013005	GANGRENOUS FOOT WOUND [壊疽]	20[redacted]-04-02	182	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-12 *	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066013007	PERIPHERAL VASCULAR DISEASE WITH GANGRENE [壊疽]	20[redacted]-12-03	58	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-03	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066029004	FEVER OF UNKNOWN ORIGIN [発熱]	20[redacted]-11-12	-92	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	-	20[redacted]-11-16	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066029004	ANEURYSM OF LEFT AV FISTULA [動静脈瘻瘤]	20[redacted]-04-10	58	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-16	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066034011	LEFT FOOT GANGRENE [壊疽]	20[redacted]-03-03	57	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-03-25	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066034019	VOLUME OVERLOAD [水分過負荷]	20[redacted]-07-19	174	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-22	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36066034026	VOLUME OVERLOAD [水分過負荷]	20[redacted]-04-16	17	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-18	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066040001	DIVERTICULOSIS [憩室]	20[redacted]-11-20	31	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-23	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066041006	HYPERCARBIC RESPIRATORY FAILURE [呼吸不全]	20[redacted]-05-21	99	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-22	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066041006	PULMONARY HYPERTENSION [肺高血圧症]	20[redacted]-05-21	99	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-05-22	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066041006	WEAKNESS [無力症]	20[redacted]-06-25	134	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-07-01	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066041006	WORSENING OF HYPOTHYROIDISM [甲状腺機能低下症]	20[redacted]-06-25	134	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-01	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36066048002	1. DIZZINESS [浮動性めまい]	20[redacted]-05-17	90	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	RELATED	20[redacted]-05-18	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066056006	CHEST PAIN - CARDIAC [狭心症]	20[redacted]-12-06 *	-24	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, EMERGENCY ROOM VISIT	-	20[redacted]-12-12 *	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066056006	GANGRENE RIGHT FOOT [壊疽]	20[redacted]-06-15 *	168	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-19 *	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066056006	RIGHT BELOW THE KNEE AMPUTATION DEHISCENCE [創離開]	20[redacted]-07-14	197	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-18	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066056011	LEFT AKA STUMP WOUND PAIN [断端痛]	20[redacted]-08-20	169	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-08-28	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36066059001	HEMATEMESIS [吐血]	20[redacted]-05-27	113	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-05-30	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066059008	RECTAL BLEEDING (EXCL GUT HAEMORRHAGE AND PILES) [直腸出血]	20[redacted]-09-27	160	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-01	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066059008	HEMORRHOID BLEEDING FRICTION RUB [痔出血]	20[redacted]-10-02	165	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-04	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066059015	INFECTED DIABETIC FOOT ULCER [糖尿病性足感染]	20[redacted]-09-17	149	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066069002	INFLUENZA A VIRUS INFECTION [インフルエンザ]	20[redacted]-03-26	-26	SEVERE	YES	Requires or Prolongs Hospitalization	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-04-04	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066069002	PULMONARY EMBOLISM [肺塞栓症]	20[redacted]-03-26	-26	SEVERE	YES	Requires or Prolongs Hospitalization	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	-	20[redacted]-04-04	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36066069007	UTERINE FIBROID [子宮平滑筋腫]	20[redacted]-08-06	122	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-07	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066069010	DEPRESSION WITH SUICIDAL IDEATION [希死念慮を有するうつ病]	20[redacted]-06-18	45	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-23	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066073001	DIABETIC GASTROPARESIS [糖尿病性胃不全麻痺]	20[redacted]-03-24	18	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-04-04	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066073001	ELEVATED LIVER ENZYME LEVELS OF UNCLEAR ETIOLOGY [肝酵素上昇]	20[redacted]-03-24	18	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-04-04	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066073001	UNCONTROLLED TYPE 1 DIABETES WITH DIABETIC KETOACIDOSIS [糖尿病性ケトアシドーシス]	20[redacted]-03-24	18	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-04	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066073004	WORSENING HYPOTENSION [低血圧]	20[redacted]-06-19	74	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-22	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066075014	LEFT SUBCLAVIAN VEIN THROMBOSIS [鎖骨下静脈血栓症]	20[redacted]-09-04	134	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	UNKNOWN

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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 + CINACALCET PLACEBO	20120360-36066075014	RIGHT CANCEROUS LUNG MASS [肺の悪性新生物]	20[redacted]-09-04	134	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	-	UNKNOWN
AMG 416 + CINACALCET PLACEBO	20120360-36066075014	SUPERIOR VENA CAVA SYNDROME [上大静脈症候群]	20[redacted]-09-04	134	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	UNKNOWN
AMG 416 + CINACALCET PLACEBO	20120360-36066078003	VOMITING [嘔吐]	20[redacted]-04-21	48	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-25	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066078003	EMESIS NON BLOODY [嘔吐]	20[redacted]-05-05	62	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-10	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083002	HYPEROSMOTIC HYPERGLYCEMIC SYNDROME [高浸透圧をともなう糖尿病]	20[redacted]-06-02	56	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-04	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083002	OSTEOMYELITIS OF THE RIGHT FOOT [骨髄炎]	20[redacted]-06-02	56	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-04	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083002	OSTEOMYELITIS RIGHT FOOT [骨髄炎]	20[redacted]-07-04	88	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-07-07	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36066083002	NON HEALING WOUND RIGHT FOOT [治癒不良]	20[redacted]-09-12	158	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-17	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083002	OSTEOMYELITIS [骨髄炎]	20[redacted]-09-24	170	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-15	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	ACUTE RESPIRATORY FAILURE [急性呼吸不全]	20[redacted]-05-08	25	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-08	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	RESPIRATORY ARREST [呼吸停止]	20[redacted]-05-08	25	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-06-26	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	CARDIAC ARREST TRANSIENT [心停止]	20[redacted]-05-09	26	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-05-09	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	COMA (NON-DIABETIC) [昏睡]	20[redacted]-05-09	26	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-05-13	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	KLIEBSIELLA PNEUMONIA [クレブシエラ菌性肺炎]	20[redacted]-05-12	29	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-24	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36066083004	HYPOTENSION [低血圧]	20[redacted]-07-10	88	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-12	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	END STAGE RENAL DISEASE [慢性腎不全]	20[redacted]-07-28	106	LIFE THREATENING	YES	Results in Death	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-07-28	FATAL
CINACALCET + AMG 416 PLACEBO	20120360-36012002002	URINARY BLADDER TUMOR [膀胱新生物]	20[redacted]-03-17	57	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-19	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36013001002	OPTIC NEURITIS [視神経炎]	20[redacted]-04-21	155	SEVERE	YES	Persist or Signif Disability/Incapacity	DRUG WITHDRAWN	OTHER, OTHER	RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36013002001	DECREASED CONSCIOUSNESS/HYPERSOMNOLENCE [傾眠]	20[redacted]-02-27	3	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-03-06	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36013004001	INVASIVE CARCINOMA PHARYNX [咽頭癌]	20[redacted]-04-28	48	SEVERE	YES	Persist or Signif Disability/Incapacity	DRUG WITHDRAWN	OTHER	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36016003004	CHEST PAIN - CARDIAC [狭心症]	20[redacted]-01-26	20	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER, OTHER	NOT RELATED	20[redacted]-01-29	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36025008001	PLACENTAL HEMORRHAGE [妊娠時出血]	20[redacted]-10-26	185	MODERATE	YES	Congenital Anomaly or Birth Defect	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-28	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36026001001	HYPERTENSIVE CRISIS [高血圧クリーゼ]	20[redacted]-05-04	-4	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-05-07	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36026001001	PROLONGED BLEEDING AFTER ROOT RESECTION OF TOOTH [処置後出血]	20[redacted]-07-16	70	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-17	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36026001001	PROLONGED BLEEDING AFTER ROOT RESECTION OF TOOTH [処置後出血]	20[redacted]-08-01	86	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-08-04	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36026001002	ILIAC VEIN STENOSIS [静脈狭窄]	20[redacted]-06-17	41	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-05	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36026001005	SCROTAL HERNIA [陰嚢ヘルニア]	20[redacted]-05-21	22	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-04	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36026003004	SPONTANEOUS FRACTURE LEFT HIP [病的骨折]	20[redacted]-04-22	8	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-16	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36026015001	WORSENING VENOUS ANASTOMOSIS STENOSIS [静脈狭窄]	20[redacted]-07-30	127	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-08-01	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36027002004	ARTERIOVENOUS GRAFT THROMBOSIS [血管グラフト血栓症]	20[redacted]-07-03	163	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-07	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36027002006	DIARRHEA [下痢]	20[redacted]-09-05	136	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-08	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36027007001	CYSTITIS [膀胱炎]	20[redacted]-02-23	124	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-02-24	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36027007003	FEVER [発熱]	20[redacted]-10-21	-30	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	-	20[redacted]-10-22	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36027007003	FEVER [発熱]	20[redacted]-11-01	-19	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-11-04	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36027007003	PAIN IN THE RIGHT HIP DUE DEGENERATIVE OSTEOARTHRITIS [変形性関節症]	20[redacted]-12-08 *	19	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-13 *	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36027007003	RIGHT HIP OSTEOARTHRITIS [変形性関節症]	20[redacted]-01-06 *	48	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-08 *	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36027007003	HIP OSTEOARTHRITIS [変形性関節症]	20[redacted]-01-12	54	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-31	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36027008004	ASEPTIC NECROSIS OF FEMUR HEAD [骨壊死]	20[redacted]-04-12	33	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-04-24	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36029006002	WORSENING OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE [慢性閉塞性肺疾患]	20[redacted]-10-24	200	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36029010009	PHLEGMONE OF LEFT FOOT [蜂巣炎]	20[redacted]-11-13	205	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-21	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36029011002	FEMORAL FRACTURE LEFT SIDED [大腿骨骨折]	20[redacted]-05-29	81	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-07	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36029011002	ANAEMIA [貧血]	20[redacted]-06-13	96	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, OTHER	NOT RELATED	20[redacted]-06-16	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36029011004	DEPRESSION [うつ病]	20[redacted]-11-07	200	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-15	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36029011005	ACUTE BRONCHITIS [気管支炎]	20[redacted]-11-18	204	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-27	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36029012005	RIGHT FEMORAL FRACTURE [大腿骨骨折]	20[redacted]-05-22	64	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-08-12	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36029012005	ANAEMIA REQIUING TRANSFUSION [貧血]	20[redacted]-07-10	113	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-07-15	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36029012013	HYPERTENISON [高血圧]	20[redacted]-07-08	86	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-20	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36033005003	STENOSIS OF VASCULAR ACCESS [血管確保合併症]	20[redacted]-05-20	43	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-07-16	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36033005003	STENOSIS OF VASCULAR ACCESS [血管確保合併症]	20[redacted]-09-20	166	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-10-01	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36033006001	BRACHIOCEPHALIC VEIN STENOSIS [腕頭静脈狭窄]	20[redacted]-04-10	116	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-05-01	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36033006001	SOPOR [昏眠]	20[redacted]-05-23	159	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-05-28	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36033006004	BRACHIOCEPHALIC VEIN STENOSIS [腕頭静脈狭窄]	20[redacted]-08-14	183	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-08-16	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36033011003	HYPERTENSIVE CRISIS [高血圧クリーゼ]	20[redacted]-03-29	26	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-31	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36033011003	ARTERO-VENOUS CEREBRAL MALFORMATION [脳血管動静脈奇形]	20[redacted]-04-02	30	MILD	YES	Congenital Anomaly or Birth Defect, Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-15	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36033011003	COLONOSCOPY UNDER ANESTHESIA FOR INSERTING IN TRANSPLANTATION WAITING LIST [結腸内視鏡検査]	20[redacted]-09-16	197	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-09-18	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36033011004	LEFT FEMUR FRACTURE [大腿骨骨折]	20[redacted]-06-30	98	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-30	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36035004001	SPONTAN INTRACEREBRAL HAEMORRHAGIA [脳出血]	20[redacted]-02-25	9	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-25	FATAL
CINACALCET + AMG 416 PLACEBO	20120360-36036002003	WORSENING OF ANEMIA [貧血]	20[redacted]-03-02	33	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-05-23	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36036002003	WORSENING OF ANEMIA [貧血]	20[redacted]-07-04	157	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-08-06	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36036002003	ACUTE TUBULO-INTERSTITIAL NEPHRITIS [尿細管間質性腎炎]	20[redacted]-08-19	203	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-12	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36036004004	BRONCHITIS [気管支炎]	20[redacted]-03-15	32	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-03-21	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36036004004	PLEURITIS [胸膜炎]	20[redacted]-05-02	80	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-05-12	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36036004004	PYELONEPHRITIS CHRONIC EXACERBATA [慢性腎盂腎炎]	20[redacted]-06-11	120	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-06-23	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36036005003	ANGINA PECTORIS UNSTABLE [不安定狭心症]	20[redacted]-08-07	148	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36036008003	CALCULUS KIDNEY [腎結石症]	20[redacted]-04-22	106	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-06	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36036008003	THROMBOSIS A-V FISTULAE [動静脈瘻血栓症]	20[redacted]-04-23	107	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-05-14	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36043001001	LEFT PYELONEPHRITIS [腎盂腎炎]	20[redacted]-07-12	116	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-24	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36043002001	CARDIAC ARREST [心停止]	20[redacted]-06-18	51	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-07-30	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36043003002	INFECTED LEG WOUND [創傷感染]	20[redacted]-07-07	146	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-08-11	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36043003003	BILARY COLIC [胆道仙痛]	20[redacted]-03-27	2	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-05-11	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36043003003	ACUTE CHOLECYSTITIS [急性胆嚢炎]	20[redacted]-04-14	20	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-17	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36043003003	BILARY COLIC [胆道仙痛]	20[redacted]-05-12	48	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-03	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36048003001	BLEEDING MENSTRUAL HEAVY [月経過多]	20[redacted]-04-01	-22	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	-	20[redacted]-04-09	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36048003001	CATHETER ACCESS PORT ISSUE [医療機器の問題]	20[redacted]-04-20	-3	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-05-09	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36048003003	HYPERKALEMIA [高カリウム血症]	20[redacted]-06-13	32	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-17	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36048003003	BRONCHITIS ACUTE [気管支炎]	20[redacted]-11-02	174	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-22	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36048010001	ATRIAL FIBRILLATION PAROXYSMAL [心房細動]	20[redacted]-09-01	111	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-05	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36048010001	CORONAROPATHY [冠動脈疾患]	20[redacted]-10-14	154	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36048010003	EPISTAXIS [鼻出血]	20[redacted]-12-09	209	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-14	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36049001002	CARDIAC ARREST [心停止]	20[redacted]-08-21	198	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-06	FATAL

