表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）
解析対象集団：SAF

	有害事象					
	ONO-5163			プラセボ		
SOC	1日目～28日目	29日目～56日目	57日目～	1日目～28日目	29日目～56日目	57日目～
PT	n （%）	n （%）	n （%）	n （%）	n （%）	n （%）
N[a)]	78	76	75	77	74	70
全体	26 (33.3)	15 (19.7)	10 (13.3)	29 (37.7)	18 (24.3)	9 (12.9)
血液およびリンパ系障害			1 (1.3)			1 (1.4)
出血性貧血			1 (1.3)			1 (1.4)
出血性素因						1 (1.4)
心臓障害		3 (3.9)		1 (1.3)		
狭心症		1 (1.3)				
大動脈弁狭窄				1 (1.3)		
心房細動		1 (1.3)				

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

出典［総括報告書 5.3.5.1-1（ONO-5163-[redacted] 試験）表 14.3.1-14］

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 1）
解析対象集団：SAF

	有害事象					
	ONO-5163			プラセボ		
SOC	1日目～28日目	29日目～56日目	57日目～	1日目～28日目	29日目～56日目	57日目～
PT	n （%）	n （%）	n （%）	n （%）	n （%）	n （%）
N[a)]	78	76	75	77	74	70
心室性期外収縮		1 (1.3)				
耳および迷路障害	2 (2.6)					
感音性難聴	1 (1.3)					
回転性めまい	1 (1.3)					
眼障害		1 (1.3)	2 (2.7)	1 (1.3)	2 (2.7)	
結膜出血				1 (1.3)		
アレルギー性結膜炎			2 (2.7)		1 (1.4)	
複視					1 (1.4)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 2）
解析対象集団：SAF

		有害事象					
		ONO-5163			プラセボ		
SOC		1日目～28日目	29日目～56日目	57日目～	1日目～28日目	29日目～56日目	57日目～
PT		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	N[a)]	78	76	75	77	74	70
眼出血			1 (1.3)				
胃腸障害		7 (9.0)	5 (6.6)	3 (4.0)	5 (6.5)	6 (8.1)	1 (1.4)
腹部膨満					1 (1.3)	1 (1.4)	
上腹部痛		1 (1.3)			1 (1.3)		
口唇炎				1 (1.3)			
便秘				2 (2.7)	2 (2.6)		
齲歯						1 (1.4)	
下痢		1 (1.3)	2 (2.6)			2 (2.7)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 3）
解析対象集団：SAF

		有害事象					
		ONO-5163			プラセボ		
SOC		1日目～28日目	29日目～56日目	57日目～	1日目～28日目	29日目～56日目	57日目～
PT		n （%）	n （%）	n （%）	n （%）	n （%）	n （%）
	N[a)]	78	76	75	77	74	70
十二指腸潰瘍					1 (1.3)		
十二指腸炎					1 (1.3)		
腸炎				1 (1.3)			1 (1.4)
胃炎		1 (1.3)					
びらん性胃炎					1 (1.3)		
歯肉痛			1 (1.3)				
歯肉腫脹				1 (1.3)			
痔核					1 (1.3)		

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 4）
解析対象集団：SAF

	有害事象					
	ONO-5163			プラセボ		
SOC	1日目～28日目	29日目～56日目	57日目～	1日目～28日目	29日目～56日目	57日目～
PT	n （%）	n （%）	n （%）	n （%）	n （%）	n （%）
N[a)]	78	76	75	77	74	70
悪心		2 (2.6)	1 (1.3)			
直腸ポリープ					1 (1.4)	
口内炎	2 (2.6)				2 (2.7)	
嘔吐	2 (2.6)	2 (2.6)				
肛門脱					1 (1.4)	
一般・全身障害および投与部位の状態	1 (1.3)	1 (1.3)			3 (4.1)	
不快感		1 (1.3)				
腫瘤					1 (1.4)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 5）
解析対象集団：SAF

SOC PT		有害事象					
		ONO-5163			プラセボ		
		1日目～28日目 n (%)	29日目～56日目 n (%)	57日目～ n (%)	1日目～28日目 n (%)	29日目～56日目 n (%)	57日目～ n (%)
	N[a)]	78	76	75	77	74	70
疼痛						1 (1.4)	
発熱						1 (1.4)	1 (1.4)
血管穿刺部位炎症		1 (1.3)					
免疫系障害							1 (1.4)
季節性アレルギー							1 (1.4)
感染症および寄生虫症		6 (7.7)	12 (15.8)	6 (8.0)	14 (18.2)	5 (6.8)	5 (7.1)
気管支炎		1 (1.3)	1 (1.3)		1 (1.3)	1 (1.4)	
結膜炎					1 (1.3)		

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 6）
解析対象集団：SAF

SOC PT		有害事象					
		ONO-5163			プラセボ		
		1日目～28日目 n (%)	29日目～56日目 n (%)	57日目～ n (%)	1日目～28日目 n (%)	29日目～56日目 n (%)	57日目～ n (%)
	N[a)]	78	76	75	77	74	70
膀胱炎				1 (1.3)			
憩室炎				1 (1.3)			
胃腸炎			1 (1.3)		2 (2.6)	1 (1.4)	
歯肉炎							2 (2.9)
インフルエンザ			3 (3.9)		1 (1.3)	1 (1.4)	
鼻咽頭炎		5 (6.4)	7 (9.2)	4 (5.3)	11 (14.3)	2 (2.7)	2 (2.9)
歯周炎						1 (1.4)	
皮膚感染			1 (1.3)				

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 7）
解析対象集団：SAF

	有害事象					
	ONO-5163			プラセボ		
SOC	1日目～28日目	29日目～56日目	57日目～	1日目～28日目	29日目～56日目	57日目～
PT	n （%）	n （%）	n （%）	n （%）	n （%）	n （%）
N[a)]	78	76	75	77	74	70
扁桃炎				1 (1.3)		
眼瞼毛包炎						1 (1.4)
腎嚢胞感染			1 (1.3)			
口腔ヘルペス					1 (1.4)	
傷害、中毒および処置合併症	5 (6.4)	1 (1.3)	1 (1.3)	6 (7.8)	5 (6.8)	5 (7.1)
凍瘡					1 (1.4)	
足骨折						1 (1.4)
裂傷				1 (1.3)		

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 8）

解析対象集団：SAF

SOC PT		有害事象					
		ONO-5163			プラセボ		
		1日目～28日目 n (%)	29日目～56日目 n (%)	57日目～ n (%)	1日目～28日目 n (%)	29日目～56日目 n (%)	57日目～ n (%)
	N[a)]	78	76	75	77	74	70
靭帯捻挫		1 (1.3)				1 (1.4)	
筋断裂							1 (1.4)
擦過傷		1 (1.3)					
挫傷					2 (2.6)	1 (1.4)	2 (2.9)
創傷							1 (1.4)
熱傷						1 (1.4)	
シャント狭窄					1 (1.3)	1 (1.4)	
処置による低血圧		2 (2.6)	1 (1.3)		1 (1.3)		

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 9）
解析対象集団：SAF

SOC PT		有害事象					
		ONO-5163			プラセボ		
		1日目～28日目 n (%)	29日目～56日目 n (%)	57日目～ n (%)	1日目～28日目 n (%)	29日目～56日目 n (%)	57日目～ n (%)
	N[a)]	78	76	75	77	74	70
歯牙破折					1 (1.3)		
処置後炎症				1 (1.3)			
処置による疼痛		1 (1.3)					
臨床検査		2 (2.6)	3 (3.9)	2 (2.7)		1 (1.4)	1 (1.4)
血中カルシウム減少		1 (1.3)	1 (1.3)	1 (1.3)			
血中カリウム増加							1 (1.4)
血圧低下						1 (1.4)	
血中アルカリホスファターゼ増加				1 (1.3)			

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 10）
解析対象集団：SAF

	有害事象					
	ONO-5163			プラセボ		
SOC	1日目～28日目	29日目～56日目	57日目～	1日目～28日目	29日目～56日目	57日目～
PT	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
N[a)]	78	76	75	77	74	70
補正カルシウム減少	1 (1.3)	2 (2.6)				
代謝および栄養障害	2 (2.6)		1 (1.3)		1 (1.4)	1 (1.4)
耐糖能障害						1 (1.4)
高カリウム血症			1 (1.3)			
高リン酸塩血症					1 (1.4)	
低カルシウム血症	1 (1.3)					
食欲減退	1 (1.3)					
筋骨格系および結合組織障害	3 (3.8)	4 (5.3)	4 (5.3)	2 (2.6)	2 (2.7)	5 (7.1)

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 11）
解析対象集団：SAF

SOC PT		有害事象					
		ONO-5163			プラセボ		
		1日目～28日目 n (%)	29日目～56日目 n (%)	57日目～ n (%)	1日目～28日目 n (%)	29日目～56日目 n (%)	57日目～ n (%)
	N[a)]	78	76	75	77	74	70
関節痛			1 (1.3)	1 (1.3)			1 (1.4)
背部痛			1 (1.3)		1 (1.3)	1 (1.4)	
尾骨痛		1 (1.3)					
側腹部痛		1 (1.3)			1 (1.3)		
筋痙縮		1 (1.3)		1 (1.3)		1 (1.4)	1 (1.4)
筋力低下							1 (1.4)
筋肉痛			1 (1.3)	1 (1.3)			1 (1.4)
頚部痛			1 (1.3)	1 (1.3)			

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 12）
解析対象集団：SAF

		有害事象					
		ONO-5163			プラセボ		
SOC		1日目～28日目	29日目～56日目	57日目～	1日目～28日目	29日目～56日目	57日目～
PT		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	N[a)]	78	76	75	77	74	70
四肢痛				1 (1.3)			1 (1.4)
神経系障害		2 (2.6)		1 (1.3)	2 (2.6)	2 (2.7)	2 (2.9)
脳梗塞		1 (1.3)					
浮動性めまい							1 (1.4)
頭痛		1 (1.3)		1 (1.3)	1 (1.3)	2 (2.7)	
感覚鈍麻					1 (1.3)		
振戦							1 (1.4)
精神障害		1 (1.3)	1 (1.3)			1 (1.4)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 13）
解析対象集団：SAF

	有害事象					
	ONO-5163			プラセボ		
SOC	1日目～28日目	29日目～56日目	57日目～	1日目～28日目	29日目～56日目	57日目～
PT	n （%）	n （%）	n （%）	n （%）	n （%）	n （%）
N[a)]	78	76	75	77	74	70
不安		1 (1.3)			1 (1.4)	
不眠症	1 (1.3)					
腎および尿路障害					1 (1.4)	
腎性高血圧					1 (1.4)	
呼吸器、胸郭および縦隔障害	1 (1.3)	1 (1.3)	1 (1.3)	1 (1.3)	3 (4.1)	2 (2.9)
喘息					1 (1.4)	
咳嗽	1 (1.3)			1 (1.3)		1 (1.4)
アレルギー性鼻炎			1 (1.3)			

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 14）
解析対象集団：SAF

		有害事象					
		ONO-5163			プラセボ		
SOC		1日目～28日目	29日目～56日目	57日目～	1日目～28日目	29日目～56日目	57日目～
PT		n （%）	n （%）	n （%）	n （%）	n （%）	n （%）
	N[a)]	78	76	75	77	74	70
上気道の炎症			1 (1.3)			2 (2.7)	1 (1.4)
皮膚および皮下組織障害		3 (3.8)	1 (1.3)	3 (4.0)	1 (1.3)	5 (6.8)	1 (1.4)
水疱				1 (1.3)			
皮膚炎						1 (1.4)	
接触性皮膚炎		1 (1.3)					
湿疹		1 (1.3)					
メラノーシス						1 (1.4)	
そう痒症			1 (1.3)		1 (1.3)	1 (1.4)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 15）
解析対象集団：SAF

		有害事象					
		ONO-5163			プラセボ		
SOC		1日目～28日目	29日目～56日目	57日目～	1日目～28日目	29日目～56日目	57日目～
PT		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	N[a)]	78	76	75	77	74	70
発疹		1 (1.3)		1 (1.3)			
皮膚剥脱				1 (1.3)			1 (1.4)
蕁麻疹						1 (1.4)	
全身性そう痒症						1 (1.4)	
血管障害			1 (1.3)	2 (2.7)	2 (2.6)		1 (1.4)
血腫				1 (1.3)			
高血圧			1 (1.3)	1 (1.3)			
低血圧					1 (1.3)		1 (1.4)

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-2　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 16）
解析対象集団：SAF

		有害事象					
		ONO-5163			プラセボ		
SOC		1日目～28日目	29日目～56日目	57日目～	1日目～28日目	29日目～56日目	57日目～
PT		n （%）	n （%）	n （%）	n （%）	n （%）	n （%）
	N[a)]	78	76	75	77	74	70
内出血					1 (1.3)		

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．
出典［総括報告書 5.3.5.1-1（ONO-5163-[redacted] 試験）表 14.3.1-14］

表 2.7.4.7-3　副作用の時期別発現頻度（ONO-5163-[redacted]試験）
解析対象集団：SAF

	副作用					
	ONO-5163			プラセボ		
SOC	1日目～28日目	29日目～56日目	57日目～	1日目～28日目	29日目～56日目	57日目～
PT	n （%）	n （%）	n （%）	n （%）	n （%）	n （%）
N[a)]	78	76	75	77	74	70
全体	8 (10.3)	3 (3.9)	4 (5.3)		2 (2.7)	1 (1.4)
心臓障害			1 (1.3)			
心房細動			1 (1.3)			
胃腸障害	2 (2.6)	2 (2.6)	2 (2.7)		1 (1.4)	
腸炎			1 (1.3)			
悪心			1 (1.3)			
口内炎	1 (1.3)				1 (1.4)	
嘔吐	1 (1.3)	2 (2.6)				

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．
a）各時期において有害事象の観察が行われた被験者とした．
出典［総括報告書 5.3.5.1-1（ONO-5163-[redacted]試験）表 14.3.1-15］

表 2.7.4.7-3　副作用の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 1）
解析対象集団：SAF

SOC PT	副作用					
	ONO-5163			プラセボ		
	1日目～28日目 n （%）	29日目～56日目 n （%）	57日目～ n （%）	1日目～28日目 n （%）	29日目～56日目 n （%）	57日目～ n （%）
N[a)]	78	76	75	77	74	70
臨床検査	2 (2.6)	2 (2.6)	1 (1.3)			
血中カルシウム減少	1 (1.3)		1 (1.3)			
補正カルシウム減少	1 (1.3)	2 (2.6)				
代謝および栄養障害	2 (2.6)					
低カルシウム血症	1 (1.3)					
食欲減退	1 (1.3)					
筋骨格系および結合組織障害	1 (1.3)		1 (1.3)			1 (1.4)
側腹部痛	1 (1.3)					

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．
a）各時期において有害事象の観察が行われた被験者とした．

表 2.7.4.7-3　副作用の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 2）
解析対象集団：SAF

		副作用					
		ONO-5163			プラセボ		
SOC		1日目～28日目	29日目～56日目	57日目～	1日目～28日目	29日目～56日目	57日目～
PT		n （%）	n （%）	n （%）	n （%）	n （%）	n （%）
	N[a)]	78	76	75	77	74	70
筋痙縮				1 (1.3)			
筋力低下							1 (1.4)
皮膚および皮下組織障害		1 (1.3)				1 (1.4)	
そう痒症						1 (1.4)	
発疹		1 (1.3)					

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．
a）各時期において有害事象の観察が行われた被験者とした．
出典［総括報告書 5.3.5.1-1（ONO-5163-[redacted] 試験）表 14.3.1-15］

表 2.7.4.7-4　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）
解析対象集団：SAF

SOC PT		有害事象 ONO-5163 0 mg n (%)	2.5 mg n (%)	5 mg n (%)	7.5 mg n (%)	10 mg n (%)	12.5 mg n (%)	15 mg n (%)
	N	23	12	78	6	44	1	16
全体		6 (26.1)	4 (33.3)	34 (43.6)	1 (16.7)	17 (38.6)		5 (31.3)
血液およびリンパ系障害		1 (4.3)						
出血性貧血		1 (4.3)						
心臓障害		2 (8.7)	1 (8.3)			1 (2.3)		
狭心症		1 (4.3)						
心房細動		1 (4.3)	1 (8.3)					
心室性期外収縮						1 (2.3)		
耳および迷路障害				2 (2.6)				

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．
出典［総括報告書 5.3.5.1-1（ONO-5163-[redacted]試験）表 14.3.1-16］

表 2.7.4.7-4　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 1）
解析対象集団：SAF

SOC PT		有害事象 ONO-5163 0 mg n (%)	2.5 mg n (%)	5 mg n (%)	7.5 mg n (%)	10 mg n (%)	12.5 mg n (%)	15 mg n (%)
	N	23	12	78	6	44	1	16
感音性難聴				1 (1.3)				
回転性めまい				1 (1.3)				
眼障害		1 (4.3)		1 (1.3)				1 (6.3)
アレルギー性結膜炎		1 (4.3)						1 (6.3)
眼出血				1 (1.3)				
胃腸障害		2 (8.7)	1 (8.3)	9 (11.5)		4 (9.1)		2 (12.5)
上腹部痛				1 (1.3)				
口唇炎				1 (1.3)				

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

表 2.7.4.7-4　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 2）
解析対象集団：SAF

SOC PT		有害事象 ONO-5163 0 mg n (%)	2.5 mg n (%)	5 mg n (%)	7.5 mg n (%)	10 mg n (%)	12.5 mg n (%)	15 mg n (%)
	N	23	12	78	6	44	1	16
便秘				1 (1.3)				1 (6.3)
下痢		1 (4.3)		2 (2.6)				
腸炎						1 (2.3)		
胃炎				1 (1.3)				
歯肉痛				1 (1.3)				
歯肉腫脹				1 (1.3)				
悪心		1 (4.3)				1 (2.3)		1 (6.3)
口内炎		1 (4.3)	1 (8.3)	1 (1.3)				