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CINACALCET + AMG 416 PLACEBO	20120360-36049004010	SEPTICEMIA DUE TO GRAM-NEGATIVE ORGANISM, UNSPECIFIED [細菌性敗血症]	20[redacted]-05-27	97	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-11	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36049004010	SEVERE EXTERIORIZATION OF CENTRAL VENOUS CATHETER [医療機器合併症]	20[redacted]-08-11	173	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-18	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36049004010	RETROPERITONEAL HEMORRAGIA [後腹膜出血]	20[redacted]-08-12	174	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-18	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36049007005	LACUNAR INFARCTION [ラクナ梗塞]	20[redacted]-06-24	190	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051001011	ENCEPHALOPATHY [脳症]	20[redacted]-10-08	197	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-23	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051002011	ARTERIOVENISIS FISTULA TROMBOSIS [動静脈瘻血栓症]	20[redacted]-02-25	-21	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-03-14	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051002011	PHLEGMON OF THE LEFT SHOULDER [蜂巣炎]	20[redacted]-07-06	111	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-22	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36051002011	INADEQUATE HAEMODIALYSIS BLOOD FLOW [血液透析合併症]	20[redacted]-08-06	142	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-08-29	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051002011	TUNNELING CATHETER INFECTION. CATHETER INFECTION [医療機器関連感染]	20[redacted]-09-10	177	LIFE THREATENING	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051002012	DYSFUNCTION OF ARTERIOVENOUS FISTULA [動静脈瘻部位合併症]	20[redacted]-10-27	183	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-29	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051002013	UPPER GASTROINTESTINAL BLEEDING [上部消化管出血]	20[redacted]-09-19	152	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-10-08	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051005002	APPENDICITIS [虫垂炎]	20[redacted]-06-09	146	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-29	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051005002	ATHEROSCLEROSIS WITH LESIONS OF THE PARIETAL BRANCHES OF THE ABDOMINAL AORTA [大動脈硬化症]	20[redacted]-06-09	146	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051005002	NECROSIS PLOT CECUM [消化管壊死]	20[redacted]-06-09	146	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-29	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051005002	PERITONITIS [腹膜炎]	20[redacted]-06-09	146	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-29	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36051005002	SEGMENTAL BRANCHES THROMBOSIS A.ILIOCOLICA [動脈血栓症]	20[redacted]-06-09	146	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-29	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051005002	SUTURE FAILURE OF THE COLON WITH THE TRANSFORMATION INTO A FUNCTIONING EXTERNAL FISTULA COLON [処置後瘻孔]	20[redacted]-06-15	152	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-29	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051007002	THROMBOSIS VASCULAR ACCESS [血管確保合併症]	20[redacted]-08-25	126	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-12	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051007042	INSUFFICIENT FUNCTION OF VASCULAR ACCESS [血管確保合併症]	20[redacted]-05-12	18	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-02	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051011005	MENSTRUAL DISORDER NOS/HYSTEROMYOMA [子宮平滑筋腫]	20[redacted]-02-17	11	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-21	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36051012007	ACUTE CORONARY SYNDROME [急性冠動脈症候群]	20[redacted]-05-02	75	LIFE THREATENING	YES	Results in Death	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-05-02	FATAL
CINACALCET + AMG 416 PLACEBO	20120360-36051013001	ARTERIOVENOUS FISTULA STENOSIS [動静脈瘻部位合併症]	20[redacted]-03-26	37	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-01	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36058003003	URINARY TRACT INFECTION BACTERIAL [細菌性尿路感染]	20[redacted]-12-20	-47	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN, NON-IV ANTIMICROBIAL TAKEN	-	20[redacted]-12-27	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
CINACALCET + AMG 416 PLACEBO	20120360-36058003003	PERFORATED COLON [大腸穿孔]	20[redacted]-02-11	7	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-02-21	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36059002001	SEPSIS [敗血症]	20[redacted]-06-22	118	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-07-04	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36060003001	CARDIAC ARREST [心停止]	20[redacted]-05-28	92	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-06-23	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36060003002	SEVERE HYPOPHOSPHATEMIA [低リン酸血症]	20[redacted]-05-15	80	SEVERE	YES	Other Medically Important Serious Event	DRUG INTERRUPTED	MEDICATION TAKEN	RELATED	20[redacted]-06-05	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36060009005	BRONCHOPNEUMONIA [気管支肺炎]	20[redacted]-08-16	145	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-08-23	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36060009005	STEMI [急性心筋梗塞]	20[redacted]-10-23	213	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-23	FATAL

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CINACALCET + AMG 416 PLACEBO	20120360-36063001001	FEVER DUE TO CATHETER RELATED INFECTION [医療機器関連感染]	20[redacted]-06-21	94	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-22	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36063001001	MIXED SENSORIMOTOR POLYNEUROPATHY [末梢性感覚運動ニューロパチー]	20[redacted]-09-02	167	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-11	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36063001001	ILEUS [イレウス]	20[redacted]-09-04	169	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-08	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36063001001	MIXED SENSORIMOTOR POLYNEUROPATHY [末梢性感覚運動ニューロパチー]	20[redacted]-09-11	176	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36063001003	FOOT DEFORMITY [足変形]	20[redacted]-07-08	65	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36063001003	PERIPHERAL ARTERIAL DISEASE [末梢動脈閉塞性疾患]	20[redacted]-07-08	65	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-10	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36063001003	CALCIPHYLAXIS [カルシフィラキシス]	20[redacted]-08-06	94	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-10	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36063001003	NECROTIC LESIONS ON FOOT [四肢壊死]	20[redacted]-08-06	94	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-08-10	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36063001003	SEPSIS [敗血症]	20[redacted]-08-08	96	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]-08-10	FATAL
CINACALCET + AMG 416 PLACEBO	20120360-36063001006	FOOT DEFORMITY [足変形]	20[redacted]-07-09	65	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-15	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36063002007	HYPERTENSION [高血圧]	20[redacted]-04-16	-22	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-04-25	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36063005002	HEMORRHOIDS [痔核]	20[redacted]-07-18	73	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-22	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066001009	HEMORRHAGE FROM AV GRAFT [動静脈グラフト部位出血]	20[redacted]-10-27	174	LIFE THREATENING	YES	Results in Death	DRUG INTERRUPTED	MEDICATION TAKEN, EMERGENCY ROOM VISIT, OTHER	NOT RELATED	20[redacted]-10-27	FATAL
CINACALCET + AMG 416 PLACEBO	20120360-36066004005	LOWER EXTREMITIES WEAKNESS [筋力低下]	20[redacted]-08-31	194	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-09-20	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36066010001	SEPSIS [敗血症]	20[redacted]-12-27	-24	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]*-01-09	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066010001	POSSIBLE CATHETER LINE SEPSIS [医療機器関連敗血症]	20[redacted]*-03-26	66	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]*-03-28	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066012002	ENCEPHALOPATHY [脳症]	20[redacted]-02-05	-12	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	-	20[redacted]-02-06	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066012004	PSYCHOSIS [精神病性障害]	20[redacted]-07-10	65	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-12	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066013017	FLUID OVERLOAD [水分過負荷]	20[redacted]-01-22	71	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-25	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066025001	ABDOMINAL ASCITES/DISTENSION [腹水]	20[redacted]-11-25	84	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-11-26	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066025001	HYPERKALEMIA [高カリウム血症]	20[redacted]-11-25	84	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-11-26	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36066025001	RAPID ATRIAL FIBRILLATION ON DIALYSIS WITH RVR [心房細動]	20[redacted]-11-25	84	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-11-26	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066025001	VOMITING [嘔吐]	20[redacted]-11-25	84	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-11-25	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066025001	WORSENING OF HYPERTENSION [高血圧]	20[redacted]-11-25	84	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-11-26	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066025001	GASTROPARESIS [胃排出不全]	20[redacted]-11-26	85	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-12-09	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066025001	RIGHT SIDED HYDRONEPHROSIS [水腎症]	20[redacted]-11-26	85	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-12-09	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066025001	SEPSIS [敗血症]	20[redacted]-11-26	85	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-12-09	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066025001	URINARY TRACT INFECTION [尿路感染]	20[redacted]-11-26	85	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-12-09	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36066029006	LEFT LEG PAIN [四肢痛]	20[redacted]-07-25	155	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-27	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066029007	ECCHYMOSIS OF LEFT ARM [斑状出血]	20[redacted]-04-30	77	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-16	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-06-17	76	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-24	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	GANGRENOUS CHOLECYSTITIS [感染性胆嚢炎]	20[redacted]-06-24	83	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-26	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	RESPIRATORY FAILURE [呼吸不全]	20[redacted]-06-24	83	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	INTRAABDOMINAL ABSCESS [腹部膿瘍]	20[redacted]-07-05	94	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	ASPIRATION PNEUMONIA [誤嚥性肺炎]	20[redacted]-07-22	111	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36066031005	PERIHEPATIC ABCESS [肝周囲膿瘍]	20[redacted]-08-08	128	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	STERNAL WOUND INFRECTION [創傷感染]	20[redacted]-08-08	128	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	ACUTE DEEP VEIN THROMBOSIS [深部静脈血栓症]	20[redacted]-09-24	175	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066034014	PAIN RIGHT UPPER QUADRANT [上腹部痛]	20[redacted]-03-22	60	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-25	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066034018	CEREBRAL VASCULAR ACCIDENT [脳血管発作]	20[redacted]-05-30	124	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-31	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066034027	INCREASED SHORTNESS OF BREATH [呼吸困難]	20[redacted]-06-26	88	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-30	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066034027	URINARY TRACT INFECTION [尿路感染]	20[redacted]-07-03	95	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-05	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066034027	SEIZURES [痙攣]	20[redacted]-08-17	140	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	RELATED	20[redacted]-08-26	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36066056001	CHEST PAIN (NON-CARDIAC) [非心臓性胸痛]	20[redacted]-01-09	38	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-11	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066056001	CHEST PAIN (NON-CARDIAC) [非心臓性胸痛]	20[redacted]-02-11	71	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-02-15	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066056001	SEVERE HYPERKALEMIA [高カリウム血症]	20[redacted]-06-08	188	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-09	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066056004	PNEUMONIA [肺炎]	20[redacted]-07-10	206	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-07-16	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066056007	DIALYSIS CATHETER OBSTRUCTION IN RIGHT ARM [医療機器閉塞]	20[redacted]-05-28	107	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-06-01	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066059004	HIP FRACTURE [股関節部骨折]	20[redacted]-01-10	-33	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	-	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	-	20[redacted]-02-01	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066059004	ALTERED LEVEL OF CONSCIOUSNESS [意識変容状態]	20[redacted]-03-31	48	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-03	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
CINACALCET + AMG 416 PLACEBO	20120360-36066059009	CLOTTED DIALYSIS ACCESS [血管グラフト血栓症]	20[redacted]-06-09	50	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-13	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066059009	HYPERKALEMIA [高カリウム血症]	20[redacted]-06-09	50	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-13	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066059010	UNSTABLE ANGINA [不安定狭心症]	20[redacted]-05-21	17	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-24	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066059011	ALTERED LEVEL OF CONSCIOUSNESS [意識変容状態]	20[redacted]-05-19	15	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-21	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066059013	TORN PATELLAR LIGAMENT [靭帯断裂]	20[redacted]-05-01	10	MILD	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-05	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066059017	HYPERKALEMIA [高カリウム血症]	20[redacted]-08-11	105	MILD	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-15	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066059020	LOW SERUM CALCIUM [血中カルシウム減少]	20[redacted]-10-05	154	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-10-07	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066059024	STUMP INFECTION IN LOWER EXTREMITY [術後創感染]	20[redacted]-07-03	59	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066069005	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-04-27	21	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-30	RECOVERED/RESOLVED

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CINACALCET + AMG 416 PLACEBO	20120360-36066069005	MITRAL VALVE DISEASE [僧帽弁疾患]	20[redacted]-04-27	21	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-30	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066075004	VERTIGO [回転性めまい]	20[redacted]-03-22	65	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-24	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066075013	BLEEDING LEFT UPPER EXTREMITY ARTERIOVENOUS GRAFT [動静脈グラフト部位出血]	20[redacted]-07-14	92	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-16	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066086003	GASTROENTERITIS [胃腸炎]	20[redacted]-06-07	31	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-08	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066086003	ACUTE PYELONEPHRITIS [急性腎盂腎炎]	20[redacted]-06-23	47	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-29	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066088004	LOWER EXTREMITY PAIN, LEFT [四肢痛]	20[redacted]-11-09	181	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-14	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066088004	GANGRENE OF LEFT FOOT [壊疽]	20[redacted]-12-10	212	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-12-22	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
CINACALCET + AMG 416 PLACEBO	20120360-36066088006	WEAKNESS GENERALIZED [無力症]	20[redacted]-11-14	204	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-06	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066092007	CEREBRAL INFARCTION [脳梗塞]	20[redacted]-08-25	155	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-08-27	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066092007	LEFT HEMIPARESIS [不全片麻痺]	20[redacted]-08-27	157	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-05	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066092016	CLOTTED LEFT ARTERIOVENOUS GRAFT [血管グラフト血栓症]	20[redacted]-09-30	167	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-05	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066092017	WORSENING OF ANEMIA [貧血]	20[redacted]-11-25	211	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-05	RECOVERED/RESOLVED
UNPLANNED TREATMENT	20120360-36035002002	PERIPHERAL ARTERIAL OCCLUSIVE DISEASE AGGRAVATED [末梢動脈閉塞性疾患]	20[redacted]-03-29	12	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-26	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
UNPLANNED TREATMENT	20120360-36035002002	DECOMPENSATED HEART FAILURE [心不全]	20[redacted]-04-30	44	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG INTERRUPTED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-03	FATAL
UNPLANNED TREATMENT	20120360-36049001003	CEREBRAL INFARCTION [脳梗塞]	20[redacted]-07-03	149	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-25	RECOVERED/RESOLVED
UNPLANNED TREATMENT	20120360-36049005002	ISCHEMIA CORONARY ARTERY ORIGIN [心筋虚血]	20[redacted]-01-02	24	LIFE THREATENING	YES	Results in Death	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-01-02	FATAL
UNPLANNED TREATMENT	20120360-36051002009	ISCHEMIC STROKE [虚血性脳卒中]	20[redacted]-03-28	4	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-02	RECOVERED/RESOLVED
UNPLANNED TREATMENT	20120360-36051002009	OSTEOARTHRITIS OF THE SECOND METATARSOPHALANGEAL JOINT [変形性関節症]	20[redacted]-03-28	4	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-02	RECOVERED/RESOLVED
UNPLANNED TREATMENT	20120360-36051002009	OSTEOMYELITIS NAIL PHALANX OF THE SECOND FINGER OF THE RIGHT FOOT [骨髄炎]	20[redacted]-03-28	4	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-02	RECOVERED/RESOLVED
UNPLANNED TREATMENT	20120360-36051002009	PHLEGMON OF PLANTAR SURFACE OF THE RIGHT FOOT [蜂巣炎]	20[redacted]-03-28	4	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-02	RECOVERED/RESOLVED

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UNPLANNED TREATMENT	20120360-36051002009	SEPSIS [敗血症]	20[redacted]-03-28	4	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG INTERRUPTED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-02	RECOVERED/RESOLVED
UNPLANNED TREATMENT	20120360-36051002009	ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-04-01	8	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DRUG INTERRUPTED	NO ACTION TAKEN	NOT RELATED	20[redacted]-04-02	FATAL

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

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表 2.7.6.17-20　投与中止に至った有害事象の一覧表（20120360 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 + CINACALCET PLACEBO	20120360-36021006001	PNEUMOTHORAX IATROGENIC ON THE RIGHT SIDE [外傷性気胸]	20[redacted]-08-18	166	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36021007006	TABLET IN VOMITUS [嘔吐]	20[redacted]-07-09	66	SEVERE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-07-14	-
AMG 416 + CINACALCET PLACEBO	20120360-36022007007	CALCIPHYLAXIS [カルシフィラキシス]	20[redacted]-06-18	44	SEVERE	YES	Persist or Signif Disability/Incapacity	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	20[redacted]-06-24	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36025012001	NAUSEA AGGRAVATION [悪心]	20[redacted]-07-24	127	MODERATE	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36025012001	VOMITING AGGRAVATION [嘔吐]	20[redacted]-07-24	127	MODERATE	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36048001002	NECROSIS OF THE RIGHT FOOT [四肢壊死]	20[redacted]-08-19	148	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-20	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36048011004	GASTROINTESTINAL BLEEDING- DUODENITIS [出血性十二指腸炎]	20[redacted]-06-04	22	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-11	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36048011004	GASTROINTESTINAL BLEEDING- EROSIVE ESOPHAGITIS [出血性食道炎]	20[redacted]-06-04	22	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-11	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36049009001	VOMITING [嘔吐]	20[redacted]-12-06	36	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-02-11*	-
AMG 416 + CINACALCET PLACEBO	20120360-36051004010	BRONCHOSPASM [気管支痙攣]	20[redacted]-06-26	115	MODERATE	NO	-	DRUG WITHDRAWN	OTHER	RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36051011008	NAUSEA [悪心]	20[redacted]-03-11	6	SEVERE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-04-08	-
AMG 416 + CINACALCET PLACEBO	20120360-36066001010	SEVERE MUSCLE WEAKNESS [筋力低下]	20[redacted]-06-16	55	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-06-18	-
AMG 416 + CINACALCET PLACEBO	20120360-36066029004	SOMNOLENCE [傾眠]	20[redacted]-07-07	146	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-10	-
AMG 416 + CINACALCET PLACEBO	20120360-36066034011	LEFT FOOT GANGRENE [壊疽]	20[redacted]-03-03	57	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-03-25	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36066073001	ELEVATED LIVER ENZYME LEVELS OF UNCLEAR ETIOLOGY [肝酵素上昇]	20[redacted]-03-24	18	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-04-04	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066073002	DERMATITIS [皮膚炎]	20[redacted]-06-20	131	MODERATE	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36066073003	DERMATITIS [皮膚炎]	20[redacted]-05-20	89	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	-	-
AMG 416 + CINACALCET PLACEBO	20120360-36066075014	WEIGHT LOSS [体重減少]	20[redacted]-06-28	66	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-09-12	-
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	CARDIAC ARREST TRANSIENT [心停止]	20[redacted]-05-09	26	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-05-09	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	COMA (NON-DIABETIC) [昏睡]	20[redacted]-05-09	26	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-05-13	RECOVERED/RESOLVED
AMG 416 + CINACALCET PLACEBO	20120360-36066083004	KLIEBSIELLA PNEUMONIA [クレブシエラ菌性肺炎]	20[redacted]-05-12	29	MODERATE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-24	RECOVERED/RESOLVED