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

表 2.7.4.7-4　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 3）
解析対象集団：SAF

		有害事象						
		ONO-5163						
SOC		0 mg	2.5 mg	5 mg	7.5 mg	10 mg	12.5 mg	15 mg
PT		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	N	23	12	78	6	44	1	16
嘔吐				2 (2.6)		2 (4.5)		
一般・全身障害および投与部位の状態				1 (1.3)		1 (2.3)		
不快感						1 (2.3)		
血管穿刺部位炎症				1 (1.3)				
感染症および寄生虫症		2 (8.7)	2 (16.7)	13 (16.7)		8 (18.2)		
気管支炎				1 (1.3)		1 (2.3)		
膀胱炎				1 (1.3)				
憩室炎						1 (2.3)		

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

表 2.7.4.7-4　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 4）
解析対象集団：SAF

SOC PT		有害事象 ONO-5163 0 mg n (%)	2.5 mg n (%)	5 mg n (%)	7.5 mg n (%)	10 mg n (%)	12.5 mg n (%)	15 mg n (%)
	N	23	12	78	6	44	1	16
胃腸炎						1 (2.3)		
インフルエンザ				1 (1.3)		2 (4.5)		
鼻咽頭炎		2 (8.7)	1 (8.3)	10 (12.8)		4 (9.1)		
皮膚感染			1 (8.3)					
腎嚢胞感染			1 (8.3)					
傷害、中毒および処置合併症				5 (6.4)		1 (2.3)		1 (6.3)
靱帯捻挫				1 (1.3)				
擦過傷				1 (1.3)				

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

表 2.7.4.7-4　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 5）
解析対象集団：SAF

SOC PT		有害事象 ONO-5163 0 mg n (%)	2.5 mg n (%)	5 mg n (%)	7.5 mg n (%)	10 mg n (%)	12.5 mg n (%)	15 mg n (%)
	N	23	12	78	6	44	1	16
処置による低血圧				2 (2.6)		1 (2.3)		
処置後炎症								1 (6.3)
処置による疼痛				1 (1.3)				
臨床検査				5 (6.4)	1 (16.7)	1 (2.3)		
血中カルシウム減少				2 (2.6)		1 (2.3)		
血中アルカリホスファターゼ増加				1 (1.3)				
補正カルシウム減少				2 (2.6)	1 (16.7)			
代謝および栄養障害				3 (3.8)				

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

表 2.7.4.7-4　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 6）
解析対象集団：SAF

		有害事象						
		ONO-5163						
SOC		0 mg	2.5 mg	5 mg	7.5 mg	10 mg	12.5 mg	15 mg
PT		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	N	23	12	78	6	44	1	16
高カリウム血症				1 (1.3)				
低カルシウム血症				1 (1.3)				
食欲減退				1 (1.3)				
筋骨格系および結合組織障害			2 (16.7)	7 (9.0)		1 (2.3)		1 (6.3)
関節痛				2 (2.6)				
背部痛			1 (8.3)					
尾骨痛				1 (1.3)				
側腹部痛				1 (1.3)				

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

表 2.7.4.7-4　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 7）
解析対象集団：SAF

		有害事象						
		ONO-5163						
SOC		0 mg	2.5 mg	5 mg	7.5 mg	10 mg	12.5 mg	15 mg
PT		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	N	23	12	78	6	44	1	16
筋痙縮			1 (8.3)	1 (1.3)				
筋肉痛						1 (2.3)		1 (6.3)
頚部痛				2 (2.6)				
四肢痛				1 (1.3)				
神経系障害				2 (2.6)		1 (2.3)		
脳梗塞				1 (1.3)				
頭痛				1 (1.3)		1 (2.3)		
精神障害				2 (2.6)				

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

表 2.7.4.7-4　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 8）
解析対象集団：SAF

SOC PT		有害事象 ONO-5163 0 mg n (%)	2.5 mg n (%)	5 mg n (%)	7.5 mg n (%)	10 mg n (%)	12.5 mg n (%)	15 mg n (%)
	N	23	12	78	6	44	1	16
不安				1 (1.3)				
不眠症				1 (1.3)				
呼吸器、胸郭および縦隔障害				1 (1.3)		1 (2.3)		1 (6.3)
咳嗽				1 (1.3)				
アレルギー性鼻炎								1 (6.3)
上気道の炎症						1 (2.3)		
皮膚および皮下組織障害				6 (7.7)		1 (2.3)		
水疱				1 (1.3)				

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

表 2.7.4.7-4　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 9）
解析対象集団：SAF

SOC PT		有害事象 ONO-5163 0 mg n (%)	2.5 mg n (%)	5 mg n (%)	7.5 mg n (%)	10 mg n (%)	12.5 mg n (%)	15 mg n (%)
	N	23	12	78	6	44	1	16
接触性皮膚炎				1 (1.3)				
湿疹				1 (1.3)				
そう痒症						1 (2.3)		
発疹				2 (2.6)				
皮膚剥脱				1 (1.3)				
血管障害				3 (3.8)				
血腫				1 (1.3)				
高血圧				2 (2.6)				

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．
出典［総括報告書 5.3.5.1-1（ONO-5163-[redacted]試験）表 14.3.1-16］

表 2.7.4.7-5　副作用の発現時投与量別発現頻度（ONO-5163-[redacted]試験）
解析対象集団：SAF

		副作用						
		ONO-5163						
SOC		0 mg	2.5 mg	5 mg	7.5 mg	10 mg	12.5 mg	15 mg
PT		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	N	23	12	78	6	44	1	16
全体			2 (16.7)	9 (11.5)	1 (16.7)	4 (9.1)		1 (6.3)
心臓障害			1 (8.3)					
心房細動			1 (8.3)					
胃腸障害				2 (2.6)		3 (6.8)		1 (6.3)
腸炎						1 (2.3)		
悪心								1 (6.3)
口内炎				1 (1.3)				
嘔吐				1 (1.3)		2 (4.5)		

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

出典［総括報告書 5.3.5.1-1（ONO-5163-[redacted]試験）表 14.3.1-17］

表 2.7.4.7-5　副作用の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 1）
解析対象集団：SAF

SOC PT		副作用 ONO-5163 0 mg n (%)	2.5 mg n (%)	5 mg n (%)	7.5 mg n (%)	10 mg n (%)	12.5 mg n (%)	15 mg n (%)
	N	23	12	78	6	44	1	16
臨床検査				3 (3.8)	1 (16.7)	1 (2.3)		
血中カルシウム減少				1 (1.3)		1 (2.3)		
補正カルシウム減少				2 (2.6)	1 (16.7)			
代謝および栄養障害				2 (2.6)				
低カルシウム血症				1 (1.3)				
食欲減退				1 (1.3)				
筋骨格系および結合組織障害			1 (8.3)	1 (1.3)				
側腹部痛				1 (1.3)				

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-5　副作用の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 2）
解析対象集団：SAF

SOC PT		副作用 ONO-5163 0 mg n (%)	2.5 mg n (%)	5 mg n (%)	7.5 mg n (%)	10 mg n (%)	12.5 mg n (%)	15 mg n (%)
	N	23	12	78	6	44	1	16
筋痙縮			1 (8.3)					
皮膚および皮下組織障害				1 (1.3)				
発疹				1 (1.3)				

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

出典［総括報告書 5.3.5.1-1（ONO-5163-[redacted]試験）表 14.3.1-17］

表 2.7.4.7-6　死亡例の一覧表［海外第Ⅲ相プラセボ対照試験（併合成績）］

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	20120229-22958001002	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	THROMBOSIS GORETEX [血管グラフト血栓症]	20[redacted]-07-05	26	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-08	RECOVERED/RESOLVED
AMG 416	20120229-22958001002	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPERPOTASSEMIA [高カリウム血症]	20[redacted]-07-06	27	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-07-09	-
AMG 416	20120229-22958001002	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	LOW SERUM CALCIUM [血中カルシウム減少]	20[redacted]-07-15	36	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	RELATED	20[redacted]-09-02	-
AMG 416	20120229-22958001002	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	CRAMPS IN LEGS [筋痙縮]	20[redacted]-08-05	57	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-08-05	-
AMG 416	20120229-22958001002	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	DIARRHEA [下痢]	20[redacted]-08-26	78	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-08-26	-
AMG 416	20120229-22958001002	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	BLOOD CALCIUM DECREASED [血中カルシウム減少]	20[redacted]-09-16	99	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	RELATED	20[redacted]-10-14	-

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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	20120229-22958001002	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPOTENSION DURING DIALYSIS [処置による低血圧]	20[redacted]-09-28T16:00	111	MILD	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-09-28T16:30	-
AMG 416	20120229-22958001002	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPERTENSION ARTERIAL [高血圧]	20[redacted]-10-11	124	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-11	-
AMG 416	20120229-22958001002	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	BLEEDING AT GRAFT SITE [移植部位出血]	20[redacted]-10-23	136	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-11-27	FATAL
AMG 416	20120229-22958001002	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	RESPIRATORY DISTRESS DUE TO POST-SURGICAL INESTABILITY [術後呼吸窮迫]	20[redacted]-10-23	136	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-29	RECOVERED/RESOLVED
AMG 416	20120229-22965007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	TRANSIENT NON-SPECIFIC GASTROINTESTINAL UPSET [腹部不快感]	20[redacted]-08-24T15:25	3	MODERATE	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	RELATED	20[redacted]-08-25	-
AMG 416	20120229-22965007001	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	DEATH - CAUSE UNKNOWN [死亡]	20[redacted]-09-01	11	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	RELATED	20[redacted]-09-02	FATAL

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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	20120229-22966017001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	LOW SERUM CALCUM [血中カルシウム減少]	20[redacted]-06-04	22	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	RELATED	20[redacted]-06-18T22:15	-
AMG 416	20120229-22966017001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	OPEN INFECTED WOUND LEFT FOOT [創傷感染]	20[redacted]-06-11T08:00	29	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-29T22:15	RECOVERED/RESOLVED
AMG 416	20120229-22966017001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	DUODENOGASTRIC REFLUX [十二指腸胃逆流]	20[redacted]-06-24	42	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-06-28	-
AMG 416	20120229-22966017001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	ATRIAL FIBRILLATION [心房細動]	20[redacted]-07-11	59	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN	NOT RELATED	20[redacted]-07-15	RECOVERED/RESOLVED
AMG 416	20120229-22966017001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	ATRIAL FLUTTER WITH RAPID VENTRICULAR RESPONSE [心房粗動]	20[redacted]-07-11	59	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-15	RECOVERED/RESOLVED
AMG 416	20120229-22966017001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	CONSTIPATION [便秘]	20[redacted]-07-12	60	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-07-12	-
AMG 416	20120229-22966017001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	HYPERPHOSHATEMIA [高リン酸塩血症]	20[redacted]-07-12	60	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-07-12	-

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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	20120229-22966017001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	ANXIETY [不安]	20[redacted]-07-13	61	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-07-14	-
AMG 416	20120229-22966017001	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	END STAGE RENAL DISEASE (ESRD) [慢性腎不全]	20[redacted]-07-29T21:29	77	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-07-29T22:15	FATAL
AMG 416	20120229-22966027002	6[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	BLOOD CALCIUM DECREASED [血中カルシウム減少]	20[redacted]-08-30	87	MILD	NO	-	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	RELATED	20[redacted]-09-04	-
AMG 416	20120229-22966027002	6[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CAR ACCIDENT [交通事故]	20[redacted]-12-27	206	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-12-27	FATAL
AMG 416	20120229-22966027004	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	BLOOD CALCIUM DECREASED [血中カルシウム減少]	20[redacted]-05-30T02:30	45	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	RELATED	20[redacted]-07-09	-
AMG 416	20120229-22966027004	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	GERD [胃食道逆流性疾患]	20[redacted]-07-09	85	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-11-09	-

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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	20120229-22966027004	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	DYSPNEA [呼吸困難]	20[redacted]-10-12	180	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-09	RECOVERED/RESOLVED
AMG 416	20120229-22966027004	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	CONSTIPATION [便秘]	20[redacted]-10-18	186	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-11-09	-
AMG 416	20120229-22966027004	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	NAUSEA AND VOMITING [嘔吐]	20[redacted]-10-18	186	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-11-09	-
AMG 416	20120229-22966027004	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	ORTHOSTATIC HYPOTENSION [起立性低血圧]	20[redacted]-10-18	186	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-11-09	-
AMG 416	20120229-22966027004	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	SORE THROAT [口腔咽頭痛]	20[redacted]-10-18	186	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-11-09	-
AMG 416	20120229-22966027004	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	AORTIC STENOSIS [大動脈狭窄]	20[redacted]-10-27	195	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-11-09	RECOVERED/RESOLVED
AMG 416	20120229-22966027004	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	HYPONATREMIA [低ナトリウム血症]	20[redacted]-10-27	195	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-11-09	-

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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	20120229-22966027004	8[redacted]	F	WHITE	NOT HISPANIC OR LATINO	WORSENING OF CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-11-06	205	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-09	FATAL
AMG 416	20120229-22966035001	4[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	MALFUNCTIONING FISTULA [動静脈瘻部位合併症]	20[redacted]-07-25T06:00	37	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-26T18:00	RECOVERED/RESOLVED
AMG 416	20120229-22966035001	4[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-08-17	60	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-08-17	FATAL
AMG 416	20120229-22966049003	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	HYPERKALEMIA [高カリウム血症]	20[redacted]-08-21	6	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-08-23	-
AMG 416	20120229-22966049003	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-08-21	6	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-09-01	RECOVERED/RESOLVED
AMG 416	20120229-22966049003	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	WEAKNESS GENERALIZED [無力症]	20[redacted]-09-20	36	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-20	-

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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	20120229-22966049003	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	DIZZINESS [浮動性めまい]	20[redacted]-10-30	76	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-30	-
AMG 416	20120229-22966049003	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	WEAKNESS GENERALIZED [無力症]	20[redacted]-10-30	76	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-30	-
AMG 416	20120229-22966049003	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CARDIAC CHEST DISCOMFORT [心不快感]	20[redacted]-11-13T13:33	90	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-11-13T14:30	-
AMG 416	20120229-22966049003	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	DYSPNEA [呼吸困難]	20[redacted]-12-09	116	MILD	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-12-09	-
AMG 416	20120229-22966049003	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	HYPERVENTILATING [過換気]	20[redacted]-01-06	144	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-01-06	-
AMG 416	20120229-22966049003	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-01-06	144	MILD	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-01-06	-
AMG 416	20120229-22966049003	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-01-10	148	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-14T14:30	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	20120229-22966049003	7[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SUDDEN CARDIAC DEATH [心突然死]	20[redacted]-01-14*	152	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]-01-14*	FATAL
AMG 416	20120229-22966169001	6[redacted]	F	WHITE	HISPANIC OR LATINO	WORSENING PROLONGED BLEEDING POST-DIALYSIS AT NEEDLE STICK SITE [穿刺部位出血]	20[redacted]-08-19T09:07	1	MODERATE	NO	-	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-08-19T11:08	-
AMG 416	20120229-22966169001	6[redacted]	F	WHITE	HISPANIC OR LATINO	LOW BLOOD CALCIUM [血中カルシウム減少]	20[redacted]-11-04*	78	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	RELATED	20[redacted]-11-18*	-
AMG 416	20120229-22966169001	6[redacted]	F	WHITE	HISPANIC OR LATINO	HYPERBILIRUBINEMIA [高ビリルビン血症]	20[redacted]-02-10*	176	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-03-18*	RECOVERED/RESOLVED
AMG 416	20120229-22966169001	6[redacted]	F	WHITE	HISPANIC OR LATINO	ACUTE LIVER FAILURE [急性肝不全]	20[redacted]-02-12*	178	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-18*	RECOVERED/RESOLVED
AMG 416	20120229-22966169001	6[redacted]	F	WHITE	HISPANIC OR LATINO	ASCITES [腹水]	20[redacted]-02-20*	186	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-03-18*	-
AMG 416	20120229-22966169001	6[redacted]	F	WHITE	HISPANIC OR LATINO	HEPATOSPLENOMEGALY [肝脾腫大]	20[redacted]-02-20*	186	MODERATE	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-03-18*	-

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Treatment Group	Usubject ID	Age (years)	Sex	Race	Ethnicity	Reported Term for the Adverse Event [Preferred Term*t]	Start Date/Time*	Study Day of Start of Adverse Event (days)	Severity/ Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time*	Outcome of Serious Adverse Event
AMG 416	20120229-22966169001	6[redacted]	F	WHITE	HISPANIC OR LATINO	CHEST PAIN - CARDIAC [狭心症]	20[redacted]-02-22T08:00	188	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-08	RECOVERED/RESOLVED
AMG 416	20120229-22966169001	6[redacted]	F	WHITE	HISPANIC OR LATINO	CIRRHOSIS OF LIVER [肝硬変]	20[redacted]-02-23	189	MODERATE	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-03-18	-
AMG 416	20120229-22966169001	6[redacted]	F	WHITE	HISPANIC OR LATINO	BILIARY CANCER WITH METASTASIS TO LIVER [遠隔転移を伴う胆道癌]	20[redacted]-03-03	197	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-18	FATAL
AMG 416	20120229-22966169001	6[redacted]	F	WHITE	HISPANIC OR LATINO	GENERALIZED PAIN [疼痛]	20[redacted]-03-10	204	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-03-18	-
AMG 416	20120229-22966169001	6[redacted]	F	WHITE	HISPANIC OR LATINO	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-03-10	204	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-03-18	-
AMG 416	20120229-22966169001	6[redacted]	F	WHITE	HISPANIC OR LATINO	WEAKNESS [無力症]	20[redacted]-03-10	204	MODERATE	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-03-18	-
AMG 416	20120229-22966169001	6[redacted]	F	WHITE	HISPANIC OR LATINO	HYPOGLYCEMIA [低血糖症]	20[redacted]-03-18	212	SEVERE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-03-18	-
AMG 416	20120229-22966181003	4[redacted]	M	WHITE	HISPANIC OR LATINO	COUGH [咳嗽]	20[redacted]-11-01	52	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-11-27	-

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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	20120229-22966181003	4[redacted]	M	WHITE	HISPANIC OR LATINO	NAUSEA [悪心]	20[redacted]-11-01	52	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]*-01-23	-
AMG 416	20120229-22966181003	4[redacted]	M	WHITE	HISPANIC OR LATINO	BRONCHITIS [気管支炎]	20[redacted]-11-15	66	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-18	RECOVERED/RESOLVED
AMG 416	20120229-22966181003	4[redacted]	M	WHITE	HISPANIC OR LATINO	HYPOGLYCEMIA [低血糖症]	20[redacted]-11-23	74	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]*-01-24	-
AMG 416	20120229-22966181003	4[redacted]	M	WHITE	HISPANIC OR LATINO	CATHETER INFECTION [医療機器関連感染]	20[redacted]-12-13	94	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-12-18	RECOVERED/RESOLVED
AMG 416	20120229-22966181003	4[redacted]	M	WHITE	HISPANIC OR LATINO	CHEST CONGESTION [気道うっ血]	20[redacted]*-01-11	123	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]*-01-23	-
AMG 416	20120229-22966181003	4[redacted]	M	WHITE	HISPANIC OR LATINO	ANEURYSM OVER RIGHT ARM HAEMODIALYSIS ARTERIOVENOUS GRAFT [動静脈グラフト瘤]	20[redacted]*-01-20	132	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]*-01-24	-
AMG 416	20120229-22966181003	4[redacted]	M	WHITE	HISPANIC OR LATINO	BIBASILAR ATELECTASIS [無気肺]	20[redacted]*-01-20	132	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]*-01-24	-

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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	20120229-22966181003	4[redacted]	M	WHITE	HISPANIC OR LATINO	NON FUNCTIONING QUINTON CATHETER REPLACED [医療機器合併症]	20[redacted]-01-20*	132	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-23*	RECOVERED/RESOLVED
AMG 416	20120229-22966181003	4[redacted]	M	WHITE	HISPANIC OR LATINO	CARDIAC ARREST [心停止]	20[redacted]-01-24*	136	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-24*	FATAL
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	-

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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	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	-

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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	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
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

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＊新薬承認情報提供時に置換えた

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	-

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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	20120229-22921009005	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	COUGH NONPRODUCTIVE [咳嗽]	20[redacted]-11-24	96	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-11-28	-
PLACEBO	20120229-22921009005	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	BACK PAIN [背部痛]	20[redacted]-12-18T09:24	120	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-18	-
PLACEBO	20120229-22921009005	6[redacted]	M	WHITE	NOT HISPANIC OR LATINO	ENDOCARDITIS BACTERIAL [細菌性心内膜炎]	20[redacted]-12-28	130	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-29	FATAL

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PLACEBO	20120229-22925007002	8[redacted]	M	-	-	AURICULO-VENTRICULAR BLOCK GRADE 3 [完全房室ブロック]	20[redacted]-07-03T13:00	-7	SEVERE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	-	20[redacted]-08-26	RECOVERED/RESOLVED
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	KNEE PAIN [関節痛]	20[redacted]-07-22	13	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-12-22	-
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	LEFT TOE PAIN [四肢痛]	20[redacted]-08-23	45	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-08-23	-
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	SCRAPING LESIONS [擦過傷]	20[redacted]-09-09	62	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-09-18	-
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	VENTRICULAR HYPER-EXCITABILITY [心室性頻脈性不整脈]	20[redacted]-09-10	63	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-22	-
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	INSOMNIA [不眠症]	20[redacted]-10-28	111	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-22	-
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	FLUID OVERLOAD [水分過負荷]	20[redacted]-11-10	124	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-11-11	RECOVERED/RESOLVED
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	SEPTICEMIA [敗血症]	20[redacted]-11-27	141	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-22	FATAL
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	HEPATIC CHOLESTASE [胆汁うっ滞]	20[redacted]-12-08	152	MILD	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-12-20	-

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PLACEBO	20120229-22925007002	8[redacted]	M	-	-	CONSTIPATION [便秘]	20[redacted]-12-09	153	MODERATE	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-12-10	-
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	DORSAL PAIN [背部痛]	20[redacted]-12-11	155	SEVERE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN, OTHER	NOT RELATED	20[redacted]-12-22	-
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	MYCOSIS BUCCAL [口腔真菌感染]	20[redacted]-12-11	155	MODERATE	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-12-22	-
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	ANEMIA [貧血]	20[redacted]-12-12	156	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-12-22	RECOVERED/RESOLVED
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	BONE MEDULLARY APLASIA [骨髄機能不全]	20[redacted]-12-12	156	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	TRANSFUSION PERFORMED, OTHER	NOT RELATED	20[redacted]-12-22	RECOVERED/RESOLVED
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	MORPHIN OVERDOSE [過量投与]	20[redacted]-12-12	156	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-12	-
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	INFECTION VESICO-PROSTATIC (VESICAL GLOBE) [泌尿生殖器感染]	20[redacted]-12-18	162	MODERATE	NO	-	DOSE NOT CHANGED	DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-12-18	-
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	PROCTORRHAGIA [直腸出血]	20[redacted]-12-19	163	SEVERE	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-12-22	-
PLACEBO	20120229-22925007002	8[redacted]	M	-	-	MALAISE INTRA DIALYSIS SESSION [倦怠感]	20[redacted]-12-20	164	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-12-20	RECOVERED/RESOLVED
PLACEBO	20120229-22929003002	7[redacted]	F	WHITE	NOT HISPANIC OR LATINO	VENTRICULAR FIBRILLATION [心室細動]	20[redacted]-06-22	18	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-06-22	FATAL

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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
PLACEBO	20120229-22948005001	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	OVERHYDRATION [水分過負荷]	20[redacted]-06-24	27	MODERATE	NO	-	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-10-09	-
PLACEBO	20120229-22948005001	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	FOLIC ACID DEFICINECY (LABORATORY RESULT) [葉酸欠乏]	20[redacted]-07-03T08:10	36	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-23	-
PLACEBO	20120229-22948005001	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	FATIGUE [疲労]	20[redacted]-10-02	127	MODERATE	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-12-23	-
PLACEBO	20120229-22948005001	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	FRACTURE RIGHT FEMUR [大腿骨骨折]	20[redacted]-10-02T04:00	127	MODERATE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-23	RECOVERED/RESOLVED
PLACEBO	20120229-22948005001	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	PAIN OF RIGHT SHOULDER [筋骨格痛]	20[redacted]-10-18	143	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-12-23	-
PLACEBO	20120229-22948005001	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	HEART FAILURE, CONGESTIVE [うっ血性心不全]	20[redacted]-12-14	200	SEVERE	YES	Results in Death, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-23	FATAL

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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
PLACEBO	20120229-22958009017	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	HYPERCALCEMIA [高カルシウム血症]	20[redacted]-07-03T13:39	1	MODERATE	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-06	-
PLACEBO	20120229-22958009017	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	HYPERPHOSPHATEMIA [高リン酸塩血症]	20[redacted]-08-07	36	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-04	-
PLACEBO	20120229-22958009017	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	VOMITING [嘔吐]	20[redacted]-09-16	76	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-09-16	-
PLACEBO	20120229-22958009017	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	LEUCOCYTOSIS [白血球増加症]	20[redacted]-09-21	81	MILD	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-10-06	-
PLACEBO	20120229-22958009017	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	CARDIOMEGALY [心拡大]	20[redacted]-09-23	83	MILD	NO	-	DRUG WITHDRAWN	DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-10-06	-
PLACEBO	20120229-22958009017	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	CONFUSIONAL STATE [錯乱状態]	20[redacted]-09-23	83	MILD	NO	-	DOSE NOT CHANGED	DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-10-06	-

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PLACEBO	20120229-22958009017	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	PNEUMONIA [肺炎]	20[redacted]-09-23T10:00	83	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-10-06	FATAL
PLACEBO	20120229-22958009017	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	AGITATION [激越]	20[redacted]-09-25	85	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-10-06	-
PLACEBO	20120229-22958009017	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	SLEEP APNEA [睡眠時無呼吸症候群]	20[redacted]-09-28	88	MODERATE	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-10-06	-
PLACEBO	20120229-22958009017	8[redacted]	M	WHITE	NOT HISPANIC OR LATINO	TACHYPNEA [頻呼吸]	20[redacted]-09-28	88	MILD	NO	-	DOSE NOT CHANGED	MEDICATION TAKEN	NOT RELATED	20[redacted]-10-06	-
PLACEBO	20120229-22966003018	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	DIABETIC FOOT INFECTION [糖尿病性足感染]	20[redacted]-12-06	108	MODERATE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]*-02-14	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
PLACEBO	20120229-22966003018	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	WORSNING DIABETIC FOOT ULCER [糖尿病性足病変]	20[redacted]-12-06	108	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION	NOT RELATED	20[redacted]*-02-14	RECOVERED/RESOLVED
PLACEBO	20120229-22966003018	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SEPTIC SHOCK [敗血症性ショック]	20[redacted]*-02-14T18:22	178	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]*-02-14T18:22	FATAL
PLACEBO	20120229-22966021005	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	BLOOD CALCIUM DECREASED [血中カルシウム減少]	20[redacted]-08-05T18:42	43	SEVERE	NO	-	DOSE ALTERED OR WITHHELD	OTHER	NOT RELATED	20[redacted]-08-09T18:13	-
PLACEBO	20120229-22966021005	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CLOSTRIDIUM DIFFICILE INFECTION [クロストリジウム・ディフィシレ感染]	20[redacted]-09-11T18:09	80	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN, NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-09-16	RECOVERED/RESOLVED
PLACEBO	20120229-22966021005	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ACUTE RENAL TRANSPLANT REJECTION [腎移植拒絶反応]	20[redacted]-09-20T15:10	89	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-09-28T15:00	RECOVERED/RESOLVED

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PLACEBO	20120229-22966021005	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	PNEUMONIA [肺炎]	20[redacted]-10-26	125	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-11-11T17:25	FATAL
PLACEBO	20120229-22966021005	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	HEART FAILURE, UNSPECIFIED [心不全]	20[redacted]-11-03T10:39	133	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-11	UNKNOWN
PLACEBO	20120229-22966021005	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CARDIAC ARREST [心停止]	20[redacted]-11-06T17:01	136	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-11	UNKNOWN
PLACEBO	20120229-22966021005	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ATRIAL FIBRILLATION [心房細動]	20[redacted]-11-08T16:31	138	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-11T17:25	UNKNOWN
PLACEBO	20120229-22966021005	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ANOXIC ENCEPHALOPATHY, ACUTE [低酸素性虚血性脳症]	20[redacted]-11-08T17:01	138	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-11-11T17:25	UNKNOWN

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PLACEBO	20120229-22966021005	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	BRAIN DEATH [脳死]	20[redacted]-11-11	141	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-11T17:25	UNKNOWN
PLACEBO	20120229-22966021005	5[redacted]	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SHOCK LIVER [虚血性肝炎]	20[redacted]-11-11T11:48	141	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-11T17:25	UNKNOWN
PLACEBO	20120229-22966089005	6[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	DIFFUSE JEJUNAL ANGIOECTASIA [胃腸毛細血管拡張症]	20[redacted]-09-07	3	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, OTHER	NOT RELATED	20[redacted]*-03-19	RECOVERED/RESOLVED
PLACEBO	20120229-22966089005	6[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	GASTROINTESTINAL BLEED [胃腸出血]	20[redacted]-09-07	3	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, EMERGENCY ROOM VISIT, OTHER	NOT RELATED	20[redacted]-10-22	RECOVERED/RESOLVED
PLACEBO	20120229-22966089005	6[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ARTERIOVENOUS MALFORMATION OF SMALL BOWEL [胃腸管動静脈奇形]	20[redacted]-09-10	6	SEVERE	NO	-	DOSE NOT CHANGED	TRANSFUSION PERFORMED	NOT RELATED	20[redacted]*-03-19	-

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PLACEBO	20120229-22966089005	6[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	AORTIC STENOSIS [大動脈狭窄]	20[redacted]-10-22	48	SEVERE	NO	-	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]*-03-19	-
PLACEBO	20120229-22966089005	6[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	WORSENING VALVULAR HEART DISEASE NOS [心臓弁膜疾患]	20[redacted]-10-22	48	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]*-03-19	FATAL
PLACEBO	20120229-22966089005	6[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	WORSENING HYPOTENSION [低血圧]	20[redacted]-10-29	55	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-01	RECOVERED/RESOLVED
PLACEBO	20120229-22966089005	6[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	INFECTION IN FEMORAL PICC LINE [医療機器関連感染]	20[redacted]-10-29T06:50	55	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-01	RECOVERED/RESOLVED
PLACEBO	20120229-22966089005	6[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	ACUTE ENCEPHALOPATHY (MULTIFACTORIAL, TOXIC METABOLIC, INFECTION & NARCOTICS USE) [脳症]	20[redacted]*-01-27	145	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]*-01-31	RECOVERED/RESOLVED
PLACEBO	20120229-22966089005	6[redacted]	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	NARCOTIC ABUSE [薬物乱用]	20[redacted]*-01-27	145	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]*-01-31	RECOVERED/RESOLVED

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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
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

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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
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	-

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
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	-
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
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

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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
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	-
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	-

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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
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
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	-

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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
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	-
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	-

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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
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
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 17.1J
AMG 416 = ONO-5163

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表 2.7.4.7-7　死亡例の一覧表（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	-

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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	20120360-36033006003	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
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	-

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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	20120360-36043003005	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	-	-
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

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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	20120360-36043003005	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	-
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

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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	20120360-36043003005	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	-
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	-

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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	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 *	-
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	-

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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 *	-
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	-

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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 *	-
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	-

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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
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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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
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	-	-

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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
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

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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	-	-
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	-

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	20120360-36066083004	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	-	-
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	-

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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
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	-
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	-

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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
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
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

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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
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
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	-

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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
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	-
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

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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	20120360-36035002002	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
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

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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	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
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

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表 2.7.4.7-8　重篤な有害事象の一覧表［海外第Ⅲ相プラセボ対照試験（併合成績）］

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120229-22911001007	EPIGASTRIC/RIGHT UPPER QUADRANT PAIN [上腹部痛]	20[redacted]-01-30	99	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-02-03	RECOVERED/RESOLVED
AMG 416	20120229-22913001001	ACUTE LUNGEDEMA [急性肺水腫]	20[redacted]-10-02T13:11	141	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-10T17:44	RECOVERED/RESOLVED
AMG 416	20120229-22913001001	MYOCARDIAL ISCHEMIC EVENT [心筋虚血]	20[redacted]-10-02T18:00	141	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-10-09T10:42	RECOVERED/RESOLVED
AMG 416	20120229-22913001001	HEART FAILURE, CONGESTIVE [うっ血性心不全]	20[redacted]-10-03T15:37	142	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120229-22913003006	RIGHT CORONAR ARTERY SUB-OCCLUSION [冠動脈閉塞]	20[redacted]-01-17	95	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-25	RECOVERED/RESOLVED
AMG 416	20120229-22913003006	URINARY RETENTION [尿閉]	20[redacted]-03-20	157	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-04-17	RECOVERED/RESOLVED
AMG 416	20120229-22913005002	THROMBOTIC AV SHUNT [シャント血栓症]	20[redacted]-11-20	50	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-20	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	20120229-22913005003	OCCLUSION OF ARTERY POPLITEA [末梢動脈閉塞性疾患]	20[redacted]-03-25	175	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-03-26	RECOVERED/RESOLVED
AMG 416	20120229-22913005003	OCCLUSION OF ARTERY POPLITEA [末梢動脈閉塞性疾患]	20[redacted]-04-14	195	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-18	RECOVERED/RESOLVED
AMG 416	20120229-22913009004	ACUTE PULMONARY OEDEMA [急性肺水腫]	20[redacted]-04-21T23:00	5	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-23	RECOVERED/RESOLVED
AMG 416	20120229-22913009004	HOSPITALISATION FOR EVALUATION OF REPEAT ACUTE PULMONARY OEDEMA [急性肺水腫]	20[redacted]-04-29T12:00	13	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-08	RECOVERED/RESOLVED
AMG 416	20120229-22916001002	DELIRIUM DUE TO A GENERAL MEDICAL CONDITION [譫妄]	20[redacted]-01-06T22:00	139	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-01-14	RECOVERED/RESOLVED
AMG 416	20120229-22916001002	ACIDOSIS METABOLIC [代謝性アシドーシス]	20[redacted]-01-07T17:34	140	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-01-09	RECOVERED/RESOLVED
AMG 416	20120229-22916001002	HYPERKALIEMIA [高カリウム血症]	20[redacted]-01-07T17:34	140	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-08	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	20120229-22916001002	UNCONTROLLED DIABETES [コントロール不良の糖尿病]	20[redacted]-01-07T17:34	140	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-01-21	RECOVERED/RESOLVED
AMG 416	20120229-22916001002	HYPERGLYCEMIA [高血糖]	20[redacted]-01-23	156	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-28	RECOVERED/RESOLVED
AMG 416	20120229-22916001008	GASTRIC ULCER [胃潰瘍]	20[redacted]-02-27	135	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, OTHER	NOT RELATED	20[redacted]-03-12	RECOVERED/RESOLVED
AMG 416	20120229-22921003002	SCAPULA FRACTURE [肩甲骨骨折]	20[redacted]-03-27	205	MODERATE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-06-18	RECOVERED/RESOLVED
AMG 416	20120229-22921005003	ACUTE SUBDURAL HEMATOMA IN THE LEFT [硬膜下血腫]	20[redacted]-11-06	148	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-17	RECOVERED/RESOLVED
AMG 416	20120229-22921005004	CHOLANGOITIS [胆管炎]	20[redacted]-12-14	192	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-27	RECOVERED/RESOLVED
AMG 416	20120229-22921005004	CHOLEDOCHOLITHIASIS [胆管結石]	20[redacted]-12-20	198	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-27	RECOVERED/RESOLVED
AMG 416	20120229-22921005004	INITIAL PANCREATITIS [膵炎]	20[redacted]-12-20	198	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	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
AMG 416	20120229-22929007011	DILATATION OF THE AV FISTULA [動静脈瘻部位合併症]	20[redacted]-12-19T07:28	86	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-20T14:00	RECOVERED/RESOLVED
AMG 416	20120229-22929007013	HOSPITALIZATION FOR ASTHMA BRONHIALE EXACERBATION [喘息]	20[redacted]-09-27T06:40	3	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-09T15:00	RECOVERED/RESOLVED
AMG 416	20120229-22932005003	UPPER RESPIRATORY TRACT INFECTION [上気道感染]	20[redacted]-01-20	132	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-26	RECOVERED/RESOLVED
AMG 416	20120229-22933001002	SEVERE HYPOTHENSION [低血圧]	20[redacted]-06-06T16:00	30	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	EMERGENCY ROOM VISIT, OTHER	RELATED	20[redacted]-06-07T00:15	RECOVERED/RESOLVED
AMG 416	20120229-22948001010	LUNG TUMOR [肺新生物]	20[redacted]-12-20T17:00 *	80	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	ONGOING *	NOT RECOVERED/NOT RESOLVED
AMG 416	20120229-22948001010	OVERHYDRATATION [水分過負荷]	20[redacted]-02-15 *	137	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-02-28 *	RECOVERED/RESOLVED
AMG 416	20120229-22948001010	STROKE [脳血管発作]	20[redacted]-06-04	246	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-10	RECOVERED/RESOLVED
AMG 416	20120229-22948003003	DYSPNOE [呼吸困難]	20[redacted]-08-30T10:14 *	31	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-09-04T10:56 *	RECOVERED/RESOLVED
AMG 416	20120229-22948003003	CHEST PAIN (NON-CARDIAC) [非心臓性胸痛]	20[redacted]-01-22T05:00	176	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-03T09:30	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	20120229-22948005002	HEART FAILURE NYHA CLASS III [心不全]	20[redacted]-06-10T17:00	13	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120229-22948005002	HOSPITALIZATION TO PLANNED CARDIOSURGERY FOR AORTIC VELVE STENOSIS [大動脈弁狭窄]	20[redacted]-09-24	119	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120229-22948005002	STROKE - LEFT HEMIPARESIS [脳血管発作]	20[redacted]-09-27	122	LIFE THREATENING	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	20120229-22948005013	GRANULOMATOSIS WITH POLYANGIITIS [多発血管炎を伴う肉芽腫症]	20[redacted]-10-21	40	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-23	RECOVERED/RESOLVED
AMG 416	20120229-22948005013	GRANULOMATOSIS WITH POLYANGIITIS [多発血管炎を伴う肉芽腫症]	20[redacted]-11-12	62	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-14	NOT RECOVERED/NOT RESOLVED
AMG 416	20120229-22948005013	BLEEDING ESOPHAGEAL ULCER [食道潰瘍出血]	20[redacted]*-02-11	153	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]*-02-17	RECOVERED/RESOLVED
AMG 416	20120229-22951001007	PNEUMONIA BILATERAL [肺炎]	20[redacted]-10-16	57	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-29	RECOVERED/RESOLVED
AMG 416	20120229-22951009004	CONVULSIVE SEIZURE [痙攣]	20[redacted]-10-23T05:30	92	MODERATE	YES	Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	RELATED	20[redacted]-10-23T05:50	RECOVERED/RESOLVED