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AMG 416 + CINACALCET PLACEBO	20120360-36066083004	END STAGE RENAL DISEASE [慢性腎不全]	20[redacted]-07-28	106	LIFE THREATENING	YES	Results in Death	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-07-28	FATAL
AMG 416 + CINACALCET PLACEBO	20120360-36066088003	FEELING FUNNY [異常感]	20[redacted]-08-02	96	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-08-07	-
CINACALCET + AMG 416 PLACEBO	20120360-36012003003	NAUSEA [悪心]	20[redacted]-07-17	122	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-08-05	-
CINACALCET + AMG 416 PLACEBO	20120360-36012007001	EMESIS [嘔吐]	20[redacted]-05-21	22	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-06-20	-
CINACALCET + AMG 416 PLACEBO	20120360-36013001002	OPTIC NEURITIS [視神経炎]	20[redacted]-04-21	155	SEVERE	YES	Persist or Signif Disability/Incapacity	DRUG WITHDRAWN	OTHER, OTHER	RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36013004001	INVASIVE CARCINOMA PHARYNX [咽頭癌]	20[redacted]-04-28	48	SEVERE	YES	Persist or Signif Disability/Incapacity	DRUG WITHDRAWN	OTHER	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36013004001	LOW SERUM CALCIUM [血中カルシウム減少]	20[redacted]-05-10	60	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-06-10	-
CINACALCET + AMG 416 PLACEBO	20120360-36025008001	PREGNANCY [妊娠]	20[redacted]-07-29	96	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-28	-
CINACALCET + AMG 416 PLACEBO	20120360-36025008001	PLACENTAL HEMORRHAGE [妊娠時出血]	20[redacted]-10-26	185	MODERATE	YES	Congenital Anomaly or Birth Defect	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-28	RECOVERED/RESOLVED

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＊＊　：「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
CINACALCET + AMG 416 PLACEBO	20120360-36026003001	DAILY DIARRHEA [下痢]	20[redacted]-05-19	50	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-05-25	-
CINACALCET + AMG 416 PLACEBO	20120360-36036001005	NAUSEA [悪心]	20[redacted]-06-11	127	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-06-25	-
CINACALCET + AMG 416 PLACEBO	20120360-36043002001	CARDIAC ARREST [心停止]	20[redacted]-06-18	51	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-07-30	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36043002001	MUSCULOSKELETAL CHEST PAIN [筋骨格系胸痛]	20[redacted]-06-19	52	MODERATE	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	20[redacted]-08-30	-
CINACALCET + AMG 416 PLACEBO	20120360-36043002001	PNEUMONIA [肺炎]	20[redacted]-06-22	55	MODERATE	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	20[redacted]-06-26	-
CINACALCET + AMG 416 PLACEBO	20120360-36043002001	URINARY TRACT INFECTION [尿路感染]	20[redacted]-06-22	55	MILD	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	20[redacted]-06-22	-
CINACALCET + AMG 416 PLACEBO	20120360-36043002001	ATRIAL FIBRILLATION [心房細動]	20[redacted]-07-03	66	MODERATE	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	20[redacted]-07-03	-
CINACALCET + AMG 416 PLACEBO	20120360-36048009001	ABDOMINAL PAIN [腹痛]	20[redacted]-01-20	18	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-01-22	-
CINACALCET + AMG 416 PLACEBO	20120360-36048009001	APPETITE DECREASED NOS [食欲減退]	20[redacted]-01-20	18	SEVERE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-01-22	-

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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
CINACALCET + AMG 416 PLACEBO	20120360-36048009001	NAUSEA [悪心]	20[redacted]-01-20	18	SEVERE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-01-22	-
CINACALCET + AMG 416 PLACEBO	20120360-36049005006	EPIGASTRIC PAIN [上腹部痛]	20[redacted]-02-17	6	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	-	-
CINACALCET + AMG 416 PLACEBO	20120360-36060003001	CARDIAC ARREST [心停止]	20[redacted]-05-28	92	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-06-23	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36060003002	HYPOPHOSPHATEMIA [低リン酸血症]	20[redacted]-07-01	127	MODERATE	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	RELATED	20[redacted]-07-10	-
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	DIARRHEA [下痢]	20[redacted]-06-20	79	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-06-20	-
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	GANGRENOUS CHOLECYSTITIS [感染性胆嚢炎]	20[redacted]-06-24	83	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-26	RECOVERED/RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	RESPIRATORY FAILURE [呼吸不全]	20[redacted]-06-24	83	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	LIVER CIRRHOSIS [肝硬変]	20[redacted]-06-26	85	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-16	-

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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
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	GALLBLADDER FOSSA HEMATOMA [血性胆汁]	20[redacted]-07-02	91	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-16	-
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	HYPOKALEMIA [低カリウム血症]	20[redacted]-07-03	92	MODERATE	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	20[redacted]-10-16	-
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	INTRAABDOMINAL ABSCESS [腹部膿瘍]	20[redacted]-07-05	94	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	PLEURAL EFFUSION [胸水]	20[redacted]-07-10	99	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-16	-
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	ASPIRATION PNEUMONIA [誤嚥性肺炎]	20[redacted]-07-22	111	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	THROMBOCYTOPENIA [血小板減少症]	20[redacted]-08-01	121	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-16	-
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	CLOSTRIDIUM DIFFICILE DIARRHEA [クロストリジウム・ディフィシレ大腸炎]	20[redacted]-08-08	128	SEVERE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	-	-
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	PERIHEPATIC ABCESS [肝周囲膿瘍]	20[redacted]-08-08	128	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	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
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	STERNAL WOUND INFECTION [創傷感染]	20[redacted]-08-08	128	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	STERNAL OSTEOMYELITIS [骨髄炎]	20[redacted]-08-11	131	MODERATE	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	-	-
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	ADRENAL INSUFFICIENCY [副腎機能不全]	20[redacted]-09-08	159	MODERATE	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	-	-
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	LEFT THIGH WOUND INFECTION [創傷感染]	20[redacted]-09-08	159	MODERATE	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	NOT RELATED	-	-
CINACALCET + AMG 416 PLACEBO	20120360-36066031005	ACUTE DEEP VEIN THROMBOSIS [深部静脈血栓症]	20[redacted]-09-24	175	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	-	NOT RECOVERED/NOT RESOLVED
CINACALCET + AMG 416 PLACEBO	20120360-36066034025	LOW SERUM CALCIUM [血中カルシウム減少]	20[redacted]-06-19	93	MILD	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	RELATED	20[redacted]-10-08	-
CINACALCET + AMG 416 PLACEBO	20120360-36066034027	SEIZURES [痙攣]	20[redacted]-08-17	140	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	RELATED	20[redacted]-08-26	RECOVERED/RESOLVED
UNPLANNED TREATMENT	20120360-36049005002	ISCHEMIA CORONARY ARTERY ORIGIN [心筋虚血]	20[redacted]-01-02	24	LIFE THREATENING	YES	Results in Death	DRUG WITHDRAWN	NO ACTION TAKEN	NOT RELATED	20[redacted]-01-02	FATAL

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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
UNPLANNED TREATMENT	20120360-36051002009	OSTEOARTHRITIS OF THE SECOND METATARSOPHALANGEAL JOINT [変形性関節症]	20[redacted]-03-28	4	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-02	RECOVERED/RESOLVED
UNPLANNED TREATMENT	20120360-36051002009	OSTEOMYELITIS NAIL PHALANX OF THE SECOND FINGER OF THE RIGHT FOOT [骨髄炎]	20[redacted]-03-28	4	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-02	RECOVERED/RESOLVED

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

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＊＊　：「翌々年」を意味する

表 2.7.6.17-21　死亡した被験者の一覧表（20120331 試験）

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
0517-1547	5[redacted]	MALE	WHITE	HISPANIC OR LATINO	ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]/03/07	35	SEVERE	YES	-	Hospitalized, Study drug withheld,Medications to treat AE	-	NO	20[redacted]/03/15	RESOLVED WITH DEATH - EVENT CONTRIBUTED
0517-1547	5[redacted]	MALE	WHITE	HISPANIC OR LATINO	HYPOGLYCEMIC EVENT [低血糖症]	20[redacted]/03/07	35	SEVERE	YES	-	Medications to treat AE	-	NO	20[redacted]/03/11	RESOLVED WITHOUT SEQUELAE
0517-1547	5[redacted]	MALE	WHITE	HISPANIC OR LATINO	GASTROINTESTINAL HEMORRHAGE [胃腸出血]	20[redacted]/03/14	42	SEVERE	YES	-	Non-med treatment to treat AE	BLOOD TRANSFUSION	NO	20[redacted]/03/15	RESOLVED WITH DEATH - EVENT CONTRIBUTED
0517-1547	5[redacted]	MALE	WHITE	HISPANIC OR LATINO	CARDIOGENIC SHOCK [心原性ショック]	20[redacted]/03/15	43	MAXIMAL/LIFE-THREATENING	YES	-	Hospitalized, Discontinued from study	-	NO	20[redacted]/03/15	RESOLVED WITH DEATH - EVENT CONTRIBUTED

*1:MedDRA Version 14.0J

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
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表 2.7.6.17-22　重篤な有害事象の一覧表（20120331 試験）

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 TSaken	Causality	End Date/Time	Outcome
0503-1550	SMALL BOWEL OBSTRUCTION [小腸閉塞]	20[redacted]/03/18	41	SEVERE	YES	-	Hospitalized,Study drug withheld	-	NO	20[redacted]/03/22	RESOLVED WITHOUT SEQUELAE
0511-1515	PNEUMONIA - COMMUNITY ACQUIRED [肺炎]	20[redacted]/03/07	28	MODERATE	YES	-	Hospitalized,Study drug withheld,Medications to treat AE,Non-med treatment to treat AE,BLOOD CULTURE, CHEST XRAY, BLOOD TESTS	O2,BLOOD CULTURE, CHEST XRAY, BLOOD TESTS	NO	20[redacted]/03/16	RESOLVED WITHOUT SEQUELAE
0517-1547	ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]/03/07	35	SEVERE	YES	-	Hospitalized,Study drug withheld,Medications to treat AE	-	NO	20[redacted]/03/15	RESOLVED WITH DEATH - EVENT CONTRIBUTED
0517-1547	HYPOGLYCEMIC EVENT [低血糖症]	20[redacted]/03/07	35	SEVERE	YES	-	Medications to treat AE	-	NO	20[redacted]/03/11	RESOLVED WITHOUT SEQUELAE
0517-1547	GASTROINTESTINAL HEMORRHAGE [胃腸出血]	20[redacted]/03/14	42	SEVERE	YES	-	Non-med treatment to treat AE	BLOOD TRANSFUSION	NO	20[redacted]/03/15	RESOLVED WITH DEATH - EVENT CONTRIBUTED
0517-1547	CARDIOGENIC SHOCK [心原性ショック]	20[redacted]/03/15	43	MAXIMAL/LIFE-THREATENING	YES	-	Hospitalized,Discontinued from study	-	NO	20[redacted]/03/15 *	RESOLVED WITH DEATH - EVENT CONTRIBUTED
0518-1535	INFILTRATING DUCTAL CARCINOMA LEFT BREAST [乳癌]	20[redacted]/12/30	-5	SEVERE	YES	-	Study drug discontinued,Discontinued from study,Non-med treatment to treat AE	OUTPATIENT SURGICAL PROCEDURE	NO	20[redacted]/01/26	RESOLVED WITH SEQUELAE