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AMG 416	20120229-22958001001	DYALISIS CATHETER REPLACEMENT [医療機器合併症]	20[redacted]-05-13	-9	MILD	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	-	20[redacted]-05-15	RECOVERED/RESOLVED
AMG 416	20120229-22958001002	THROMBOSIS GORETEX [血管グラフト血栓症]	20[redacted]-07-05	26	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-08	RECOVERED/RESOLVED
AMG 416	20120229-22958001002	BLEEDING AT GRAFT SITE [移植部位出血]	20[redacted]-10-23	136	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-11-27	FATAL
AMG 416	20120229-22958001002	RESPIRATORY DISTRESS DUE TO POST-SURGICAL INESTABILITY [術後呼吸窮迫]	20[redacted]-10-23	136	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-29	RECOVERED/RESOLVED
AMG 416	20120229-22958001006	PNEUMONIA [肺炎]	20[redacted]-03-04	148	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-18	RECOVERED/RESOLVED
AMG 416	20120229-22958003011	ATRIAL FIBRILLATION WITH SLOW VENTRICULAR RESPONSE [心房細動]	20[redacted]-08-21	35	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-09-05	RECOVERED/RESOLVED
AMG 416	20120229-22958005001	CARDIAC FAILURE [心不全]	20[redacted]-10-08	106	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-11-04	RECOVERED/RESOLVED
AMG 416	20120229-22958005001	CARDIAC SHOCK [心原性ショック]	20[redacted]-10-08	106	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-26	RECOVERED/RESOLVED

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AMG 416	20120229-22958005001	HEMORRAGIC SHOCK [出血性ショック]	20[redacted]-10-08	106	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-21	RECOVERED/RESOLVED
AMG 416	20120229-22958005001	ISCHEMIC CHEST PAIN [狭心症]	20[redacted]-10-08	106	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-21	RECOVERED/RESOLVED
AMG 416	20120229-22958005001	SEPTIC SHOCK [敗血症性ショック]	20[redacted]-10-08	106	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-10-18	RECOVERED/RESOLVED
AMG 416	20120229-22958005001	SHOCK [ショック]	20[redacted]-10-08	106	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-21	RECOVERED/RESOLVED
AMG 416	20120229-22965005002	INSUFFICIENT VASCULAR ACCESS [医療機器合併症]	20[redacted]-11-29	66	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-30	RECOVERED/RESOLVED
AMG 416	20120229-22965007001	DEATH - CAUSE UNKNOWN [死亡]	20[redacted]-09-01	11	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	RELATED	20[redacted]-09-02	FATAL
AMG 416	20120229-22966001003	CHEST PAIN - VENTRICULAR TACHYCARDIA [心室性頻脈]	20[redacted]-01-14T22:00	107	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-18	RECOVERED/RESOLVED

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AMG 416	20120229-22966001003	SEPTIC PULMONARY EMBOLI [敗血症性塞栓]	20[redacted]-01-24	117	MODERATE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-03-30	RECOVERED/RESOLVED
AMG 416	20120229-22966001004	INFLUENZA A VIRUS SUBTYPE H1N1 [Ｈ１Ｎ１インフルエンザ]	20[redacted]-01-26	119	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-02-04	RECOVERED/RESOLVED
AMG 416	20120229-22966005004	WORSENING ANXIETY [不安]	20[redacted]-03-25	203	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-26	RECOVERED/RESOLVED
AMG 416	20120229-22966009022	PSEUDOANEURYSM OF AV FISTULA [血管偽動脈瘤]	20[redacted]-09-05	-20	MODERATE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	-	20[redacted]-09-06	RECOVERED/RESOLVED
AMG 416	20120229-22966009022	STENOSIS OF LEFT UPPER EXTREMITY AV FISTULA [動静脈瘻部位合併症]	20[redacted]-09-30	6	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-07	RECOVERED/RESOLVED
AMG 416	20120229-22966009022	LEFT CENTRAL VEIN STENOSIS [静脈狭窄]	20[redacted]-10-30	36	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-07	RECOVERED/RESOLVED
AMG 416	20120229-22966011014	RIGHT FEMUR FRACTURE [大腿骨骨折]	20[redacted]-01-02	86	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-01-16	RECOVERED/RESOLVED

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AMG 416	20120229-22966013006	WORSENING PERIPHERAL VASCULAR DISEASE [末梢血管障害]	20[redacted]-12-05 *	121	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-08 *	RECOVERED/RESOLVED
AMG 416	20120229-22966013006	MALFUNCTIONING ARTERIOVENOUS DIALYSIS ACCESS GRAFT [移植血管合併症]	20[redacted]-01-30	177	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-02-03	RECOVERED/RESOLVED
AMG 416	20120229-22966013007	WORSENING CORONARY ARTERY DISEASE [冠動脈疾患]	20[redacted]-10-22 *	56	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-23 *	RECOVERED/RESOLVED
AMG 416	20120229-22966013007	CHEST PAIN - CARDIAC [狭心症]	20[redacted]-02-14	171	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-15	RECOVERED/RESOLVED
AMG 416	20120229-22966017001	OPEN INFECTED WOUND LEFT FOOT [創傷感染]	20[redacted]-06-11T08:00	29	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-29T22:15	RECOVERED/RESOLVED
AMG 416	20120229-22966017001	ATRIAL FIBRILLATION [心房細動]	20[redacted]-07-11	59	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN	NOT RELATED	20[redacted]-07-15	RECOVERED/RESOLVED
AMG 416	20120229-22966017001	ATRIAL FLUTTER WITH RAPID VENTRICULAR RESPONSE [心房粗動]	20[redacted]-07-11	59	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-15	RECOVERED/RESOLVED
AMG 416	20120229-22966017001	END STAGE RENAL DISEASE (ESRD) [慢性腎不全]	20[redacted]-07-29T21:29	77	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-07-29T22:15	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
AMG 416	20120229-22966023007	SEPSIS [敗血症]	20[redacted]-09-06T21:03	74	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-11T02:19	RECOVERED/RESOLVED
AMG 416	20120229-22966023007	HYPERVOLEMIA [血液量増加症]	20[redacted]-10-22T17:04	120	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-24T07:34	RECOVERED/RESOLVED
AMG 416	20120229-22966023007	WORSENING OF UNDERLYING CHRONIC OBSTRUCTIVE PULMONARY DISEASE [慢性閉塞性肺疾患]	20[redacted]-12-26T12:14	185	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-27T04:08	RECOVERED/RESOLVED
AMG 416	20120229-22966027001	CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-09-15	69	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-19	RECOVERED/RESOLVED
AMG 416	20120229-22966027001	ACUTE EXACERBATION OF CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-11-18	133	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-21	RECOVERED/RESOLVED
AMG 416	20120229-22966027002	CAR ACCIDENT [交通事故]	20[redacted]-12-27	206	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-12-27	FATAL
AMG 416	20120229-22966027004	DYSPNEA [呼吸困難]	20[redacted]-10-12	180	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-09	RECOVERED/RESOLVED
AMG 416	20120229-22966027004	AORTIC STENOSIS [大動脈狭窄]	20[redacted]-10-27	195	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-11-09	RECOVERED/RESOLVED
AMG 416	20120229-22966027004	WORSENING OF CONGESTIVE HEART FAILURE [うっ血性心不全]	20[redacted]-11-06	205	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-09	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
AMG 416	20120229-22966029001	CHEST PAIN - CARDIAC NON MI [狭心症]	20[redacted]-08-18T16:58	33	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-08-19	RECOVERED/RESOLVED
AMG 416	20120229-22966029001	AORTIC VALVULAR STENOSIS [大動脈弁狭窄]	20[redacted]-09-05 *	51	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-28 *	RECOVERED/RESOLVED
AMG 416	20120229-22966029001	GASTROENTERITIS [胃腸炎]	20[redacted]-02-17	216	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-24	RECOVERED/RESOLVED
AMG 416	20120229-22966031006	WORSENING OF INTERMITTENT FLUID OVERLOAD [水分過負荷]	20[redacted]-09-22T19:00	26	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-23	RECOVERED/RESOLVED
AMG 416	20120229-22966035001	MALFUNCTIONING FISTULA [動静脈瘻部位合併症]	20[redacted]-07-25T06:00	37	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-26T18:00	RECOVERED/RESOLVED
AMG 416	20120229-22966035001	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-08-17	60	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-08-17	FATAL
AMG 416	20120229-22966035005	TRANSPOSITION OF AV FISTULA [動静脈瘻手術]	20[redacted]-06-13T08:00	-11	MILD	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-06-14	RECOVERED/RESOLVED
AMG 416	20120229-22966035005	CARDIAC GENERAL CHEST PAIN [狭心症]	20[redacted]-07-03T11:30	10	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-05	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	20120229-22966035005	ULCER OF RLE. [皮膚潰瘍]	20[redacted]-07-14T06:00	21	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-09-21	RECOVERED/RESOLVED
AMG 416	20120229-22966035005	CELLULITIS OF RLE [蜂巣炎]	20[redacted]-07-14T08:00	21	LIFE THREATENING	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-09-21	RECOVERED/RESOLVED
AMG 416	20120229-22966035005	OSTEOMYELITIS [骨髄炎]	20[redacted]-09-14	83	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-21	RECOVERED/RESOLVED
AMG 416	20120229-22966037001	PANCREATITIS [膵炎]	20[redacted]-09-12 *	-50	SEVERE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-09-15 *	RECOVERED/RESOLVED
AMG 416	20120229-22966037001	PNEUMONIA [肺炎]	20[redacted]-01-27T12:00	88	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-30T12:00	RECOVERED/RESOLVED
AMG 416	20120229-22966037003	HYPOGLYCAEMIA [低血糖症]	20[redacted]-11-19T15:00	54	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-24T10:00	RECOVERED/RESOLVED
AMG 416	20120229-22966037003	HYPERGLYCEMIA [高血糖]	20[redacted]-12-02T12:00	67	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-07T12:00	RECOVERED/RESOLVED

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AMG 416	20120229-22966037003	GASTROENTERITIS [胃腸炎]	20[redacted]-03-08T12:00 *	163	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-10T12:00	RECOVERED/RESOLVED
AMG 416	20120229-22966037003	LEFT SECOND TOE GANGRENE [壊疽]	20[redacted]-04-11T06:00 *	197	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING *	NOT RECOVERED/NOT RESOLVED
AMG 416	20120229-22966037003	NON ST ELEVATION MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-04-30 *	216	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-04 *	RECOVERED/RESOLVED
AMG 416	20120229-22966037003	MELENAY'S SYNDROME [壊死性筋膜炎]	20[redacted]-05-05	221	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-05	RECOVERED/RESOLVED
AMG 416	20120229-22966041002	ANEURYSM ARTERIOVENOUS [動静脈瘤]	20[redacted]-09-02	-35	MILD	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-09-04	RECOVERED/RESOLVED
AMG 416	20120229-22966041002	ANEURYSM ARTERIOVENOUS [動静脈瘤]	20[redacted]-10-03	-4	MILD	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-10-03	RECOVERED/RESOLVED
AMG 416	20120229-22966041002	CATHETER ACCESS PORT ISSUE [医療機器の問題]	20[redacted]-10-31	25	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-02	RECOVERED/RESOLVED
AMG 416	20120229-22966041002	CATHETER ACCESS PORT ISSUE [医療機器の問題]	20[redacted]-11-18	43	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-19	RECOVERED/RESOLVED
AMG 416	20120229-22966041002	CATHETER ACCESS PORT ISSUE [医療機器の問題]	20[redacted]-12-10	65	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-11	RECOVERED/RESOLVED
AMG 416	20120229-22966045001	LOBAR PNEUMONIA [大葉性肺炎]	20[redacted]-01-27T04:00	148	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-29T19:30	RECOVERED/RESOLVED

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AMG 416	20120229-22966045001	VOLUME OVERLOAD [水分過負荷]	20[redacted]-01-27T04:00	148	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-29T19:30	RECOVERED/RESOLVED
AMG 416	20120229-22966045006	ACUTE RESPIRATORY DISTRESS [急性呼吸窮迫症候群]	20[redacted]-11-05T06:00	9	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-11-07T06:00	RECOVERED/RESOLVED
AMG 416	20120229-22966045006	VOLUME OVERLOAD [水分過負荷]	20[redacted]-11-05T06:00	9	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-07T06:00	RECOVERED/RESOLVED
AMG 416	20120229-22966045010	COLON POLYPS [大腸ポリープ]	20[redacted]-04-17	165	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-22	RECOVERED/RESOLVED
AMG 416	20120229-22966049003	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-08-21 *	6	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-09-01 *	RECOVERED/RESOLVED
AMG 416	20120229-22966049003	ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞]	20[redacted]-01-10 *	148	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-14T14:30 *	RECOVERED/RESOLVED
AMG 416	20120229-22966049003	SUDDEN CARDIAC DEATH [心突然死]	20[redacted]-01-14	152	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]-01-14	FATAL
AMG 416	20120229-22966049006	CHOLECYSTITIS [胆嚢炎]	20[redacted]-11-16	51	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-21	RECOVERED/RESOLVED
AMG 416	20120229-22966051006	BRONCHITIS ASTHMATIC [喘息]	20[redacted]-11-03	138	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-06	RECOVERED/RESOLVED

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AMG 416	20120229-22966051006	CHEST PAIN (NON-CARDIAC) [非心臓性胸痛]	20[redacted]-12-15	180	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-24	RECOVERED/RESOLVED
AMG 416	20120229-22966051009	HYPERKALEMIA [高カリウム血症]	20[redacted]-07-14	52	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-07-16	RECOVERED/RESOLVED
AMG 416	20120229-22966051009	PULMONARY EDEMA [肺水腫]	20[redacted]-08-04	73	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER, OTHER	NOT RELATED	20[redacted]-08-06	RECOVERED/RESOLVED
AMG 416	20120229-22966051014	RIGHT-SIDED PNEUMONIA [肺炎]	20[redacted]-01-06T09:00	169	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-01-11	RECOVERED/RESOLVED
AMG 416	20120229-22966053002	ACUTE VIRAL UPPER RESPIRATORY INFECTION [ウイルス性上気道感染]	20[redacted]-08-14	85	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-15	RECOVERED/RESOLVED
AMG 416	20120229-22966053003	INTERVERTEBRAL DISCITIS [椎間板炎]	20[redacted]-08-05	-21	SEVERE	YES	Requires or Prolongs Hospitalization	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	-	20[redacted]-08-22	RECOVERED/RESOLVED
AMG 416	20120229-22966061005	SYNCOPE [失神]	20[redacted]-06-29	10	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-30	RECOVERED/RESOLVED
AMG 416	20120229-22966061008	HYPOTENSION [低血圧]	20[redacted]-01-30	88	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-01	RECOVERED/RESOLVED

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AMG 416	20120229-22966089006	HYPERKALEMIA [高カリウム血症]	20[redacted]-01-12	130	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER	NOT RELATED	20[redacted]-01-13	RECOVERED/RESOLVED
AMG 416	20120229-22966089007	HEALTH CARE ASSOCIATED PNEUMONIA. [肺炎]	20[redacted]-02-10	148	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-02-14	RECOVERED/RESOLVED
AMG 416	20120229-22966089013	ATRIAL FIBRILLATION [心房細動]	20[redacted]-11-07 *	25	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-12	RECOVERED/RESOLVED
AMG 416	20120229-22966089013	PNEUMONIA, HEALTH CARE ASSOCIATED BILATERAL LUNGS [肺炎]	20[redacted]-04-05 *	174	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120229-22966089013	SEVERE SEPSIS [敗血症]	20[redacted]-04-05 *	174	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120229-22966089013	UTI URINARY TRACT INFECTION [尿路感染]	20[redacted]-04-05 *	174	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	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
AMG 416	20120229-22966121007	MENTAL STATUS CHANGES [精神状態変化]	20[redacted]-03-28	205	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-01	RECOVERED/RESOLVED
AMG 416	20120229-22966133007	SUPRAVENTRICULAR TACHYCARDIA [上室性頻脈]	20[redacted]-08-29T09:50	36	MODERATE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-08-29	RECOVERED/RESOLVED
AMG 416	20120229-22966133007	RECURRENT SVT [上室性頻脈]	20[redacted]-10-18T18:00	86	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120229-22966133012	HIP FRACTURE [股関節部骨折]	20[redacted]-11-12T12:00	70	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-19	RECOVERED/RESOLVED
AMG 416	20120229-22966133012	HIP FRACTURE, LEFT [股関節部骨折]	20[redacted]-03-27	205	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-04-01	RECOVERED/RESOLVED
AMG 416	20120229-22966167002	ALTERED MENTAL STATUS [精神状態変化]	20[redacted]-05-09	-179	SEVERE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-06-12	RECOVERED/RESOLVED
AMG 416	20120229-22966167002	ACUTE BLOOD LOSS ANEMIA [貧血]	20[redacted]-06-08	-149	SEVERE	YES	Requires or Prolongs Hospitalization	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	-	20[redacted]-06-11	RECOVERED/RESOLVED
AMG 416	20120229-22966167002	HEMORRHAGIC SHOCK SECONDARY TO PERINEPHRIC RETROPERITONEAL BLEED [出血性ショック]	20[redacted]-06-08	-149	LIFE THREATENING	YES	Requires or Prolongs Hospitalization	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	-	20[redacted]-06-11	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 of Serious Adverse Event
AMG 416	20120229-22966167002	WEAKNESS [無力症]	20[redacted]-06-13 *	-144	MODERATE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-06-14 *	RECOVERED/RESOLVED
AMG 416	20120229-22966167002	GASTROENTERITIS [胃腸炎]	20[redacted]-01-15T12:04 *	73	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-15 *	RECOVERED/RESOLVED
AMG 416	20120229-22966167002	GASTROPARESIS [胃排出不全]	20[redacted]-01-15T12:04 *	73	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-15 *	RECOVERED/RESOLVED
AMG 416	20120229-22966167002	ABDOMINAL DISCOMFORT [腹部不快感]	20[redacted]-01-20T18:25 *	78	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-25 *	RECOVERED/RESOLVED
AMG 416	20120229-22966167002	CHEST PAIN (NON-CARDIAC) [非心臓性胸痛]	20[redacted]-01-20T18:25 *	78	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-20 *	RECOVERED/RESOLVED
AMG 416	20120229-22966167002	VOMITING [嘔吐]	20[redacted]-01-20T18:25	78	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-01-20	RECOVERED/RESOLVED
AMG 416	20120229-22966169001	HYPERBILIRUBINEMIA [高ビリルビン血症]	20[redacted]-02-10	176	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-03-18	RECOVERED/RESOLVED
AMG 416	20120229-22966169001	ACUTE LIVER FAILURE [急性肝不全]	20[redacted]-02-12	178	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-18	RECOVERED/RESOLVED
AMG 416	20120229-22966169001	CHEST PAIN - CARDIAC [狭心症]	20[redacted]-02-22T08:00	188	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-08	RECOVERED/RESOLVED
AMG 416	20120229-22966169001	BILIARY CANCER WITH METASTASIS TO LIVER [遠隔転移を伴う胆道癌]	20[redacted]-03-03	197	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-18	FATAL

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AMG 416	20120229-22966169004	MELANOMA OF SKIN (MALIGNANT) [悪性黒色腫]	20[redacted]-11-19	26	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	SURGICAL INTERVENTION	NOT RELATED	20[redacted]-12-10	RECOVERED/RESOLVED
AMG 416	20120229-22966171001	SEPTIC ARTHRITIS [細菌性関節炎]	20[redacted]-12-12	109	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-19	RECOVERED/RESOLVED
AMG 416	20120229-22966181003	BRONCHITIS [気管支炎]	20[redacted]-11-15	66	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-18	RECOVERED/RESOLVED
AMG 416	20120229-22966181003	CATHETER INFECTION [医療機器関連感染]	20[redacted]-12-13	94	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-12-18	RECOVERED/RESOLVED
AMG 416	20120229-22966181003	NON FUNCTIONING QUINTON CATHETER REPLACED [医療機器合併症]	20[redacted]-01-20*	132	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-23*	RECOVERED/RESOLVED
AMG 416	20120229-22966181003	CARDIAC ARREST [心停止]	20[redacted]-01-24*	136	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-24*	FATAL
AMG 416	20120229-22966181004	ABDOMINAL PAIN [腹痛]	20[redacted]-09-03T00:00	-8	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	-	20[redacted]-09-04T00:00	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	20120229-22966233001	OSTEOMYELITIS OF THE LEFT INDEX FINGER [骨髄炎]	20[redacted]-11-10	40	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN, NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-11-21	RECOVERED/RESOLVED
AMG 416	20120229-22966285001	HYPERTENSIVE EMERGENCY [高血圧緊急症]	20[redacted]-01-16	73	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-18	RECOVERED/RESOLVED
AMG 416	20120229-22966285001	HYPOGLYCEMIA [低血糖症]	20[redacted]-01-16	73	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-18	RECOVERED/RESOLVED
AMG 416	20120229-22966285001	CORONARY ARTERY DISEASE [冠動脈疾患]	20[redacted]-01-22	79	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
AMG 416	20120229-22966285001	HYPERKALEMIA [高カリウム血症]	20[redacted]-01-22	79	MILD	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-23	RECOVERED/RESOLVED
AMG 416	20120229-22966285001	CHEST PAIN (NON-CARDIAC) [非心臓性胸痛]	20[redacted]-02-11	99	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-16	RECOVERED/RESOLVED

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AMG 416	20120229-22966285001	CONSTIPATION [便秘]	20[redacted]-02-11	99	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-16	RECOVERED/RESOLVED
AMG 416	20120229-22966285001	ANGINA TYPE CARDIAC CHEST PAIN [狭心症]	20[redacted]-03-28	144	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-31	RECOVERED/RESOLVED
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

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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
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

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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
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

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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
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

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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	20120230-23032002006	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
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

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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	20120230-23058006005	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
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

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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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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
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

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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
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

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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

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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
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
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

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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	20120230-23066034009	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
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

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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	20120230-23066078010	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
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

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term"]	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	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

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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	20120230-23066150005	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
AMG 416	20120230-23066152012	ACUTE MYOCARDIAL INFARCTION TYPE I [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

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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
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

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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
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

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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	20120229-22911001003	MSSA AND E.COLI INFECTION OF RIGHT 4TH TOE [限局性感染]	20[redacted]-09-16	-37	SEVERE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	-	20[redacted]-09-25	RECOVERED/RESOLVED
PLACEBO	20120229-22911001008	HYPERTENSION EXACERBATED [高血圧]	20[redacted]-03-25	162	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-01	RECOVERED/RESOLVED
PLACEBO	20120229-22911003003	NON DISPLACED WEBBER B FRACTURE RIGHT ANKLE [足関節部骨折]	20[redacted]-11-04T16:00	75	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-11-05	RECOVERED/RESOLVED
PLACEBO	20120229-22912003001	HIGH GRADE RESTENOSIS OF ARERIAL BYPASS OF LEFT LOWER LIMB [末梢動脈再狭窄]	20[redacted]-10-04	45	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-02-15	RECOVERED/RESOLVED
PLACEBO	20120229-22913007006	RIGHT ILIAC ARTERIAL STENOSIS [末梢動脈狭窄]	20[redacted]-08-14	50	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-06	RECOVERED/RESOLVED
PLACEBO	20120229-22913009003	SYNCOPE [失神]	20[redacted]-09-05	148	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-25	RECOVERED/RESOLVED

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term[1]]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
PLACEBO	20120229-22916003001	LEAK OF SURGERY WOUND [創部分泌]	20[redacted]-02-12T14:00	119	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120229-22916003001	HEMATOMA LEFT PERI KIDNEY TRANSPLANT [腎周囲血腫]	20[redacted]-02-16T08:00	123	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-02-18	RECOVERED/RESOLVED
PLACEBO	20120229-22921005002	PAROXYSMAL ATRIAL FLUTTER [心房粗動]	20[redacted]-11-05	147	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-11-06	RECOVERED/RESOLVED
PLACEBO	20120229-22921009005	ENDOCARDITIS BACTERIAL [細菌性心内膜炎]	20[redacted]-12-28	130	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-29	FATAL
PLACEBO	20120229-22925007001	UNSTABLE ANGINA [不安定狭心症]	20[redacted]-11-03	117	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-20	RECOVERED/RESOLVED
PLACEBO	20120229-22925007002	AURICULO-VENTRICULAR BLOCK GRADE 3 [完全房室ブロック]	20[redacted]-07-03T13:00	-7	SEVERE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	-	20[redacted]-08-26	RECOVERED/RESOLVED
PLACEBO	20120229-22925007002	FLUID OVERLOAD [水分過負荷]	20[redacted]-11-10	124	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-11-11	RECOVERED/RESOLVED

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PLACEBO	20120229-22925007002	SEPTICEMIA [敗血症]	20[redacted]-11-27	141	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-22	FATAL
PLACEBO	20120229-22925007002	ANEMIA [貧血]	20[redacted]-12-12	156	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-12-22	RECOVERED/RESOLVED
PLACEBO	20120229-22925007002	BONE MEDULLARY APLASIA [骨髄機能不全]	20[redacted]-12-12	156	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	TRANSFUSION PERFORMED, OTHER	NOT RELATED	20[redacted]-12-22	RECOVERED/RESOLVED
PLACEBO	20120229-22925007002	MALAISE INTRA DIALYSIS SESSION [倦怠感]	20[redacted]-12-20	164	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	OTHER	NOT RELATED	20[redacted]-12-20	RECOVERED/RESOLVED
PLACEBO	20120229-22925007003	VASCULAR ACCES STENOSIS [血管狭窄]	20[redacted]-09-12	50	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-26	RECOVERED/RESOLVED
PLACEBO	20120229-22925007003	ACUTE CONFUSION STATE [錯乱状態]	20[redacted]-12-03	132	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120229-22925007003	SEPSIS [敗血症]	20[redacted]-12-04	133	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, IV ANTIBIOTICS TAKEN	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120229-22925007003	ATRIAL FIBRILLATION [心房細動]	20[redacted]-12-07	136	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-07	RECOVERED/RESOLVED
PLACEBO	20120229-22925007003	BLOOD PRESSURE ASYMETRY [血圧変動]	20[redacted]-12-07	136	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	ONGOING	UNKNOWN

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PLACEBO	20120229-22925007003	MYOCARDIAL INFARCTION [心筋梗塞]	20[redacted]-12-07T15:00	136	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120229-22926005008	PERIPHERAL ARTERIAL OCCLUSIVE DISEASE AGGRAVATED LEFT LEG [末梢動脈閉塞性疾患]	20[redacted]-02-05T08:00	107	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120229-22926005008	WORSENING OF PAIN IN SPINAL STENOSIS OF LUMBAR REGION [腰部脊柱管狭窄症]	20[redacted]-05-13	204	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-05-15	RECOVERED/RESOLVED
PLACEBO	20120229-22926005009	LUNG OVERHYDRATION [肺水腫]	20[redacted]-02-17	141	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-22	RECOVERED/RESOLVED
PLACEBO	20120229-22926007001	FRACTURE OF THE PELVIC RING [骨盤骨折]	20[redacted]-03-11T13:00	134	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120229-22926007001	HYPOGLYCEMIA [低血糖症]	20[redacted]-05-15T13:24	199	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-05-21T16:28	RECOVERED/RESOLVED
PLACEBO	20120229-22929003002	VENTRICULAR FIBRILLATION [心室細動]	20[redacted]-06-22	18	LIFE THREATENING	YES	Results in Death, Is Life Threatening	DOSE NOT CHANGED	NO ACTION TAKEN	NOT RELATED	20[redacted]-06-22	FATAL
PLACEBO	20120229-22929003004	CORONARY ARTERY DISEASE [冠動脈疾患]	20[redacted]-12-12T08:10	162	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-13T10:00	RECOVERED/RESOLVED
PLACEBO	20120229-22929007004	BRADYARRHYTHMIA [徐脈性不整脈]	20[redacted]-11-29T15:30	171	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-10T08:00	RECOVERED/RESOLVED
PLACEBO	20120229-22929007005	URINARY TRACT INFECTION [尿路感染]	20[redacted]-08-26T12:00	62	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-02	RECOVERED/RESOLVED

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PLACEBO	20120229-22929007008	ABSCESS OF TOE [四肢膿瘍]	20[redacted]-11-26T12:39	97	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-05T08:39	RECOVERED/RESOLVED
PLACEBO	20120229-22929007008	THE WOUND OF THE LEFT FOURTH TOE ABLATION INFLAMMATION [創傷]	20[redacted]*-01-23	155	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120229-22929007008	LEFT FIFTH FINGER TROPHIC ULCER [皮膚潰瘍]	20[redacted]*-03-11T13:58	202	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]*-03-18	RECOVERED/RESOLVED
PLACEBO	20120229-22929007008	PERIPHERAL ARTERY DISEASE [末梢動脈閉塞性疾患]	20[redacted]*-03-11T13:58	202	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]*-03-18T09:58	RECOVERED/RESOLVED
PLACEBO	20120229-22929007010	PYELONEPHRITIS ACUTE [急性腎盂腎炎]	20[redacted]-09-17T13:11	-2	MODERATE	YES	Requires or Prolongs Hospitalization	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-10-08T06:00	RECOVERED/RESOLVED
PLACEBO	20120229-22929007012	ISCHEMIC HEART DISEASE [心筋虚血]	20[redacted]-03-28	185	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	UNKNOWN
PLACEBO	20120229-22929007017	HOSPITALIZATION FOR LEFT OVARIAL CYST [卵巣嚢胞]	20[redacted]-11-04T17:05	34	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-08T11:30	RECOVERED/RESOLVED
PLACEBO	20120229-22929007017	IMPACTED WISDOM TEETH [埋伏歯]	20[redacted]-11-28T07:49	58	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-29	RECOVERED/RESOLVED
PLACEBO	20120229-22929007017	HOSPITALIZATION FOR WORSENING OF ANAEMIA [貧血]	20[redacted]-12-02	62	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-05T16:00	RECOVERED/RESOLVED
PLACEBO	20120229-22929007017	IMPACTED WISDOM TEETH [埋伏歯]	20[redacted]*-01-09T08:34	100	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]*-01-10T08:40	RECOVERED/RESOLVED

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PLACEBO	20120229-22929011002	SEIZURE [痙攣]	20[redacted]-11-02T06:10	31	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	RELATED	20[redacted]-11-16	RECOVERED/RESOLVED
PLACEBO	20120229-22932003004	ENDOVASCULAR INFECTION (INFECTED VASCULAR GRAFT) [動静脈グラフト部位感染]	20[redacted]-01-19T22:00	97	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-13	RECOVERED/RESOLVED
PLACEBO	20120229-22932003004	SEPSIS MRSA [ブドウ球菌性敗血症]	20[redacted]-01-19T22:00	97	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-13	RECOVERED/RESOLVED
PLACEBO	20120229-22932003004	SUBACUTE BACTERIAL ENDOCARDITIS [亜急性心内膜炎]	20[redacted]-01-30	108	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-13	RECOVERED/RESOLVED
PLACEBO	20120229-22948001004	CKD ANEMIA AGGRAVATED [腎性貧血]	20[redacted]-09-04T07:00	85	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-09-07	RECOVERED/RESOLVED
PLACEBO	20120229-22948003002	GONARTHRITIS [関節炎]	20[redacted]-01-09T17:00	164	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-16T22:51	RECOVERED/RESOLVED
PLACEBO	20120229-22948003002	SPINAL PAIN SYNDROME [脊椎痛]	20[redacted]-02-20T17:00	206	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-01T22:30	RECOVERED/RESOLVED
PLACEBO	20120229-22948005001	FRACTURE RIGHT FEMUR [大腿骨骨折]	20[redacted]-10-02T04:00	127	MODERATE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-23	RECOVERED/RESOLVED

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PLACEBO	20120229-22948005001	HEART FAILURE, CONGESTIVE [うっ血性心不全]	20[redacted]-12-14	200	SEVERE	YES	Results in Death, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-23	FATAL
PLACEBO	20120229-22948005006	COPD EXACERBATION [慢性閉塞性肺疾患]	20[redacted]-07-29T12:00	47	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-08-01	RECOVERED/RESOLVED
PLACEBO	20120229-22948005006	BONE GIANT CELL TUMOR BENIGN [良性骨巨細胞腫]	20[redacted]-09-12	92	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-09-13	RECOVERED/RESOLVED
PLACEBO	20120229-22948005006	OVERHYDRATION [水分過負荷]	20[redacted]-09-17T02:00	97	MODERATE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-17T12:00	RECOVERED/RESOLVED
PLACEBO	20120229-22948005008	DYSFUNCTION AND THROMBOSIS OF A-V FISTULAE-HOSPITALIZATION ON SURGERY DEPARTMENT [動静脈瘻血栓症]	20[redacted]-06-26T19:10	21	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-06-28	RECOVERED/RESOLVED
PLACEBO	20120229-22948005009	THROMBOSIS OF A-V FISTULA IN LEFT ARM [動静脈瘻血栓症]	20[redacted]-10-11	128	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-10-13	RECOVERED/RESOLVED
PLACEBO	20120229-22948007002	ABSCESS OF THE ABDOMINAL WALL [腹壁膿瘍]	20[redacted]-01-06T06:00	69	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIMICROBIAL TAKEN	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120229-22951001002	HEMORRHAGIC CEREBRAL INFARCTION [出血性脳梗塞]	20[redacted]-12-22T22:00	181	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-20*	RECOVERED/RESOLVED