*1:MedDRA Version 14.0J

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表 2.7.6.17-23　投与中止に至った有害事象の一覧表（20120331 試験）

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
0511-1504	SKIN PAPULES [丘疹]	20[redacted]/03/13	63	MILD	NO	-	Study drug discontinued	-	YES	ONGOING	-
0517-1547	CARDIOGENIC SHOCK [心原性ショック]	20[redacted]/03/15	43	MAXIMAL/LIFE-THREATENING	YES	-	Hospitalized,Discontinued from study	-	NO	20[redacted]/03/15 *	RESOLVED WITH DEATH - EVENT CONTRIBUTED
0518-1535	INFILTRATING DUCTAL CARCINOMA LEFT BREAST [乳癌]	20[redacted]/12/30	-5	SEVERE	YES	-	Study drug discontinued,Discontinued from study,Non-med treatment to treat AE	OUTPATIENT SURGICAL PROCEDURE	NO	20[redacted]/01/26	RESOLVED WITH SEQUELAE

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表 2.7.6.17-24　有害事象の SOC・PT 別発現頻度（20120334 試験）
解析対象集団：FAS

SOC PT	有害事象 ONO-5163 n/Y (yrs)	s	c (%)
N	30		
全体	30/5.3	563.7	100.0
血液およびリンパ系障害	3/43.0	7.0	10.0
貧血	3/44.9	6.7	10.0
凝血異常	1/45.1	2.2	3.3
白血球増加症	1/44.9	2.2	3.3
血小板減少症	1/43.2	2.3	3.3
血小板増加症	1/45.0	2.2	3.3
心臓障害	6/40.3	14.9	20.0
狭心症	2/42.9	4.7	6.7
不整脈	1/45.1	2.2	3.3
徐脈	1/43.1	2.3	3.3
冠動脈疾患	1/44.9	2.2	3.3
動悸	1/44.8	2.2	3.3
頻脈	1/45.0	2.2	3.3
耳および迷路障害	2/43.8	4.6	6.7
難聴	1/44.1	2.3	3.3
耳痛	1/44.9	2.2	3.3
内分泌障害	2/43.9	4.6	6.7
副甲状腺機能低下症	1/44.7	2.2	3.3
甲状腺機能低下症	1/44.3	2.3	3.3

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．
n＝有害事象発現例数．
Y＝ 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．
s＝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/ Y．
c＝有害事象発現率＝100*n/N．
出典［総括報告書 5.3.5.2-3（20120334 試験）Table 14-6.4 改変］

表 2.7.6.17-24 有害事象の SOC・PT 別発現頻度（20120334 試験）（続き 1）
解析対象集団：FAS

SOC PT	有害事象 ONO-5163 n/Y (yrs)	s	c (%)
N	30		
眼障害	5/43.7	11.4	16.7
一過性黒内障	1/44.7	2.2	3.3
白内障	1/44.7	2.2	3.3
霰粒腫	1/44.9	2.2	3.3
結膜出血	1/45.0	2.2	3.3
光視症	1/45.1	2.2	3.3
胃腸障害	13/26.8	48.5	43.3
下痢	7/38.8	18.1	23.3
悪心	5/38.4	13.0	16.7
胃腸出血	3/42.0	7.1	10.0
腹痛	2/43.5	4.6	6.7
腹部不快感	1/43.8	2.3	3.3
腹部膨満	1/44.6	2.2	3.3
上腹部痛	1/44.6	2.2	3.3
後天性食道ウエッブ	1/45.1	2.2	3.3
便秘	1/44.8	2.2	3.3
口内乾燥	1/44.2	2.3	3.3
消化不良	1/44.9	2.2	3.3
胃炎	1/45.1	2.2	3.3
消化器痛	1/43.1	2.3	3.3

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた.
n = 有害事象発現例数.
Y = 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.
s = 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/ Y.
c = 有害事象発現率 = 100*n/N.

表 2.7.6.17-24　有害事象の SOC・PT 別発現頻度（20120334 試験）（続き 2）
解析対象集団：FAS

SOC PT	有害事象 ONO-5163 n/Y (yrs)	s	c (%)
N	30		
胃食道逆流性疾患	1/43.8	2.3	3.3
胃排出不全	1/43.7	2.3	3.3
下部消化管出血	1/43.5	2.3	3.3
肛門周囲痛	1/43.0	2.3	3.3
直腸出血	1/43.0	2.3	3.3
小腸閉塞	1/43.8	2.3	3.3
歯痛	1/43.7	2.3	3.3
嘔吐	1/44.9	2.2	3.3
一般・全身障害および投与部位の状態	9/35.3	25.5	30.0
発熱	3/43.6	6.9	10.0
無力症	2/44.0	4.5	6.7
カテーテル留置部位出血	2/41.3	4.8	6.7
非心臓性胸痛	2/43.6	4.6	6.7
胸痛	1/44.8	2.2	3.3
全身性浮腫	1/43.8	2.3	3.3
注入部位血管外漏出	1/44.2	2.3	3.3
局所腫脹	1/44.9	2.2	3.3
倦怠感	1/44.9	2.2	3.3
医療機器合併症	1/43.2	2.3	3.3
疼痛	1/44.1	2.3	3.3

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．
n = 有害事象発現例数．
Y = 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．
s = 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/ Y．
c = 有害事象発現率 = 100*n/N．

表 2.7.6.17-24　有害事象の SOC・PT 別発現頻度（20120334 試験）（続き 3）
解析対象集団：FAS

SOC PT	有害事象 ONO-5163 n/Y (yrs)	s	c (%)
N	30		
血管穿刺部位内出血	1/44.5	2.2	3.3
肝胆道系障害	5/39.3	12.7	16.7
胆石症	3/40.9	7.3	10.0
胆管結石	1/45.1	2.2	3.3
急性胆嚢炎	1/44.7	2.2	3.3
高ビリルビン血症	1/44.1	2.3	3.3
免疫系障害	5/39.4	12.7	16.7
季節性アレルギー	4/41.4	9.7	13.3
腎移植拒絶反応	1/43.1	2.3	3.3
感染症および寄生虫症	19/22.7	83.8	63.3
上気道感染	9/37.1	24.3	30.0
肺炎	6/36.6	16.4	20.0
鼻咽頭炎	3/41.8	7.2	10.0
副鼻腔炎	3/43.1	7.0	10.0
菌血症	2/43.6	4.6	6.7
医療機器関連感染	2/43.3	4.6	6.7
骨髄炎	2/44.6	4.5	6.7
咽頭炎	2/44.1	4.5	6.7
敗血症	2/44.0	4.5	6.7
皮膚感染	2/42.9	4.7	6.7

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．
n = 有害事象発現例数．
Y = 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．
s = 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/ Y．
c = 有害事象発現率 = 100*n/N．

表 2.7.6.17-24　有害事象の SOC・PT 別発現頻度（20120334 試験）（続き 4）
解析対象集団：FAS

SOC PT	有害事象 ONO-5163 n/Y (yrs)	s	c (%)
N	30		
動静脈瘻部位感染	1/44.3	2.3	3.3
動静脈グラフト部位感染	1/45.1	2.2	3.3
気管支炎	1/44.6	2.2	3.3
カテーテル留置部位感染	1/43.7	2.3	3.3
心内膜炎	1/44.8	2.2	3.3
眼感染	1/43.0	2.3	3.3
皮膚真菌感染	1/44.0	2.3	3.3
せつ	1/44.8	2.2	3.3
壊疽	1/45.1	2.2	3.3
胃腸炎	1/44.6	2.2	3.3
ウイルス性胃腸炎	1/42.9	2.3	3.3
ＨＩＶ感染	1/43.7	2.3	3.3
インフルエンザ	1/45.0	2.2	3.3
椎間板炎	1/44.1	2.3	3.3
クレブシエラ性菌血症	1/43.2	2.3	3.3
限局性感染	1/44.6	2.2	3.3
髄膜炎	1/44.1	2.3	3.3
外耳炎	1/44.6	2.2	3.3
敗血症性ショック	1/43.9	2.3	3.3
ブドウ球菌性菌血症	1/44.3	2.3	3.3

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．
n = 有害事象発現例数．
Y = 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．
s = 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/ Y．
c = 有害事象発現率 = 100*n/N．

表 2.7.6.17-24　有害事象の SOC・PT 別発現頻度（20120334 試験）（続き 5）
解析対象集団：FAS

SOC PT	有害事象 ONO-5163 n/Y (yrs)	s	c (%)
N	30		
ブドウ球菌感染	1/44.8	2.2	3.3
皮下組織膿瘍	1/44.9	2.2	3.3
傷害、中毒および処置合併症	19/21.9	87.0	63.3
動静脈瘻部位合併症	4/40.5	9.9	13.3
動静脈瘻血栓症	4/40.7	9.8	13.3
処置による低血圧	3/42.5	7.1	10.0
動静脈瘻瘤	2/43.7	4.6	6.7
挫傷	2/42.4	4.7	6.7
裂傷	2/43.4	4.6	6.7
靭帯捻挫	2/42.3	4.7	6.7
処置による嘔吐	2/41.5	4.8	6.7
移植血管合併症	2/42.8	4.7	6.7
血管グラフト血栓症	2/42.9	4.7	6.7
動静脈瘻部位血腫	1/44.1	2.3	3.3
動静脈瘻部位出血	1/44.7	2.2	3.3
動静脈グラフト部位出血	1/44.4	2.3	3.3
造影剤反応	1/42.8	2.3	3.3
擦過傷	1/43.8	2.3	3.3
転倒	1/44.1	2.3	3.3
爪裂離	1/44.8	2.2	3.3

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた.
n = 有害事象発現例数.
Y = 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.
s = 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/ Y.
c = 有害事象発現率 = 100*n/N.

表 2.7.6.17-24　有害事象の SOC・PT 別発現頻度（20120334 試験）（続き 6）
解析対象集団：FAS

SOC PT	有害事象 ONO-5163 n/Y (yrs)	s	c (%)
N	30		
外傷後疼痛	1/44.2	2.3	3.3
処置によるめまい	1/43.5	2.3	3.3
処置による悪心	1/43.3	2.3	3.3
処置による疼痛	1/44.5	2.2	3.3
交通事故	1/44.2	2.3	3.3
シャント機能不全	1/43.4	2.3	3.3
シャント狭窄	1/43.8	2.3	3.3
シャント血栓症	1/43.4	2.3	3.3
熱傷	1/43.1	2.3	3.3
脛骨骨折	1/44.9	2.2	3.3
外傷性潰瘍	1/44.7	2.2	3.3
創傷	1/43.6	2.3	3.3
臨床検査	13/34.0	38.3	43.3
血中カルシウム減少	10/36.7	27.3	33.3
血中副甲状腺ホルモン減少	2/44.6	4.5	6.7
血圧上昇	2/43.8	4.6	6.7
アスパラギン酸アミノトランスフェラーゼ増加	1/43.7	2.3	3.3
心電図ＱＴ延長	1/44.4	2.3	3.3
心拍数不整	1/44.8	2.2	3.3
国際標準比増加	1/44.4	2.3	3.3

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた.
n＝有害事象発現例数.
Y＝ 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.
s＝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/ Y.
c＝有害事象発現率＝100*n/N.