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PLACEBO	20120229-22951003002	FRACTURE OF RIGHT FEMUR COLLUM [大腿骨骨折]	20[redacted]-02-18	191	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-15	RECOVERED/RESOLVED
PLACEBO	20120229-22951009002	HEMARTHROSIS OF KNEE [出血性関節症]	20[redacted]-08-25T21:00	61	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-01T16:00	RECOVERED/RESOLVED
PLACEBO	20120229-22958009006	FEBRILE SINDROME [発熱]	20[redacted]-10-26	151	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-14	RECOVERED/RESOLVED
PLACEBO	20120229-22958009006	OSTEOMYELITIS IN THE FIRST LEFT TOE [骨髄炎]	20[redacted]-11-28	184	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-12-18	RECOVERED/RESOLVED
PLACEBO	20120229-22958009015	ACUTE BI-VENTRICULAR HEART FAILURE [急性心不全]	20[redacted]-06-18T21:54	-8	MILD	YES	Requires or Prolongs Hospitalization	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	-	20[redacted]-06-25T15:39	RECOVERED/RESOLVED
PLACEBO	20120229-22958009015	COPD EXACERBATION [慢性閉塞性肺疾患]	20[redacted]-06-18T21:54	-8	MILD	YES	Requires or Prolongs Hospitalization	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, IV ANTIBIOTICS TAKEN	-	20[redacted]-06-25T15:39	RECOVERED/RESOLVED
PLACEBO	20120229-22958009015	URINARY INFECTION [尿路感染]	20[redacted]-07-03T20:35	8	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-07-19T13:00	RECOVERED/RESOLVED

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PLACEBO	20120229-22958009017	PNEUMONIA [肺炎]	20[redacted]-09-23T10:00	83	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-10-06	FATAL
PLACEBO	20120229-22966003005	CHOLECYSTITIS [胆嚢炎]	20[redacted]-11-23	193	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-12-02	RECOVERED/RESOLVED
PLACEBO	20120229-22966003018	DIABETIC FOOT INFECTION [糖尿病性足感染]	20[redacted]-12-06	108	MODERATE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]*-02-14	RECOVERED/RESOLVED
PLACEBO	20120229-22966003018	WORSNING DIABETIC FOOT ULCER [糖尿病性足病変]	20[redacted]*-12-06	108	LIFE THREATENING	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION	NOT RELATED	20[redacted]*-02-14	RECOVERED/RESOLVED
PLACEBO	20120229-22966003018	SEPTIC SHOCK [敗血症性ショック]	20[redacted]-02-14T18:22	178	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-14T18:22	FATAL
PLACEBO	20120229-22966005005	CHOLEDOCHOLITHIASIS [胆管結石]	20[redacted]-01-31	150	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-02-04	RECOVERED/RESOLVED
PLACEBO	20120229-22966009008	CONCUSSION, UNSPECIFIED [脳振盪]	20[redacted]-05-12	46	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-12	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
PLACEBO	20120229-22966009008	LEFT 4TH TOE PROXIMAL PHALANX OPEN FRACTURE [足骨折]	20[redacted]-05-12	46	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-10-24	RECOVERED/RESOLVED
PLACEBO	20120229-22966009008	LEFT CLAVICLE FRACTURE [鎖骨骨折]	20[redacted]-05-12	46	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-24	RECOVERED/RESOLVED
PLACEBO	20120229-22966009008	LEFT FOURTH RIB FRACTURE [肋骨骨折]	20[redacted]-05-12	46	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-24	RECOVERED/RESOLVED
PLACEBO	20120229-22966009015	EXACERBATION OF PAROXYSMAL RAPID ATRIAL FIBRILLATION [心房細動]	20[redacted]-05-14	-16	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-05-15	RECOVERED/RESOLVED
PLACEBO	20120229-22966009015	EXACERBATION OF ATRIAL FIBRILLATION [心房細動]	20[redacted]-08-14T08:00	77	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-08-21	RECOVERED/RESOLVED
PLACEBO	20120229-22966009015	UPPER GASTR0INTESTINAL BLEED [上部消化管出血]	20[redacted]-09-04T04:40	98	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-09-09T16:00	RECOVERED/RESOLVED
PLACEBO	20120229-22966009017	ACUTE OSTEOMYELITIS [急性骨髄炎]	20[redacted]-12-01	26	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN, OTHER	NOT RELATED	20[redacted]-12-20	RECOVERED/RESOLVED

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PLACEBO	20120229-22966009017	LEFT LEG, PERIPHERAL VASCULAR DISEASE [末梢血管障害]	20[redacted]-12-01 *	26	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-12-13 *	RECOVERED/RESOLVED
PLACEBO	20120229-22966009017	DEEP VEIN THROMBOSIS [深部静脈血栓症]	20[redacted]-02-13T08:00 *	100	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-02-25 *	RECOVERED/RESOLVED
PLACEBO	20120229-22966009017	LEFT FOOT NONHEALING ULCER [治癒不良]	20[redacted]-04-05T10:00	151	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-15	RECOVERED/RESOLVED
PLACEBO	20120229-22966011018	NON-ISCHEMIC CARDIOMYOPATHY [心筋症]	20[redacted]-10-30	3	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-02	RECOVERED/RESOLVED
PLACEBO	20120229-22966019008	GRAFT INFECTION (DIALYSIS ACCESS SITE RIGHT ARM) [動静脈グラフト部位感染]	20[redacted]-09-27	-5	MODERATE	YES	Requires or Prolongs Hospitalization	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	-	20[redacted]-10-01	RECOVERED/RESOLVED
PLACEBO	20120229-22966021002	DIABETIC KETOACIDOSIS [糖尿病性ケトアシドーシス]	20[redacted]-07-21T06:50	82	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-29T18:50	RECOVERED/RESOLVED

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PLACEBO	20120229-22966021002	SEPSIS [敗血症]	20[redacted]-07-21T06:50	82	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-09-16T10:15	RECOVERED/RESOLVED
PLACEBO	20120229-22966021005	CLOSTRIDIUM DIFFICILE INFECTION [クロストリジウム・ディフィシレ感染]	20[redacted]-09-11T18:09	80	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN, NON-IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-09-16	RECOVERED/RESOLVED
PLACEBO	20120229-22966021005	ACUTE RENAL TRANSPLANT REJECTION [腎移植拒絶反応]	20[redacted]-09-20T15:10	89	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-09-28T15:00	RECOVERED/RESOLVED
PLACEBO	20120229-22966021005	PNEUMONIA [肺炎]	20[redacted]-10-26	125	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN	NOT RELATED	20[redacted]-11-11T17:25	FATAL
PLACEBO	20120229-22966021005	HEART FAILURE, UNSPECIFIED [心不全]	20[redacted]-11-03T10:39	133	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-11	UNKNOWN

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PLACEBO	20120229-22966021005	CARDIAC ARREST [心停止]	20[redacted]-11-06T17:01	136	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-11	UNKNOWN
PLACEBO	20120229-22966021005	ATRIAL FIBRILLATION [心房細動]	20[redacted]-11-08T16:31	138	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-11T17:25	UNKNOWN
PLACEBO	20120229-22966021005	ANOXIC ENCEPHALOPATHY, ACUTE [低酸素性虚血性脳症]	20[redacted]-11-08T17:01	138	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-11-11T17:25	UNKNOWN
PLACEBO	20120229-22966021005	BRAIN DEATH [脳死]	20[redacted]-11-11	141	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-11T17:25	UNKNOWN
PLACEBO	20120229-22966021005	SHOCK LIVER [虚血性肝炎]	20[redacted]-11-11T11:48	141	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-11T17:25	UNKNOWN
PLACEBO	20120229-22966021007	FLUID OVERLOAD [水分過負荷]	20[redacted]-11-22	23	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-11-26	RECOVERED/RESOLVED
PLACEBO	20120229-22966023005	DECOMPENSATED HEART FAILURE [心不全]	20[redacted]-04-22	-9	SEVERE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-04-25	RECOVERED/RESOLVED
PLACEBO	20120229-22966023005	HYPOTENSION [低血圧]	20[redacted]-05-16	16	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-18	RECOVERED/RESOLVED

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PLACEBO	20120229-22966023005	ANEMIA [貧血]	20[redacted]-05-29	29	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-06-05	RECOVERED/RESOLVED
PLACEBO	20120229-22966023005	GASTRO INTESTINAL BLEEDING [胃腸出血]	20[redacted]-07-11	72	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-11	RECOVERED/RESOLVED
PLACEBO	20120229-22966023005	HYPOTENSION [低血圧]	20[redacted]-08-24	116	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-26	RECOVERED/RESOLVED
PLACEBO	20120229-22966023005	GASTRO INTESTINAL BLEEDING [胃腸出血]	20[redacted]-09-07T12:00	130	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-10T14:01	RECOVERED/RESOLVED
PLACEBO	20120229-22966023005	GASTROINTESTINAL BLEED [胃腸出血]	20[redacted]-09-28T05:56	151	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-29T09:35	RECOVERED/RESOLVED
PLACEBO	20120229-22966027007	ABDOMINAL PAIN GENERALIZED [腹痛]	20[redacted]-08-26	69	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-08-29	RECOVERED/RESOLVED
PLACEBO	20120229-22966027007	CHOLELITHIASIS [胆石症]	20[redacted]-08-26	69	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-10-31	RECOVERED/RESOLVED
PLACEBO	20120229-22966027007	DIARRHEA AGGRAVATED [下痢]	20[redacted]-08-26	69	MILD	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-08-29	RECOVERED/RESOLVED
PLACEBO	20120229-22966029003	CORONARY ARTERY DISEASE [冠動脈疾患]	20[redacted]-11-17T12:30 *	56	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-19T12:35 *	RECOVERED/RESOLVED
PLACEBO	20120229-22966029003	CORONARY ARTERY DISEASE [冠動脈疾患]	20[redacted]-01-30T14:00	130	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-03	RECOVERED/RESOLVED

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PLACEBO	20120229-22966029005	PNEUMONIA [肺炎]	20[redacted]-10-06T17:33	7	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-10T10:42	RECOVERED/RESOLVED
PLACEBO	20120229-22966029005	PNEUMONIA [肺炎]	20[redacted]-11-25T07:29 *	57	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-29T15:16 *	RECOVERED/RESOLVED
PLACEBO	20120229-22966029005	FLUID OVERLOAD [水分過負荷]	20[redacted]-01-12T15:37	105	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-13T08:21	RECOVERED/RESOLVED
PLACEBO	20120229-22966031005	HEMATOMA TO GRION [血腫]	20[redacted]-01-22	182	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-23T19:45	RECOVERED/RESOLVED
PLACEBO	20120229-22966035010	ACID REFLUX (ESOPHAGEAL) [胃食道逆流性疾患]	20[redacted]-01-13	153	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-16	RECOVERED/RESOLVED
PLACEBO	20120229-22966041004	GANGRENE CUTANEOUS [壊疽]	20[redacted]-03-24	161	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120229-22966057005	ARTIFICIAL KIDNEY CLOTTING DURING DIALYSIS [医療機器関連の血栓症]	20[redacted]-07-25	44	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-07-26	RECOVERED/RESOLVED
PLACEBO	20120229-22966057010	INCREASED TOTAL BILIRUBIN SECONDARY TO SICKLE CELL CRISIS [鎌状赤血球貧血クリーゼ]	20[redacted]-11-01T01:00	89	SEVERE	YES	Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED

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PLACEBO	20120229-22966057010	HYPOXIC RESPIRATORY FAILURE [呼吸不全]	20[redacted]-11-11T22:00	99	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-11-22	RECOVERED/RESOLVED
PLACEBO	20120229-22966057010	PLEAURAL EFFUSION OF UNKNOWN ETIOLOGY [胸水]	20[redacted]-11-12	100	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, IV ANTIMICROBIAL TAKEN	NOT RELATED	20[redacted]-11-22	RECOVERED/RESOLVED
PLACEBO	20120229-22966057010	SICKLE CELL PAIN CRISIS [鎌状赤血球貧血クリーゼ]	20[redacted]-11-12	100	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-22	RECOVERED/RESOLVED
PLACEBO	20120229-22966059003	HYPERKALEMIA [高カリウム血症]	20[redacted]-10-07	173	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-08	RECOVERED/RESOLVED
PLACEBO	20120229-22966059004	CELLULITIS [蜂巣炎]	20[redacted]-04-06	3	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-04-24	RECOVERED/RESOLVED
PLACEBO	20120229-22966059004	CELLULITIS [蜂巣炎]	20[redacted]-05-28	55	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-31	RECOVERED/RESOLVED
PLACEBO	20120229-22966059005	CHEST PAIN (NON-CARDIAC) [非心臓性胸痛]	20[redacted]-05-06	20	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	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
PLACEBO	20120229-22966059005	CHEST PAIN (NON-CARDIAC) [非心臓性胸痛]	20[redacted]-07-25	100	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-07-26	RECOVERED/RESOLVED
PLACEBO	20120229-22966059005	FLUID OVERLOAD [水分過負荷]	20[redacted]-09-29	166	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-02	RECOVERED/RESOLVED
PLACEBO	20120229-22966059005	PULMONARY EDEMA [肺水腫]	20[redacted]-10-10	177	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-12	RECOVERED/RESOLVED
PLACEBO	20120229-22966059005	ACUTE PULMONARY EDEMA [急性肺水腫]	20[redacted]-10-29	196	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-31	RECOVERED/RESOLVED
PLACEBO	20120229-22966079002	PARTIAL SMALL BOWEL OBSTRUCTION [小腸閉塞]	20[redacted]-06-19	3	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-06-21	RECOVERED/RESOLVED
PLACEBO	20120229-22966079004	BACTEREMIA [菌血症]	20[redacted]-01-17	131	MODERATE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-01-24	RECOVERED/RESOLVED
PLACEBO	20120229-22966081006	BENIGN LEFT OVARIAN CYSTIC MASS [卵巣嚢胞]	20[redacted]-12-10	93	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-12-14	RECOVERED/RESOLVED
PLACEBO	20120229-22966087002	OSTEOARTHRITIS GENERALISED [変形性関節症]	20[redacted]-08-06T06:00	76	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-08-07T18:00	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	20120229-22966087005	VASCULAR ACCESS RUPTURE [血管破裂]	20[redacted]-11-22T20:00	101	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION	NOT RELATED	20[redacted]-11-24T16:00	RECOVERED/RESOLVED
PLACEBO	20120229-22966087005	AGGRAVATED ANEMIA [貧血]	20[redacted]-11-25T19:00	104	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-11-27	RECOVERED/RESOLVED
PLACEBO	20120229-22966087006	SHORTNESS OF BREATH [呼吸困難]	20[redacted]-11-16T10:00	81	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-11-21T18:00	RECOVERED/RESOLVED
PLACEBO	20120229-22966087006	CLOTTED AV ACCESS [動静脈瘻血栓症]	20[redacted]-12-20T17:00	115	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER	NOT RELATED	20[redacted]-12-23T11:00	RECOVERED/RESOLVED
PLACEBO	20120229-22966087007	1ST DEGREE AV BLOCK [第一度房室ブロック]	20[redacted]-11-11T10:00	71	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-11-16T15:00	RECOVERED/RESOLVED
PLACEBO	20120229-22966087007	BLOODY STOOL [血便排泄]	20[redacted]-12-21T10:00	111	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-12-23T13:00	RECOVERED/RESOLVED
PLACEBO	20120229-22966089005	DIFFUSE JEJUNAL ANGIOECTASIA [胃腸毛細血管拡張症]	20[redacted]-09-07	3	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, OTHER	NOT RELATED	20[redacted]*-03-19	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
PLACEBO	20120229-22966089005	GASTROINTESTINAL BLEED [胃腸出血]	20[redacted]-09-07	3	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, EMERGENCY ROOM VISIT, OTHER	NOT RELATED	20[redacted]-10-22 *	RECOVERED/RESOLVED
PLACEBO	20120229-22966089005	WORSENING VALVULAR HEART DISEASE NOS [心臓弁膜疾患]	20[redacted]-10-22	48	LIFE THREATENING	YES	Results in Death, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-03-19	FATAL
PLACEBO	20120229-22966089005	WORSENING HYPOTENSION [低血圧]	20[redacted]-10-29	55	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-01	RECOVERED/RESOLVED
PLACEBO	20120229-22966089005	INFECTION IN FEMORAL PICC LINE [医療機器関連感染]	20[redacted]-10-29T06:50 *	55	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-01 *	RECOVERED/RESOLVED
PLACEBO	20120229-22966089005	ACUTE ENCEPHALOPATHY (MULTIFACTORIAL, TOXIC METABOLIC, INFECTION & NARCOTICS USE) [脳症]	20[redacted]-01-27 *	145	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-31 *	RECOVERED/RESOLVED
PLACEBO	20120229-22966089005	NARCOTIC ABUSE [薬物乱用]	20[redacted]-01-27 *	145	SEVERE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-31 *	RECOVERED/RESOLVED
PLACEBO	20120229-22966097002	THROMBOSED AV GRAFT [血管グラフト血栓症]	20[redacted]-11-01T09:30	47	MILD	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-11-05T07:12	RECOVERED/RESOLVED

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PLACEBO	20120229-22966097002	THROMBOSED AV GRAFT [血管グラフト血栓症]	20[redacted]-11-25	71	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-11-27	RECOVERED/RESOLVED
PLACEBO	20120229-22966097003	PANCREATITIS [膵炎]	20[redacted]-04-16T06:00	171	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-19T11:00	RECOVERED/RESOLVED
PLACEBO	20120229-22966097004	NON CARDIAC CHEST PAIN [非心臓性胸痛]	20[redacted]-11-21	11	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-29	RECOVERED/RESOLVED
PLACEBO	20120229-22966097004	NON CARDIAC CHEST PAIN [非心臓性胸痛]	20[redacted]-12-19T09:00	39	MILD	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-21	RECOVERED/RESOLVED
PLACEBO	20120229-22966097004	NON CARDIAC CHEST PAIN [非心臓性胸痛]	20[redacted]-12-29T11:30 *	49	MILD	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-31 *	RECOVERED/RESOLVED
PLACEBO	20120229-22966097004	CHEST PAIN (NON-CARDIAC) [非心臓性胸痛]	20[redacted]-02-13T03:00	95	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-14T12:00	RECOVERED/RESOLVED
PLACEBO	20120229-22966113003	SEPSIS MRSA [ブドウ球菌性敗血症]	20[redacted]-08-16	-19	MODERATE	YES	Requires or Prolongs Hospitalization	-	HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN	-	20[redacted]-08-31	RECOVERED/RESOLVED
PLACEBO	20120229-22966121002	CHILLS [悪寒]	20[redacted]-02-04T15:00	90	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-08	RECOVERED/RESOLVED
PLACEBO	20120229-22966121002	FEVER [発熱]	20[redacted]-02-04T15:00	90	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-08	RECOVERED/RESOLVED

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PLACEBO	20120229-22966121002	MALAISE [倦怠感]	20[redacted]-02-04T15:00	90	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-02-08	RECOVERED/RESOLVED
PLACEBO	20120229-22966121002	ANTICOAGULATION DRUG LEVEL ABOVE THERAPEUTIC [抗凝固薬濃度治療量以上]	20[redacted]-03-08T19:20	122	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED	NOT RELATED	20[redacted]-03-11	RECOVERED/RESOLVED
PLACEBO	20120229-22966133003	TOE INJURY [四肢損傷]	20[redacted]-09-26T23:00	109	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	ONGOING	NOT RECOVERED/NOT RESOLVED
PLACEBO	20120229-22966133014	FLUID OVERLOAD [水分過負荷]	20[redacted]-10-13T18:00	-3	MODERATE	YES	Requires or Prolongs Hospitalization, Is Life Threatening	-	HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER	-	20[redacted]-10-15T12:00	RECOVERED/RESOLVED
PLACEBO	20120229-22966133014	EXERTIONAL DYSPNEA [労作性呼吸困難]	20[redacted]-04-06 *	173	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-04-08 *	RECOVERED/RESOLVED
PLACEBO	20120229-22966133014	PNEUMONIA [肺炎]	20[redacted]-05-14T14:00	211	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-05-19	RECOVERED/RESOLVED
PLACEBO	20120229-22966133015	BACK PAIN (WITH RADIATION) [背部痛]	20[redacted]-10-21T18:00	14	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN, OTHER	NOT RELATED	20[redacted]-11-06	RECOVERED/RESOLVED

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PLACEBO	20120229-22966133015	BACLOFEN INDUCED NEUROPATHY [末梢性ニューロパチー]	20[redacted]-11-15	39	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER	NOT RELATED	20[redacted]-11-22	RECOVERED/RESOLVED
PLACEBO	20120229-22966181005	SHINGLES [帯状疱疹]	20[redacted]-08-04T00:00	-66	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-08-05T00:00	RECOVERED/RESOLVED
PLACEBO	20120229-22966181005	ALTERED STATE OF CONSCIOUSNESS [意識変容状態]	20[redacted]-08-05T00:00	-65	MODERATE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	-	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	-	20[redacted]-08-07T00:00	RECOVERED/RESOLVED
PLACEBO	20120229-22966187001	CHILLS WITH NO INFECTION [悪寒]	20[redacted]-09-13	15	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-25	RECOVERED/RESOLVED
PLACEBO	20120229-22966187001	FEVER [発熱]	20[redacted]-09-14	16	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-09-23	RECOVERED/RESOLVED
PLACEBO	20120229-22966193002	HIGH BLOOD PRESSURE [高血圧]	20[redacted]-10-06T10:00	55	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-11T10:00	RECOVERED/RESOLVED
PLACEBO	20120229-22966193006	GASTRITIS ACUTE [胃炎]	20[redacted]-11-07T08:00 *	79	SEVERE	YES	Persist or Signif Disability/Incapacity, Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-27 *	RECOVERED/RESOLVED
PLACEBO	20120229-22966193006	FIBRILLATION ATRIAL [心房細動]	20[redacted]-01-13T13:00	146	MILD	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-01-23	RECOVERED/RESOLVED
PLACEBO	20120229-22966207004	SEIZURE [痙攣]	20[redacted]-10-29	19	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-01	RECOVERED/RESOLVED

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PLACEBO	20120229-22966207004	SEVERE ACCELERATED HYPERTENSION [進行性高血圧]	20[redacted]-10-29	19	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-01	RECOVERED/RESOLVED
PLACEBO	20120229-22966207004	SEVERE HYPERGLYCEMIA [高血糖]	20[redacted]-10-29	19	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-11-01	RECOVERED/RESOLVED
PLACEBO	20120229-22966207004	SEIZURE [痙攣]	20[redacted]-12-28	79	SEVERE	YES	Other Medically Important Serious Event	DOSE NOT CHANGED	MEDICATION TAKEN, EMERGENCY ROOM VISIT	NOT RELATED	20[redacted]-12-28	RECOVERED/RESOLVED
PLACEBO	20120229-22966213001	ALLERGIC CONJUNCTIVITIS [アレルギー性結膜炎]	20[redacted]-09-26T11:00	24	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION, UNKNOWN, UNKNOWN, UNKNOWN	NOT RELATED	20[redacted]-10-09T15:15	RECOVERED/RESOLVED
PLACEBO	20120229-22966213001	STATUS POST HEPATIC ENCEPHALOPATHY [肝性脳症]	20[redacted]-12-13	102	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-17	RECOVERED/RESOLVED
PLACEBO	20120229-22966213001	STOMACH PAIN [上腹部痛]	20[redacted]-12-13	102	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-17T17:15	RECOVERED/RESOLVED
PLACEBO	20120229-22966213001	ABDOMINAL PAIN [腹痛]	20[redacted]-12-28	117	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-30T19:30	RECOVERED/RESOLVED
PLACEBO	20120229-22966241004	CARDIAC CHEST PAIN [狭心症]	20[redacted]-12-21	47	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-12-22	RECOVERED/RESOLVED
PLACEBO	20120229-22966285003	HYPOGLYCEMIA [低血糖症]	20[redacted]-10-25	2	SEVERE	YES	Requires or Prolongs Hospitalization	DOSE ALTERED OR WITHHELD	HOSPITALIZED / PROLONGED HOSPITALIZATION	NOT RELATED	20[redacted]-10-28	RECOVERED/RESOLVED

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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
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

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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	20120230-23011006005	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
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

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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	20120230-23013006005	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
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

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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
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

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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
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

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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
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

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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
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

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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
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

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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
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

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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	20120230-23066004024	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
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

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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	20120230-23066006018	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
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

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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
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

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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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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	20120230-23066048001	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

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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	20120230-23066078004	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
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
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

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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
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

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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	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

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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
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

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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
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

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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
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

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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	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
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 17.1J
AMG 416 = ONO-5163

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表 2.7.4.7-9　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
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

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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	20120360-36016005002	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
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

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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	20120360-36022004002	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
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

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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	20120360-36025012001	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
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

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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	20120360-36027001001	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
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

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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
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

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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
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

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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	20120360-36036004005	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
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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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	20120360-36043003005	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
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	20120360-36048011004	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
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

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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
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

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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
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

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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
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

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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
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

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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
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

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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
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

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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
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
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

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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
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

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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
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

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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
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

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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
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

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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
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

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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	20120360-36027007003	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
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

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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	20120360-36029011002	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
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

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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
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

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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
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

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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
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

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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
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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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	20120360-36049004010	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
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

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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
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

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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
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

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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
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

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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
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

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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
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

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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
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

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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	20120360-36066025001	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
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

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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	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	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 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	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

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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	20120360-36066034027	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
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
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

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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	20120360-36066092007	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
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

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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	20120360-36049001003	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
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 17.0J
AMG 416 = ONO-5163

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表 2.7.4.7-10　投与中止の原因となった有害事象の一覧表［海外第III相プラセボ対照試験（併合成績）］

Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
AMG 416	20120229-22912001004	GASTROINTESTINAL ANOMALY [胃腸奇形]	20[redacted]-10-04	1	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-12-09	-
AMG 416	20120229-22912001004	SWEATING ATTACK [多汗症]	20[redacted]-10-04	1	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-12-09	-
AMG 416	20120229-22921001007	DRUG ALERGY - CALCIUM EFFERVESCENS [薬物過敏症]	20[redacted]-02-14	124	MODERATE	NO	-	DRUG WITHDRAWN	OTHER	NOT RELATED	ONGOING	-
AMG 416	20120229-22929007019	LOW SERUM CALCIUM [血中カルシウム減少]	20[redacted]-03-24	166	MODERATE	NO	-	DRUG WITHDRAWN	OTHER	RELATED	ONGOING	-
AMG 416	20120229-22965003005	NAUSEA [悪心]	20[redacted]-02-11T21:00	125	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-02-16	-
AMG 416	20120229-22965003005	VOMITING [嘔吐]	20[redacted]-02-11T21:00	125	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-02-16	-
AMG 416	20120229-22965011006	BLOOD CALCIUM DECREASED [血中カルシウム減少]	20[redacted]-02-19T14:15	113	MILD	NO	-	DRUG WITHDRAWN	CULTURE TAKEN	RELATED	20[redacted]-03-06T14:32	-
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	20120229-22926003004	HYPERPHOSPHATEMIA [高リン酸塩血症]	20[redacted]-10-15	62	MODERATE	NO	-	DRUG WITHDRAWN	REMOVED FROM STUDY	RELATED	ONGOING	-
PLACEBO	20120229-22926005009	LOST OF APPETITE [食欲減退]	20[redacted]-10-16T08:00	17	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-10-30	-
PLACEBO	20120229-22926005009	PERIORAL PARAESTHESIA [口の錯感覚]	20[redacted]-10-23	24	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	ONGOING	-
PLACEBO	20120229-22926005009	NECK PAIN [頚部痛]	20[redacted]-10-23T08:00	24	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	ONGOING	-
PLACEBO	20120229-22926005009	TASTE DISTURBANCE [味覚異常]	20[redacted]-10-25T12:46	26	MILD	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	ONGOING	-

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Treatment Group	Usubject ID	Reported Term for the Adverse Event [Preferred Term*1]	Start Date/Time	Study Day of Start of Adverse Event (days)	Severity/Intensity	Serious	Serious Criteria	Action Taken with Study Treatment	Other Action Taken	Causality	End Date/Time	Outcome of Serious Adverse Event
PLACEBO	20120229-22958009017	CARDIOMEGALY [心拡大]	20[redacted]-09-23	83	MILD	NO	-	DRUG WITHDRAWN	DEVICE / PROCEDURE INTERVENTION	NOT RELATED	20[redacted]-10-06	-
PLACEBO	20120229-22958009017	PNEUMONIA [肺炎]	20[redacted]-09-23T10:00	83	LIFE THREATENING	YES	Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization	DRUG WITHDRAWN	HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN	NOT RELATED	20[redacted]-10-06	FATAL
PLACEBO	20120229-22966089005	DIFFUSE JEJUNAL ANGIOECTASIA [胃腸毛細血管拡張症]	20[redacted]-09-07	3	SEVERE	YES	Requires or Prolongs Hospitalization	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, OTHER	NOT RELATED	20[redacted]*-03-19	RECOVERED/RESOLVED
PLACEBO	20120229-22966133015	BACK PAIN (WITH RADIATION) [背部痛]	20[redacted]-10-21T18:00	14	SEVERE	YES	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	DRUG WITHDRAWN	MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN, OTHER	NOT RELATED	20[redacted]-11-06	RECOVERED/RESOLVED
PLACEBO	20120229-22966215004	POST INFLAMMATORY HYPERPIGMENTATION SECONDARY TO UNDEFINED DERMATITIS [皮膚炎]	20[redacted]-12-06	33	MODERATE	NO	-	DRUG WITHDRAWN	MEDICATION TAKEN	RELATED	20[redacted]*-02-20	-
PLACEBO	20120229-22966241004	FLUSHING [潮紅]	20[redacted]-02-24	112	MODERATE	NO	-	DRUG WITHDRAWN	NO ACTION TAKEN	RELATED	20[redacted]-03-03	-
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	-

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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	20120230-23066042005	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
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 17.1J
AMG 416 = ONO-5163

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表 2.7.4.7-11　投与中止の原因とな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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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	20120360-36048011004	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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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	20120360-36066073001	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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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	-
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	-

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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	-
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	-

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
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
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	STERNAL OSTEOMYELITIS [骨髄炎]	20[redacted]-08-11	131	MODERATE	NO	-	DRUG WITHDRAWN	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	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	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
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

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 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
全体		184 (96.8)	53 (27.9)
軽度		151 (79.5)	47 (24.7)
中等度		20 (10.5)	3 (1.6)
高度		13 (6.8)	3 (1.6)
血液およびリンパ系障害		7 (3.7)	
軽度		6 (3.2)	
中等度		1 (0.5)	
貧血		1 (0.5)	
軽度		1 (0.5)	
鉄欠乏性貧血		1 (0.5)	
軽度		1 (0.5)	
リンパ節症		1 (0.5)	
軽度		1 (0.5)	
腎性貧血		4 (2.1)	
軽度		3 (1.6)	
中等度		1 (0.5)	
心臓障害		8 (4.2)	3 (1.6)
軽度		5 (2.6)	2 (1.1)

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

出典［総括報告書 5.3.5.2-1（ONO-5163-[redacted] 試験）表 14.3.1-11］

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 1）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
中等度	2 (1.1)	
高度	1 (0.5)	1 (0.5)
心房細動	1 (0.5)	
中等度	1 (0.5)	
うっ血性心不全	2 (1.1)	
軽度	1 (0.5)	
中等度	1 (0.5)	
心筋梗塞	1 (0.5)	1 (0.5)
高度	1 (0.5)	1 (0.5)
動悸	1 (0.5)	
軽度	1 (0.5)	
上室性期外収縮	1 (0.5)	1 (0.5)
軽度	1 (0.5)	1 (0.5)
心室性期外収縮	1 (0.5)	
軽度	1 (0.5)	
頻脈性不整脈	1 (0.5)	1 (0.5)
軽度	1 (0.5)	1 (0.5)
耳および迷路障害	13 (6.8)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 2）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
軽度		11 (5.8)	
中等度		2 (1.1)	
耳鳴		1 (0.5)	
軽度		1 (0.5)	
回転性めまい		10 (5.3)	
軽度		8 (4.2)	
中等度		2 (1.1)	
頭位性回転性めまい		2 (1.1)	
軽度		2 (1.1)	
眼障害		21 (11.1)	1 (0.5)
軽度		20 (10.5)	1 (0.5)
高度		1 (0.5)	
眼瞼炎		2 (1.1)	1 (0.5)
軽度		2 (1.1)	1 (0.5)
白内障		4 (2.1)	
軽度		4 (2.1)	
結膜出血		5 (2.6)	
軽度		5 (2.6)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 3）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
アレルギー性結膜炎		3 (1.6)	
軽度		3 (1.6)	
角膜沈着物		1 (0.5)	
軽度		1 (0.5)	
眼乾燥		1 (0.5)	
軽度		1 (0.5)	
眼瞼湿疹		1 (0.5)	
軽度		1 (0.5)	
眼脂		1 (0.5)	
軽度		1 (0.5)	
眼瞼下垂		1 (0.5)	
軽度		1 (0.5)	
網膜剥離		1 (0.5)	
高度		1 (0.5)	
網膜出血		1 (0.5)	
軽度		1 (0.5)	
高血圧性網膜症		1 (0.5)	
軽度		1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 4）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
硝子体浮遊物		1 (0.5)	
軽度		1 (0.5)	
強膜出血		1 (0.5)	
軽度		1 (0.5)	
結膜充血		1 (0.5)	
軽度		1 (0.5)	
眼そう痒症		1 (0.5)	
軽度		1 (0.5)	
胃腸障害		91 (47.9)	10 (5.3)
軽度		83 (43.7)	8 (4.2)
中等度		5 (2.6)	2 (1.1)
高度		3 (1.6)	
腹部不快感		5 (2.6)	1 (0.5)
軽度		5 (2.6)	1 (0.5)
腹部膨満		1 (0.5)	
軽度		1 (0.5)	
腹痛		1 (0.5)	
軽度		1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 5）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
下腹部痛	2 (1.1)	
軽度	2 (1.1)	
上腹部痛	4 (2.1)	
軽度	4 (2.1)	
口唇炎	1 (0.5)	
軽度	1 (0.5)	
慢性胃炎	1 (0.5)	
軽度	1 (0.5)	
便秘	12 (6.3)	1 (0.5)
軽度	12 (6.3)	1 (0.5)
齲歯	7 (3.7)	
軽度	7 (3.7)	
下痢	34 (17.9)	3 (1.6)
軽度	34 (17.9)	3 (1.6)
腸憩室	1 (0.5)	
中等度	1 (0.5)	
出血性腸憩室	1 (0.5)	
高度	1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 6）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
十二指腸炎	1 (0.5)	
軽度	1 (0.5)	
消化不良	1 (0.5)	
軽度	1 (0.5)	
小腸炎	1 (0.5)	
軽度	1 (0.5)	
腸炎	1 (0.5)	
軽度	1 (0.5)	
胃アトニー	1 (0.5)	
軽度	1 (0.5)	
胃ポリープ	7 (3.7)	
軽度	7 (3.7)	
胃炎	5 (2.6)	
軽度	5 (2.6)	
胃食道逆流性疾患	4 (2.1)	1 (0.5)
軽度	3 (1.6)	
中等度	1 (0.5)	1 (0.5)
歯肉痛	1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 7）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
軽度	1 (0.5)	
舌炎	1 (0.5)	
軽度	1 (0.5)	
痔核	8 (4.2)	
軽度	7 (3.7)	
中等度	1 (0.5)	
裂孔ヘルニア	1 (0.5)	
軽度	1 (0.5)	
大腸穿孔	1 (0.5)	
高度	1 (0.5)	
口唇潰瘍	1 (0.5)	
軽度	1 (0.5)	
悪心	9 (4.7)	1 (0.5)
軽度	7 (3.7)	
中等度	2 (1.1)	1 (0.5)
急性膵炎	1 (0.5)	
高度	1 (0.5)	
口内炎	4 (2.1)	1 (0.5)