表 2.7.6.17-24　有害事象の SOC・PT 別発現頻度（20120334 試験）（続き 7）
解析対象集団：FAS

SOC PT	有害事象 ONO-5163 n/Y (yrs)	s	c (%)
N		30	
代謝および栄養障害	11/32.5	33.9	36.7
水分過負荷	4/39.2	10.2	13.3
低カルシウム血症	4/43.3	9.2	13.3
高カリウム血症	2/43.9	4.6	6.7
コントロール不良の糖尿病	1/43.0	2.3	3.3
脂質異常症	1/44.1	2.3	3.3
体液貯留	1/43.9	2.3	3.3
筋骨格系および結合組織障害	8/36.8	21.8	26.7
四肢痛	4/42.1	9.5	13.3
関節痛	1/44.7	2.2	3.3
滑液包炎	1/43.0	2.3	3.3
筋痙縮	1/43.8	2.3	3.3
筋力低下	1/44.6	2.2	3.3
筋骨格不快感	1/44.8	2.2	3.3
筋肉痛	1/43.5	2.3	3.3
変形性関節症	1/44.3	2.3	3.3
脊柱管狭窄症	1/44.1	2.3	3.3
変形性脊椎症	1/44.1	2.3	3.3
椎間孔狭窄	1/44.1	2.3	3.3
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）	3/43.5	6.9	10.0

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．
n = 有害事象発現例数．
Y = 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．
s = 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/ Y．
c = 有害事象発現率 = 100*n/N．

表 2.7.6.17-24　有害事象の SOC・PT 別発現頻度（20120334 試験）（続き 8）
解析対象集団：FAS

SOC PT	有害事象 ONO-5163 n/Y (yrs)	s	c (%)
N	30		
慢性骨髄性白血病	1/45.0	2.2	3.3
遠隔転移を伴う悪性黒色腫	1/45.0	2.2	3.3
前立腺癌	1/43.7	2.3	3.3
神経系障害	11/34.1	32.2	36.7
浮動性めまい	2/42.9	4.7	6.7
末梢性ニューロパチー	2/41.8	4.8	6.7
錯感覚	2/42.6	4.7	6.7
失神	2/44.1	4.5	6.7
異痛症	1/43.6	2.3	3.3
手根管症候群	1/44.3	2.3	3.3
脳血管発作	1/44.7	2.2	3.3
頭痛	1/44.7	2.2	3.3
感覚鈍麻	1/44.8	2.2	3.3
嗜眠	1/43.0	2.3	3.3
失神寸前の状態	1/45.1	2.2	3.3
副鼻腔炎に伴う頭痛	1/43.7	2.3	3.3
三叉神経痛	1/44.7	2.2	3.3
刺激無反応	1/44.7	2.2	3.3
精神障害	4/42.9	9.3	13.3
不安	2/43.2	4.6	6.7

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．
n = 有害事象発現例数．
Y = 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．
s = 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/ Y．
c = 有害事象発現率 = 100*n/N．

表 2.7.6.17-24　有害事象の SOC・PT 別発現頻度（20120334 試験）（続き 9）
解析対象集団：FAS

	有害事象		
	ONO-5163		
SOC PT	n/Y (yrs)	s	c (%)
N	30		
うつ病	2/43.8	4.6	6.7
譫妄	1/44.1	2.3	3.3
精神状態変化	1/45.1	2.2	3.3
腎および尿路障害	2/44.8	4.5	6.7
高窒素血症	1/45.1	2.2	3.3
腎結石症	1/44.9	2.2	3.3
呼吸器、胸郭および縦隔障害	9/36.4	24.7	30.0
咳嗽	3/42.1	7.1	10.0
低酸素症	2/44.0	4.5	6.7
胸水	2/43.3	4.6	6.7
肺水腫	2/43.7	4.6	6.7
睡眠時無呼吸症候群	2/43.3	4.6	6.7
急性呼吸不全	1/45.1	2.2	3.3
無気肺	1/44.1	2.3	3.3
呼吸困難	1/44.9	2.2	3.3
労作性呼吸困難	1/45.0	2.2	3.3
鼻出血	1/44.8	2.2	3.3
肺塞栓症	1/44.3	2.3	3.3
鼻漏	1/44.7	2.2	3.3
副鼻腔うっ血	1/43.8	2.3	3.3

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．
n＝有害事象発現例数．
Y＝ 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．
s＝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/ Y．
c＝有害事象発現率＝100*n/N．

表 2.7.6.17-24　有害事象の SOC・PT 別発現頻度（20120334 試験）（続き 10）
解析対象集団：FAS

	有害事象		
	ONO-5163		
SOC PT	n/Y (yrs)	s	c (%)
N		30	
上気道咳症候群	1/44.0	2.3	3.3
喘鳴	1/44.3	2.3	3.3
皮膚および皮下組織障害	7/38.7	18.1	23.3
そう痒症	3/42.2	7.1	10.0
皮膚乾燥	2/44.1	4.5	6.7
アレルギー性皮膚炎	1/43.0	2.3	3.3
接触性皮膚炎	1/44.2	2.3	3.3
内出血発生の増加傾向	1/44.4	2.3	3.3
内方発育毛	1/44.5	2.2	3.3
網状皮斑	1/44.1	2.3	3.3
爪床出血	1/44.1	2.3	3.3
発疹	1/44.7	2.2	3.3
皮膚腫瘤	1/44.7	2.2	3.3
皮膚潰瘍	1/44.9	2.2	3.3
外科および内科処置	1/44.8	2.2	3.3
ヘルニア修復	1/44.8	2.2	3.3
血管障害	10/39.9	25.1	33.3
高血圧	2/42.0	4.8	6.7
低血圧	2/44.9	4.5	6.7
静脈狭窄	2/44.7	4.5	6.7

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．
n = 有害事象発現例数．
Y = 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．
s = 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/ Y．
c = 有害事象発現率 = 100*n/N．

表 2.7.6.17-24　有害事象の SOC・PT 別発現頻度（20120334 試験）（続き 11）
解析対象集団：FAS

SOC PT	有害事象 ONO-5163 n/Y (yrs)	s	c (%)
N	30		
動脈硬化症	1/44.1	2.3	3.3
深部静脈血栓症	1/45.0	2.2	3.3
失血	1/45.1	2.2	3.3
高血圧緊急症	1/45.1	2.2	3.3
大静脈血栓症	1/44.9	2.2	3.3

医師から報告された有害事象名は，MedDRA ver17.0Jを用いて読み替えた．
n = 有害事象発現例数．
Y = 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．
s = 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/ Y．
c = 有害事象発現率 = 100*n/N．
出典［総括報告書 5.3.5.2-3（20120334 試験）Table 14-6.4 改変］

表 2.7.6.17-25 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

（20120334 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		
	ONO-5163		
SOC PT	n/Y (yrs)	s	c (%)
N	30		
全体	13/34.5	37.7	43.3
心臓障害	1/44.8	2.2	3.3
動悸	1/44.8	2.2	3.3
内分泌障害	1/44.7	2.2	3.3
副甲状腺機能低下症	1/44.7	2.2	3.3
臨床検査	9/36.9	24.4	30.0
血中カルシウム減少	9/36.9	24.4	30.0
血中副甲状腺ホルモン減少	2/44.6	4.5	6.7
心拍数不整	1/44.8	2.2	3.3
代謝および栄養障害	4/43.3	9.2	13.3
低カルシウム血症	4/43.3	9.2	13.3
神経系障害	1/44.1	2.3	3.3
錯感覚	1/44.1	2.3	3.3

医師から報告された有害事象名は，MedDRA ver17.0J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．
Y＝ 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．
s＝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/ Y．
c＝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 5.3.5.2-3（20120334 試験）Table 14-6.8 改変］

表 2.7.6.17-26　死亡した被験者の一覧表（20120334 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
AMG 416	KAI-4169-005-0511-1543	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	EXSANGUINATION FROM A-V FISTULA [失血]	20[redacted]/10/30	202	LIFE THREATENING	Y	Event Contributed to Death	-	DISCONTINUED FROM STUDY	NOT RELATED	20[redacted]/10/30	FATAL
AMG 416	KAI-4169-005-0511-1543	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	LEFT THIRD FINGER INFECTION [限局性感染]	20[redacted]/04/22	11	MODERATE	N	Unknown	-	MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/05/11	RECOVERED/ RESOLVED WITH SEQUELAE
AMG 416	KAI-4169-005-0511-1543	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]/10/15	187	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/10/22	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1543	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	OSTEOMYELITIS OF LEFT THIRD FINGER [骨髄炎]	20[redacted]/05/02	21	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED,MEDICATIONS TO TREAT AE,NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/05/05	RECOVERED/ RESOLVED WITH SEQUELAE
AMG 416	KAI-4169-005-0516-1511	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	DEPRESSION [うつ病]	20[redacted]/03/28	-19	MODERATE	N	Unknown	-	MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/08/02	NOT RECOVERED/ NOT RESOLVED
AMG 416	KAI-4169-005-0516-1511	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	FLU [インフルエンザ]	20[redacted]/05/19	33	MODERATE	N	Unknown	DOSE NOT CHANGED	NONE	NOT RELATED	20[redacted]/06/06	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1511	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	MELANOMA, METASTATIC [遠隔転移を伴う悪性黒色腫]	20[redacted]/05/30	44	LIFE THREATENING	Y	Event Contributed to Death	DRUG WITHDRAWN	DISCONTINUED FROM STUDY	NOT RELATED	20[redacted]/08/02	FATAL