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 8）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
軽度	4 (2.1)	1 (0.5)
歯痛	1 (0.5)	
軽度	1 (0.5)	
嘔吐	18 (9.5)	2 (1.1)
軽度	17 (8.9)	1 (0.5)
中等度	1 (0.5)	1 (0.5)
口唇のひび割れ	1 (0.5)	
軽度	1 (0.5)	
大腸ポリープ	4 (2.1)	
軽度	4 (2.1)	
心窩部不快感	1 (0.5)	1 (0.5)
軽度	1 (0.5)	1 (0.5)
痔出血	1 (0.5)	1 (0.5)
軽度	1 (0.5)	1 (0.5)
ブルンネル腺過形成	1 (0.5)	
軽度	1 (0.5)	
口の感覚鈍麻	1 (0.5)	1 (0.5)
軽度	1 (0.5)	1 (0.5)

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 9）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
腹膜穿孔	1 (0.5)	
軽度	1 (0.5)	
肛門びらん	1 (0.5)	
軽度	1 (0.5)	
口腔粘膜血腫	1 (0.5)	
軽度	1 (0.5)	
軟便	2 (1.1)	1 (0.5)
軽度	2 (1.1)	1 (0.5)
一般・全身障害および投与部位の状態	17 (8.9)	2 (1.1)
軽度	16 (8.4)	1 (0.5)
高度	1 (0.5)	1 (0.5)
胸痛	5 (2.6)	
軽度	5 (2.6)	
異常感	1 (0.5)	
軽度	1 (0.5)	
倦怠感	3 (1.6)	1 (0.5)
軽度	3 (1.6)	1 (0.5)
発熱	2 (1.1)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 10）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
軽度	2 (1.1)	
突然死	1 (0.5)	1 (0.5)
高度	1 (0.5)	1 (0.5)
虚血性潰瘍	1 (0.5)	
軽度	1 (0.5)	
穿刺部位疼痛	1 (0.5)	
軽度	1 (0.5)	
血管穿刺部位そう痒感	1 (0.5)	
軽度	1 (0.5)	
穿刺部位腫脹	2 (1.1)	
軽度	2 (1.1)	
肝胆道系障害	2 (1.1)	
軽度	1 (0.5)	
高度	1 (0.5)	
胆管結石	1 (0.5)	
高度	1 (0.5)	
胆嚢ポリープ	1 (0.5)	
軽度	1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 11）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
免疫系障害		2 (1.1)	
軽度		2 (1.1)	
季節性アレルギー		1 (0.5)	
軽度		1 (0.5)	
造影剤アレルギー		1 (0.5)	
軽度		1 (0.5)	
感染症および寄生虫症		137 (72.1)	1 (0.5)
軽度		131 (68.9)	1 (0.5)
中等度		5 (2.6)	
高度		1 (0.5)	
細菌性膣症		1 (0.5)	
軽度		1 (0.5)	
気管支炎		9 (4.7)	
軽度		9 (4.7)	
気管支肺炎		1 (0.5)	
軽度		1 (0.5)	
慢性副鼻腔炎		1 (0.5)	
軽度		1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 12）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
結膜炎		2 (1.1)	
軽度		2 (1.1)	
膀胱炎		8 (4.2)	
軽度		8 (4.2)	
感染性皮膚炎		2 (1.1)	
軽度		2 (1.1)	
毛包炎		4 (2.1)	
軽度		4 (2.1)	
せつ		1 (0.5)	
軽度		1 (0.5)	
胃腸炎		10 (5.3)	
軽度		9 (4.7)	
中等度		1 (0.5)	
歯肉炎		4 (2.1)	
軽度		4 (2.1)	
単純ヘルペス		1 (0.5)	1 (0.5)
軽度		1 (0.5)	1 (0.5)
麦粒腫		4 (2.1)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 13）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
軽度	4 (2.1)	
インフルエンザ	5 (2.6)	
軽度	3 (1.6)	
中等度	2 (1.1)	
大葉性肺炎	1 (0.5)	
中等度	1 (0.5)	
リステリア菌性髄膜炎	1 (0.5)	
高度	1 (0.5)	
鼻咽頭炎	109 (57.4)	
軽度	109 (57.4)	
爪真菌症	3 (1.6)	
軽度	3 (1.6)	
精巣炎	1 (0.5)	
軽度	1 (0.5)	
中耳炎	1 (0.5)	
軽度	1 (0.5)	
歯冠周囲炎	1 (0.5)	
軽度	1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 14）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
歯周炎		3 (1.6)	
軽度		3 (1.6)	
咽頭炎		5 (2.6)	
軽度		5 (2.6)	
偽膜性大腸炎		1 (0.5)	
軽度		1 (0.5)	
歯髄炎		1 (0.5)	
軽度		1 (0.5)	
膿皮症		1 (0.5)	
軽度		1 (0.5)	
皮下組織膿瘍		1 (0.5)	
軽度		1 (0.5)	
足部白癬		5 (2.6)	
軽度		5 (2.6)	
尿路感染		1 (0.5)	
中等度		1 (0.5)	
肛径部感染		1 (0.5)	
軽度		1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 15）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
細菌性咽頭炎		1 (0.5)	
軽度		1 (0.5)	
シャント感染		5 (2.6)	
軽度		5 (2.6)	
腎嚢胞感染		1 (0.5)	
中等度		1 (0.5)	
細菌性結膜炎		1 (0.5)	
軽度		1 (0.5)	
ウイルス性腸炎		1 (0.5)	
軽度		1 (0.5)	
化膿		1 (0.5)	
軽度		1 (0.5)	
細菌性腸炎		1 (0.5)	
軽度		1 (0.5)	
口腔ヘルペス		3 (1.6)	
軽度		3 (1.6)	
感染性皮膚嚢腫		5 (2.6)	
軽度		5 (2.6)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 16）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
傷害、中毒および処置合併症		83 (43.7)	
軽度		78 (41.1)	
中等度		3 (1.6)	
高度		2 (1.1)	
足関節部骨折		1 (0.5)	
中等度		1 (0.5)	
節足動物刺傷		2 (1.1)	
軽度		2 (1.1)	
上顎炎		1 (0.5)	
軽度		1 (0.5)	
足骨折		2 (1.1)	
軽度		2 (1.1)	
上腕骨骨折		1 (0.5)	
高度		1 (0.5)	
裂傷		2 (1.1)	
軽度		1 (0.5)	
中等度		1 (0.5)	
靱帯捻挫		2 (1.1)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 17）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
軽度	2 (1.1)	
爪裂離	1 (0.5)	
軽度	1 (0.5)	
引っかき傷	1 (0.5)	
軽度	1 (0.5)	
シャント閉塞	3 (1.6)	
軽度	1 (0.5)	
中等度	1 (0.5)	
高度	1 (0.5)	
皮下血腫	2 (1.1)	
軽度	2 (1.1)	
外傷性血腫	1 (0.5)	
軽度	1 (0.5)	
擦過傷	12 (6.3)	
軽度	12 (6.3)	
挫傷	30 (15.8)	
軽度	30 (15.8)	
創傷	16 (8.4)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 18）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
軽度	16 (8.4)	
熱傷	7 (3.7)	
軽度	7 (3.7)	
外耳道損傷	1 (0.5)	
軽度	1 (0.5)	
シャント狭窄	7 (3.7)	
軽度	7 (3.7)	
舌損傷	1 (0.5)	
軽度	1 (0.5)	
シャント機能不全	4 (2.1)	
軽度	4 (2.1)	
処置による低血圧	14 (7.4)	
軽度	14 (7.4)	
歯牙破折	1 (0.5)	
軽度	1 (0.5)	
処置後炎症	1 (0.5)	
軽度	1 (0.5)	
シャント血流過剰	1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 19）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
軽度		1 (0.5)	
熱中症		1 (0.5)	
軽度		1 (0.5)	
爪損傷		1 (0.5)	
軽度		1 (0.5)	
血液透析合併症		1 (0.5)	
軽度		1 (0.5)	
眼挫傷		1 (0.5)	
軽度		1 (0.5)	
臨床検査		41 (21.6)	36 (18.9)
軽度		40 (21.1)	35 (18.4)
中等度		1 (0.5)	1 (0.5)
血中カルシウム減少		16 (8.4)	16 (8.4)
軽度		16 (8.4)	16 (8.4)
血中カルシウム増加		1 (0.5)	
軽度		1 (0.5)	
血中クレアチンホスホキナーゼ増加		4 (2.1)	
軽度		4 (2.1)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 20）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
血中カリウム増加		1 (0.5)	
軽度		1 (0.5)	
血圧低下		2 (1.1)	
軽度		2 (1.1)	
心電図ＳＴ部分下降		1 (0.5)	1 (0.5)
軽度		1 (0.5)	1 (0.5)
尿量減少		2 (1.1)	2 (1.1)
軽度		2 (1.1)	2 (1.1)
補正カルシウム減少		19 (10.0)	18 (9.5)
軽度		18 (9.5)	17 (8.9)
中等度		1 (0.5)	1 (0.5)
代謝および栄養障害		12 (6.3)	2 (1.1)
軽度		11 (5.8)	2 (1.1)
中等度		1 (0.5)	
脱水		1 (0.5)	
中等度		1 (0.5)	
糖尿病		1 (0.5)	
軽度		1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 21）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
高カルシウム血症		1 (0.5)	
軽度		1 (0.5)	
高リン酸塩血症		4 (2.1)	
軽度		4 (2.1)	
低カルシウム血症		2 (1.1)	2 (1.1)
軽度		2 (1.1)	2 (1.1)
低血糖症		1 (0.5)	
軽度		1 (0.5)	
栄養障害		1 (0.5)	
軽度		1 (0.5)	
食欲減退		2 (1.1)	
軽度		2 (1.1)	
筋骨格系および結合組織障害		59 (31.1)	2 (1.1)
軽度		59 (31.1)	2 (1.1)
関節痛		7 (3.7)	
軽度		7 (3.7)	
関節炎		3 (1.6)	
軽度		3 (1.6)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 22）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
背部痛		16 (8.4)	
軽度		16 (8.4)	
滑液包炎		1 (0.5)	
軽度		1 (0.5)	
肋軟骨炎		1 (0.5)	
軽度		1 (0.5)	
筋膜炎		2 (1.1)	
軽度		2 (1.1)	
側腹部痛		1 (0.5)	
軽度		1 (0.5)	
腰部脊柱管狭窄症		2 (1.1)	
軽度		2 (1.1)	
筋痙縮		4 (2.1)	1 (0.5)
軽度		4 (2.1)	1 (0.5)
筋力低下		1 (0.5)	
軽度		1 (0.5)	
筋骨格痛		6 (3.2)	
軽度		6 (3.2)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 23）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
筋肉痛		3 (1.6)	
軽度		3 (1.6)	
頚部痛		6 (3.2)	
軽度		6 (3.2)	
変形性関節症		3 (1.6)	
軽度		3 (1.6)	
四肢痛		10 (5.3)	
軽度		10 (5.3)	
関節周囲炎		3 (1.6)	
軽度		3 (1.6)	
側弯症		1 (0.5)	
軽度		1 (0.5)	
変形性脊椎症		3 (1.6)	
軽度		3 (1.6)	
腱鞘炎		2 (1.1)	
軽度		2 (1.1)	
下肢腫瘤		1 (0.5)	
軽度		1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 24）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
筋骨格硬直	1 (0.5)	
軽度	1 (0.5)	
狭窄性腱鞘炎	1 (0.5)	
軽度	1 (0.5)	
脊椎すべり症	1 (0.5)	1 (0.5)
軽度	1 (0.5)	1 (0.5)
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）	8 (4.2)	
軽度	4 (2.1)	
中等度	2 (1.1)	
高度	2 (1.1)	
カルチノイド腫瘍	1 (0.5)	
中等度	1 (0.5)	
ケラトアカントーマ	1 (0.5)	
軽度	1 (0.5)	
肺腺癌	1 (0.5)	
中等度	1 (0.5)	
脂漏性角化症	1 (0.5)	
軽度	1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 25）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
骨の良性新生物		1 (0.5)	
軽度		1 (0.5)	
胃新生物		1 (0.5)	
軽度		1 (0.5)	
肝細胞癌		2 (1.1)	
高度		2 (1.1)	
神経系障害		35 (18.4)	5 (2.6)
軽度		31 (16.3)	5 (2.6)
中等度		2 (1.1)	
高度		2 (1.1)	
脳幹出血		1 (0.5)	
高度		1 (0.5)	
手根管症候群		4 (2.1)	1 (0.5)
軽度		4 (2.1)	1 (0.5)
アルツハイマー型認知症		1 (0.5)	
中等度		1 (0.5)	
浮動性めまい		2 (1.1)	
軽度		2 (1.1)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 26）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
味覚異常	3 (1.6)	2 (1.1)
軽度	3 (1.6)	2 (1.1)
ジスキネジア	2 (1.1)	1 (0.5)
軽度	2 (1.1)	1 (0.5)
頭痛	5 (2.6)	
軽度	5 (2.6)	
感覚鈍麻	5 (2.6)	
軽度	5 (2.6)	
意識消失	3 (1.6)	
軽度	3 (1.6)	
末梢性ニューロパチー	2 (1.1)	
軽度	2 (1.1)	
視神経炎	1 (0.5)	1 (0.5)
軽度	1 (0.5)	1 (0.5)
傾眠	2 (1.1)	
軽度	2 (1.1)	
失神	1 (0.5)	
軽度	1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 27）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
緊張性頭痛	2 (1.1)	
軽度	2 (1.1)	
ラクナ梗塞	1 (0.5)	
中等度	1 (0.5)	
下肢静止不能症候群	2 (1.1)	
軽度	2 (1.1)	
橋本脳症	1 (0.5)	
高度	1 (0.5)	
精神障害	6 (3.2)	
軽度	5 (2.6)	
中等度	1 (0.5)	
うつ病	1 (0.5)	
軽度	1 (0.5)	
不眠症	4 (2.1)	
軽度	3 (1.6)	
中等度	1 (0.5)	
神経症	1 (0.5)	
軽度	1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 28）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
夢遊症		1 (0.5)	
軽度		1 (0.5)	
腎および尿路障害		2 (1.1)	
軽度		1 (0.5)	
中等度		1 (0.5)	
尿路結石		1 (0.5)	
軽度		1 (0.5)	
水腎症		1 (0.5)	
中等度		1 (0.5)	
生殖系および乳房障害		1 (0.5)	
軽度		1 (0.5)	
卵巣嚢胞		1 (0.5)	
軽度		1 (0.5)	
呼吸器、胸郭および縦隔障害		23 (12.1)	1 (0.5)
軽度		23 (12.1)	1 (0.5)
慢性気管支炎		1 (0.5)	
軽度		1 (0.5)	
咳嗽		2 (1.1)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 29）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
軽度	2 (1.1)	
呼吸困難	1 (0.5)	
軽度	1 (0.5)	
鼻出血	4 (2.1)	1 (0.5)
軽度	4 (2.1)	1 (0.5)
気胸	1 (0.5)	
軽度	1 (0.5)	
湿性咳嗽	1 (0.5)	
軽度	1 (0.5)	
肺うっ血	1 (0.5)	
軽度	1 (0.5)	
鼻漏	2 (1.1)	
軽度	2 (1.1)	
上気道の炎症	6 (3.2)	
軽度	6 (3.2)	
縦隔出血	1 (0.5)	
軽度	1 (0.5)	
口腔咽頭不快感	1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 30）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
軽度		1 (0.5)	
口腔咽頭痛		2 (1.1)	
軽度		2 (1.1)	
皮膚および皮下組織障害		52 (27.4)	1 (0.5)
軽度		52 (27.4)	1 (0.5)
水疱		1 (0.5)	
軽度		1 (0.5)	
皮膚嚢腫		1 (0.5)	
軽度		1 (0.5)	
アレルギー性皮膚炎		1 (0.5)	
軽度		1 (0.5)	
接触性皮膚炎		12 (6.3)	
軽度		12 (6.3)	
皮膚乾燥		3 (1.6)	
軽度		3 (1.6)	
湿疹		11 (5.8)	
軽度		11 (5.8)	
貨幣状湿疹		1 (0.5)	

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 31）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
軽度	1 (0.5)	
紅斑	2 (1.1)	
軽度	2 (1.1)	
皮下出血	2 (1.1)	
軽度	2 (1.1)	
嵌入爪	2 (1.1)	
軽度	2 (1.1)	
ケロイド瘢痕	1 (0.5)	
軽度	1 (0.5)	
そう痒症	8 (4.2)	
軽度	8 (4.2)	
発疹	5 (2.6)	1 (0.5)
軽度	5 (2.6)	1 (0.5)
脂漏性皮膚炎	1 (0.5)	
軽度	1 (0.5)	
皮膚剥脱	9 (4.7)	
軽度	9 (4.7)	
皮膚潰瘍	1 (0.5)	

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因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted] 試験）（続き 32）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC	有害事象	副作用
PT	ONO-5163	ONO-5163
程度	n （%）	n （%）
N	190	190
軽度	1 (0.5)	
蕁麻疹	1 (0.5)	
軽度	1 (0.5)	
乾皮症	1 (0.5)	
軽度	1 (0.5)	
皮脂欠乏症	1 (0.5)	
軽度	1 (0.5)	
血管障害	19 (10.0)	1 (0.5)
軽度	16 (8.4)	
中等度	1 (0.5)	
高度	2 (1.1)	1 (0.5)
大動脈解離	1 (0.5)	1 (0.5)
高度	1 (0.5)	1 (0.5)
血腫	1 (0.5)	
軽度	1 (0.5)	
高血圧	7 (3.7)	
軽度	6 (3.2)	
中等度	1 (0.5)	

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同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

表 2.7.4.7-12　有害事象及び副作用の程度別発現頻度（ONO-5163-[redacted]試験）（続き 33）
（治験薬投与開始 365 日目の評価時）
解析対象集団：SAF

SOC		有害事象	副作用
PT		ONO-5163	ONO-5163
程度		n （%）	n （%）
	N	190	190
起立性低血圧		2（ 1.1）	
軽度		2（ 1.1）	
末梢冷感		1（ 0.5）	
軽度		1（ 0.5）	
血管痛		2（ 1.1）	
軽度		2（ 1.1）	
動脈瘤破裂		1（ 0.5）	
高度		1（ 0.5）	
内出血		4（ 2.1）	
軽度		4（ 2.1）	

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同一被験者にて，同じ有害事象が複数回発現している場合は，最も高い程度の事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

出典［総括報告書 5.3.5.2-1（ONO-5163-[redacted]試験）表 14.3.1-11］