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
AMG 416	KAI-4169-005-0516-1511	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	INCREASED FREQUENCY OF KIDNEY STONES EPISODE [腎結石症]	20[redacted]/05/11	25	MODERATE	N	Unknown	DOSE NOT CHANGED	NONE	NOT RELATED	20[redacted]/06/06	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1511	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	FRACTURED LEFT TIBIA, PROXIMAL, CLOSED [脛骨骨折]	20[redacted]/04/16 *	0	MODERATE	N	Unknown	-	NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/06/06 *	RECOVERED/ RESOLVED WITH SEQUELAE
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	ACUTE RESPIRATORY FAILURE [急性呼吸不全]	20[redacted]/02/13 *	308	MODERATE	N	Unknown	DRUG INTERRUPTED	NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/03/24 *	NOT RECOVERED/ NOT RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	WITHDRAWAL FROM DIALYSIS/UREMIA [高窒素血症]	20[redacted]/02/12 *	307	LIFE THREATENING	Y	Event Contributed to Death	DOSE NOT CHANGED	NONE	NOT RELATED	20[redacted]/03/24 *	FATAL
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	ELEVATED BLOOD PRESSURE [血圧上昇]	20[redacted]/01/23	287	MILD	N	Unknown	DRUG INTERRUPTED	-	NOT RELATED	20[redacted]/01/23	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	CHEST PAIN UNKNOWN ETIOLOGY [胸痛]	20[redacted]/11/26	229	MILD	N	Unknown	-	MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/11/26	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	CHEST PAIN OF UNKNOWN ETIOLOGY [胸痛]	20[redacted]/12/23 *	256	MILD	N	Unknown	-	MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/12/23 *	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	SUBCONJUNCTIVAL HEMORRHAGE, BILATERAL [結膜出血]	20[redacted]/01/10	274	MILD	N	Unknown	DOSE NOT CHANGED	NONE	NOT RELATED	20[redacted]/01/15	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
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	COUGH [咳嗽]	20[redacted]/02/08 *	303	MILD	N	Unknown	-	MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/03/24 *	NOT RECOVERED/ NOT RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	EXERTIONAL DYSPNEA [労作性呼吸困難]	20[redacted]/01/09 *	273	MILD	N	Unknown	-	MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/03/23	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	ACUTE GASTROENTERITIS [胃腸炎]	20[redacted]/09/14 *	156	MILD	N	Unknown	DOSE NOT CHANGED	NONE	NOT RELATED	20[redacted]/09/17 *	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPERTENSIVE EMERGENCY [高血圧緊急症]	20[redacted]/02/13 *	308	MODERATE	N	Unknown	-	MEDICATIONS TO TREAT AE,OTHER	NOT RELATED	20[redacted]/02/13 *	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPOXEMIA [低酸素症]	20[redacted]/02/11 *	306	MODERATE	N	Unknown	DRUG INTERRUPTED	-	NOT RELATED	20[redacted]/03/24 *	NOT RECOVERED/ NOT RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	SPONTANEOUS BRUISE, LEFT SHIN [内出血発生の増加傾向]	20[redacted]/06/17	67	MILD	N	Unknown	DOSE NOT CHANGED	NONE	NOT RELATED	20[redacted]/06/28	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	LACERATED WOUND, LEFT LEG [裂傷]	20[redacted]/09/23	165	MILD	N	Unknown	-	NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/10/08	RECOVERED/ RESOLVED WITH SEQUELAE

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
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	LEFT LEG LACERATION WITH SUTURES IN PLACE [裂傷]	20[redacted]/10/08	180	MODERATE	N	Unknown	-	MEDICATIONS TO TREAT AE,NON-MED TREATMENT TO TREAT AE,OTHER	NOT RELATED	20[redacted]/10/15 *	RECOVERED/ RESOLVED WITH SEQUELAE
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	LEFT HAND SWELLING [局所腫脹]	20[redacted]/12/07	240	MILD	N	Unknown	DOSE NOT CHANGED	NONE	NOT RELATED	20[redacted]/03/24	NOT RECOVERED/ NOT RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	AVULSION, LEFT GREAT TOENAIL [爪裂離]	20[redacted]/11/23	226	MILD	N	Unknown	-	MEDICATIONS TO TREAT AE,NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/11/23	RECOVERED/ RESOLVED WITH SEQUELAE
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	PHARYNGITIS [咽頭炎]	20[redacted]/09/19 *	161	MILD	N	Unknown	DOSE NOT CHANGED	NONE	NOT RELATED	20[redacted]/09/24 *	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	PNUEMONIA [肺炎]	20[redacted]/02/11 *	306	SEVERE	N	Unknown	DRUG INTERRUPTED	OTHER	NOT RELATED	20[redacted]/03/24 *	NOT RECOVERED/ NOT RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	PULMONARY EDEMA [肺水腫]	20[redacted]/02/11 *	306	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED,OTHER	NOT RELATED	20[redacted]/03/24 *	NOT RECOVERED/ NOT RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	SEPSIS [敗血症]	20[redacted]/02/13 *	308	MODERATE	N	Unknown	-	MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/02/19	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
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	VENOUS STASIS ULCERATION, LEFT ANTERIOR TIBIAL REGION [皮膚潰瘍]	20[redacted]/12/05	238	MODERATE	N	Unknown	-	NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/12/19	RECOVERED/ RESOLVED WITH SEQUELAE
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	VENOUS STASIS ULCERATION, LEFT ANTERIOR TIBIAL REGION - IMPROVING [皮膚潰瘍]	20[redacted]/12/19	252	MILD	N	Unknown	-	NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/03/24*	NOT RECOVERED/ NOT RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	LEFT LEG TRAUMATIC ULCERATION [外傷性潰瘍]	20[redacted]/10/15	187	MODERATE	N	Unknown	-	MEDICATIONS TO TREAT AE,NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/10/29	RECOVERED/ RESOLVED WITH SEQUELAE
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	TRAUMATIC ULCERATION, LEFT ANTERIOR SHIN [外傷性潰瘍]	20[redacted]/10/29	201	MODERATE	N	Unknown	-	MEDICATIONS TO TREAT AE,NON-MED TREATMENT TO TREAT AE,OTHER	NOT RELATED	20[redacted]/11/07	RECOVERED/ RESOLVED WITH SEQUELAE
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	TRAUMATIC ULCERATION TO LEFT ANTERIOR TIBIAL REGION [外傷性潰瘍]	20[redacted]/11/07	210	MODERATE	N	Unknown	-	NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/12/05	RECOVERED/ RESOLVED WITH SEQUELAE

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
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	TRIGEMINAL NEURALGIA [三叉神経痛]	20[redacted]/09/17	159	MILD	N	Unknown	-	MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/09/24	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	UPPER RESPERATORY INFECTION [上気道感染]	20[redacted]*/02/11	306	MILD	N	Unknown	DRUG INTERRUPTED	-	NOT RELATED	20[redacted]*/03/24	NOT RECOVERED/ NOT RESOLVED
AMG 416	KAI-4169-005-0516-1544	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	VENIPUNCTURE SITE LEFT ARM BRUISING, INTERMITTENT [血管穿刺部位内出血]	20[redacted]/07/17	97	MILD	N	Unknown	DOSE NOT CHANGED	NONE	NOT RELATED	20[redacted]*/03/24	NOT RECOVERED/ NOT RESOLVED
AMG 416	KAI-4169-005-0517-1516	3[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CARDIAC ARRHYTHMIA [不整脈]	20[redacted]/08/26	116	LIFE THREATENING	Y	Event Contributed to Death	DRUG WITHDRAWN	-	NOT RELATED	20[redacted]/08/26	FATAL
AMG 416	KAI-4169-005-0517-1516	3[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	BOIL ON BACK [せつ]	20[redacted]/04/30	-2	MILD	N	Unknown	-	MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/06/13	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0517-1516	3[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SYMPTOMATIC HYPOCALCEMIA [低カルシウム血症]	20[redacted]/05/09	7	MODERATE	N	Unknown	DRUG INTERRUPTED	-	RELATED	20[redacted]/05/14	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0517-1516	3[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SYMPTOMATIC HYPOCALCEMIA [低カルシウム血症]	20[redacted]/07/11	70	MODERATE	N	Unknown	DRUG INTERRUPTED	MEDICATIONS TO TREAT AE	RELATED	20[redacted]/08/01	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0517-1516	3[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SYMPTOMATIC HYPOCALCEMIA [低カルシウム血症]	20[redacted]/08/16	106	MODERATE	N	Unknown	DRUG INTERRUPTED	-	RELATED	20[redacted]/08/22	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
AMG 416	KAI-4169-005-0517-1516	3[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	UPPER RESPIRATORY INFECTION [上気道感染]	20[redacted]/07/04	63	MODERATE	N	Unknown	-	MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/07/27	RECOVERED/ RESOLVED

*1:MedDRA Version 17.0J
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 2.7.6.17-27　重篤な有害事象の一覧表（20120334 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
AMG 416	KAI-4169-005-0503-1507	CARDIAC CHEST PAIN [狭心症]	20[redacted]/07/19 **	466	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/07/20 **	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0503-1507	GASTRITIS [胃炎]	20[redacted]/04/25	746	MODERATE	Y	Unknown	-	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/04/26	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0503-1507	PROSTATE CANCER [前立腺癌]	20[redacted]/11/08	213	SEVERE	Y	Unknown	DOSE NOT CHANGED	NONE	NOT RELATED	ONGOING	-
AMG 416	KAI-4169-005-0503-1507	PULMONARY EMBOLUS (LEFT LOWER LOBE) [肺塞栓症]	20[redacted]/07/09	456	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/07/16	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0503-1550	PARTIAL SMALL BOWEL OBSTRUCTION [小腸閉塞]	20[redacted]/10/02	141	SEVERE	Y	Unknown	-	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/10/05	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1505	CENTRAL VENOUS CATHETER ASSOCIATED STAPH AUREUS BACTEREMIA [医療機器関連感染]	20[redacted]/02/07	309	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/02/17	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1505	CENTRAL VENOUS CATHETER ASSOCIATED STAPH AUREUS BACTEREMIA [医療機器関連感染]	20[redacted]/06/09	431	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/06/18	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1505	FLUID OVERLOAD WORSENING [水分過負荷]	20[redacted]/02/07	309	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/02/17	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1505	EXACERBATION OF FLUID OVERLOAD [水分過負荷]	20[redacted]/06/09	431	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/06/18	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1505	PNEUMONIA [肺炎]	20[redacted]/07/25	112	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/08/03	RECOVERED/ RESOLVED WITH SEQUELAE
AMG 416	KAI-4169-005-0511-1505	SEPTIC SHOCK [敗血症性ショック]	20[redacted]/02/08	310	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/02/11	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
AMG 416	KAI-4169-005-0511-1515	CHEST PAIN - CARDIAC [狭心症]	20[redacted]/11/15	197	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/11/20	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1515	CHEST PAIN - CARDIAC [狭心症]	20[redacted]/11/28 **	210	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/12/02 **	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1515	CHEST PAIN - CARDIAC [狭心症]	20[redacted]/01/26 **	634	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/01/31 **	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1515	CHEST PAIN, CARDIAC RECURRENT [狭心症]	20[redacted]/03/24 **	691	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/04/01	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1515	BILE DUCT STONE [胆管結石]	20[redacted]/03/24 **	691	MODERATE	Y	Unknown	-	HOSPITALIZED	NOT RELATED	ONGOING **	-
AMG 416	KAI-4169-005-0511-1515	CORONARY ARTERY DISEASE EXACERBATION [冠動脈疾患]	20[redacted]/02/07	646	MODERATE	Y	Unknown	DRUG INTERRUPTED	NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/02/12	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1515	GASTROPARESIS [胃排出不全]	20[redacted]/11/15 **	197	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/11/20 **	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1515	GASTROPARESIS, EXACERBATION [胃排出不全]	20[redacted]/01/26	634	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/02/12	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1515	PNEUMONIA [肺炎]	20[redacted]/11/28	210	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/12/02	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1515	PULMONARY EDEMA [肺水腫]	20[redacted]/11/28 *	210	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/12/02 *	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1532	BLEEDING FROM A-V GRAFT [動静脈グラフト部位出血]	20[redacted]/08/06 **	503	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED,NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/08/09 **	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1532	A-V GRAFT HEMORRHAGE [動静脈グラフト部位出血]	20[redacted]/03/04	713	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/03/07	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
AMG 416	KAI-4169-005-0511-1532	RIGHT UPPER ARM EXTREMITY A-V GRAFT INFECTION [動静脈グラフト部位感染]	20[redacted]/03/11 **	720	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE,OTHER	NOT RELATED	20[redacted]/03/24 **	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1532	DIPHTEROID BACTEREMIA [菌血症]	20[redacted]/11/08 *	597	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/11/19 *	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1532	CEREBROVASCULAR ACCIDENT [脳血管発作]	20[redacted]/11/08 *	597	MILD	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/11/19 *	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1532	DEEP VEIN THROMBOSIS LEFT FEMORAL VEIN [深部静脈血栓症]	20[redacted]/02/02 **	683	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	ONGOING	-
AMG 416	KAI-4169-005-0511-1532	MITRAL VALVE ENDOCARDITIS [心内膜炎]	20[redacted]/11/18 *	607	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/12/24 *	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1532	LEFT FOOT GANGRENE [壊疽]	20[redacted]/03/11 **	720	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/03/14 **	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1532	GASTROINTESTINAL BLEED [胃腸出血]	20[redacted]/04/12 *	22	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE,NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/04/28 *	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1532	GASTROINTESTINAL BLEED - RECURRENT [胃腸出血]	20[redacted]/09/19	547	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED,NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/09/25	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1532	KLEBSIELLA PNEUMONIAE BACTEREMIA [クレブシエラ性菌血症]	20[redacted]/05/16	56	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/05/24	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1532	LOWER GASTROINTESTINAL BLEED [下部消化管出血]	20[redacted]/09/04	167	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE,NON-MED TREATMENT TO TREAT AE	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
AMG 416	KAI-4169-005-0511-1532	LOWER GASTROINTESTINAL BLEED [下部消化管出血]	20[redacted]/09/14 **	177	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED,NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/09/19	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1532	OSTEOMYELITIS OF LEFT FOOT [骨髄炎]	20[redacted]/03/12 *	721	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE,OTHER	NOT RELATED	ONGOING *	-
AMG 416	KAI-4169-005-0511-1532	HEMORRHAGIC PLEURAL EFFUSION [胸水]	20[redacted]/01/31	316	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/02/14	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1532	PNEUMONIA [肺炎]	20[redacted]/03/25 *	4	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE,NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/03/30 *	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1532	A-V GRAFT THOMBOSIS [血管グラフト血栓症]	20[redacted]/08/06	503	MODERATE	Y	Unknown	DRUG INTERRUPTED	OTHER	NOT RELATED	20[redacted]/08/09	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1534	A-V FISTULA INFECTION [動静脈瘻部位感染]	20[redacted]/06/27	463	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/07/02	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1534	CENTRAL VENOUS CATHETER ASSOCIATED BACTEREMIA [医療機器関連感染]	20[redacted]/09/25	553	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/10/07	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1534	STAPH AUREUS BACTEREMIA [ブドウ球菌性菌血症]	20[redacted]/06/27 *	463	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE,NON-MED TREATMENT TO TREAT AE,OTHER	NOT RELATED	20[redacted]/07/02 *	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1534	NONOCCLUSIVE THROMBUS OF SUPERIOR VENA CAVA [大静脈血栓症]	20[redacted]/01/21	671	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/01/27	RECOVERED/ RESOLVED WITH SEQUELAE
AMG 416	KAI-4169-005-0511-1537	FLUID OVERLOAD [水分過負荷]	20[redacted]/09/19	175	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED,OTHER	NOT RELATED	20[redacted]/09/22	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
AMG 416	KAI-4169-005-0511-1537	FLUID OVERLOAD [水分過負荷]	20[redacted]/02/25*	334	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/02/26*	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1537	PNEUMONIA [肺炎]	20[redacted]/03/08*	345	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/03/12*	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1538	HIV [ＨＩＶ感染]	20[redacted]/11/05	222	MILD	Y	Unknown	-	MEDICATIONS TO TREAT AE	NOT RELATED	ONGOING	-
AMG 416	KAI-4169-005-0511-1543	EXSANGUINATION FROM A-V FISTULA [失血]	20[redacted]/10/30	202	LIFE THREATENING	Y	Event Contributed to Death	-	DISCONTINUED FROM STUDY	NOT RELATED	20[redacted]/10/30	FATAL
AMG 416	KAI-4169-005-0511-1543	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]/10/15	187	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/10/22	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0511-1543	OSTEOMYELITIS OF LEFT THIRD FINGER [骨髄炎]	20[redacted]/05/02	21	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE,NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/05/05	RECOVERED/ RESOLVED WITH SEQUELAE
AMG 416	KAI-4169-005-0516-1511	MELANOMA, METASTATIC [遠隔転移を伴う悪性黒色腫]	20[redacted]/05/30	44	LIFE THREATENING	Y	Event Contributed to Death	DRUG WITHDRAWN	DISCONTINUED FROM STUDY	NOT RELATED	20[redacted]/08/02	FATAL
AMG 416	KAI-4169-005-0516-1540	BACTEREMIA [菌血症]	20[redacted]/03/24	356	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/03/29	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1540	ACUTE DELIRIUM [譫妄]	20[redacted]/03/23	355	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/03/29	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1540	HYPOXIA [低酸素症]	20[redacted]/03/24	356	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/03/29	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1540	MENINGITIS [髄膜炎]	20[redacted]/03/24	356	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/03/29	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0516-1540	SEPSIS [敗血症]	20[redacted]/03/24	356	MODERATE	Y	Unknown	-	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/04	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
AMG 416	KAI-4169-005-0516-1544	WITHDRAWAL FROM DIALYSIS/UREMIA [高窒素血症]	20[redacted]/02/12	307	LIFE THREATENING	Y	Event Contributed to Death	DOSE NOT CHANGED	NONE	NOT RELATED	20[redacted]/03/24	FATAL
AMG 416	KAI-4169-005-0516-1544	PULMONARY EDEMA [肺水腫]	20[redacted]/02/11	306	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED,OTHER	NOT RELATED	20[redacted]/03/24	NOT RECOVERED/ NOT RESOLVED
AMG 416	KAI-4169-005-0517-1510	WORSENING SECONDARY HYPERPARATHYROIDISM [続発性副甲状腺機能亢進症]	20[redacted]/06/06	56	SEVERE	Y	Unknown	DRUG WITHDRAWN	DISCONTINUED FROM STUDY	NOT RELATED	20[redacted]/06/08/21:18	RECOVERED/ RESOLVED WITH SEQUELAE
AMG 416	KAI-4169-005-0517-1510	SYMPTOMATIC HYPOCALCEMIA [低カルシウム血症]	20[redacted]/04/26	15	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE	RELATED	20[redacted]/04/29	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0517-1510	SYMPTOMATIC HYPOCALCEMIA [低カルシウム血症]	20[redacted]/06/09	59	SEVERE	Y	Unknown	-	HOSPITALIZED	NOT RELATED	20[redacted]/06/15/15:50	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0517-1510	SYMPTOMATIC HYPOCALCEMIA [低カルシウム血症]	20[redacted]/06/19	69	SEVERE	Y	Unknown	-	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/06/22	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0517-1512	VOLUME OVERLOAD [水分過負荷]	20[redacted]/05/27	38	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED,NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/05/28	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0517-1516	CARDIAC ARRHYTHMIA [不整脈]	20[redacted]/08/26	116	LIFE THREATENING	Y	Event Contributed to Death	DRUG WITHDRAWN	-	NOT RELATED	20[redacted]/08/26	FATAL
AMG 416	KAI-4169-005-0517-1546	ACUTE CHOLECYSTITIS [急性胆嚢炎]	20[redacted]/07/13/11:50	79	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE	NOT RELATED	20[redacted]/07/18/20:45	RECOVERED/ RESOLVED WITH SEQUELAE
AMG 416	KAI-4169-005-0518-1501	ANEMIA [貧血]	20[redacted]/06/08/11:59	72	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/06/10/14:00	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0518-1501	COAGULOPATHY [凝血異常]	20[redacted]/06/08/11:59	72	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/06/10/14:00	RECOVERED/ RESOLVED WITH SEQUELAE

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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
AMG 416	KAI-4169-005-0518-1501	GI BLEED - ACUTE [胃腸出血]	20[redacted]/06/08/11:59	72	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE,NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/06/10/14:00	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0518-1501	HYPOTENSION [低血圧]	20[redacted]/06/08/11:59	72	SEVERE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED	NOT RELATED	20[redacted]/06/10/14:00	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0518-1536	CLOTTED AV FISTULA [動静脈瘻血栓症]	20[redacted]/08/18/06:30	143	MODERATE	Y	Unknown	DRUG INTERRUPTED	HOSPITALIZED, MEDICATIONS TO TREAT AE,NON-MED TREATMENT TO TREAT AE	NOT RELATED	20[redacted]/08/23/18:55	RECOVERED/ RESOLVED
AMG 416	KAI-4169-005-0518-1536	CHRONIC MYLOGENOUS LUEKEMIA [慢性骨髄性白血病]	20[redacted]/08/28/06:40	153	SEVERE	Y	Unknown	DRUG WITHDRAWN	DISCONTINUED FROM STUDY	NOT RELATED	ONGOING	-

*1:MedDRA Version 17.0J
AMG 416 = ONO-5163

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＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

表 2.7.6.17-28　投与中止に至った有害事象の一覧表（20120334 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
AMG 416	KAI-4169-005-0511-1543	EXSANGUINATION FROM A-V FISTULA [失血]	20[redacted]/10/30	202	LIFE THREATENING	Y	Event Contributed to Death	-	DISCONTINUED FROM STUDY	NOT RELATED	20[redacted]/10/30	FATAL
AMG 416	KAI-4169-005-0516-1511	MELANOMA, METASTATIC [遠隔転移を伴う悪性黒色腫]	20[redacted]/05/30	44	LIFE THREATENING	Y	Event Contributed to Death	DRUG WITHDRAWN	DISCONTINUED FROM STUDY	NOT RELATED	20[redacted]/08/02	FATAL
AMG 416	KAI-4169-005-0517-1510	WORSENING SECONDARY HYPERPARATHYROIDISM [続発性副甲状腺機能亢進症]	20[redacted]/06/06	56	SEVERE	Y	Unknown	DRUG WITHDRAWN	DISCONTINUED FROM STUDY	NOT RELATED	20[redacted]/06/08/21:18	RECOVERED/ RESOLVED WITH SEQUELAE
AMG 416	KAI-4169-005-0517-1516	CARDIAC ARRHYTHMIA [不整脈]	20[redacted]/08/26	116	LIFE THREATENING	Y	Event Contributed to Death	DRUG WITHDRAWN	-	NOT RELATED	20[redacted]/08/26	FATAL
AMG 416	KAI-4169-005-0518-1536	WORSENING ANEMIA [貧血]	20[redacted]/08/30/06:40	155	SEVERE	N	Unknown	DRUG WITHDRAWN	-	NOT RELATED	ONGOING	-
AMG 416	KAI-4169-005-0518-1536	CHRONIC MYLOGENOUS LUEKEMIA [慢性骨髄性白血病]	20[redacted]/08/28/06:40	153	SEVERE	Y	Unknown	DRUG WITHDRAWN	DISCONTINUED FROM STUDY	NOT RELATED	ONGOING	-
AMG 416	KAI-4169-005-0518-1536	WORSENING LUEKOCYTOSIS [白血球増加症]	20[redacted]/08/30/06:40	155	SEVERE	N	Unknown	DRUG WITHDRAWN	DISCONTINUED FROM STUDY	NOT RELATED	ONGOING	-

*1:MedDRA Version 17.0J
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