Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	ARGENTINA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	骨痛	20[redacted]	7	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	死亡	20[redacted]	231	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	ARGENTINA	PLACEBO		6[redacted]	F	WHITE	四肢痛	20[redacted]	53	106	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO		6[redacted]	F	WHITE	敗血症	20[redacted]	62	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ARGENTINA	PLACEBO		6[redacted]	F	WHITE	発熱	20[redacted]	99	2	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO		6[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	107	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	ARGENTINA	PLACEBO		6[redacted]	F	WHITE	肺炎	20[redacted]	107	52	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ARGENTINA	PLACEBO		6[redacted]	F	WHITE	細菌性関節炎	20[redacted]	122	37	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	ARGENTINA	PLACEBO		6[redacted]	F	WHITE	胸水	20[redacted]	143	16	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	四肢痛	20[redacted]	13	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	心停止	20[redacted]	87	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢性浮腫	20[redacted]	103	41	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢性浮腫	20[redacted]	.	201	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋拘縮	20[redacted]	263	101	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頚部痛	20[redacted]	370	187	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	皮膚病変	20[redacted]	420	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節損傷	20[redacted]	420	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格痛	20[redacted]	455	102	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	457	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	536	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	低カリウム血症	20[redacted]	546	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	556	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	臍ヘルニア	20[redacted]	.	366	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	.	135	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	卵巣癌	20[redacted]	.	45	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	上腹部痛	20[redacted]	333	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	嘔吐	20[redacted]	341	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	腹痛	20[redacted]	341	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	血性下痢	20[redacted]	341	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO		6[redacted]	F	WHITE	死亡	20[redacted]	228	1	Y	Grade 5	NOT RELATED	FATAL	DRUG WITHDRAWN	NO ACTION TAKEN	Y
[redacted]	BRAZIL	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	132	8	Y	Grade 5	NOT RELATED	FATAL	DRUG WITHDRAWN	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	頭蓋脳損傷	20[redacted]	62	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	アルツハイマー型認知症	20[redacted]	212	211	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	267	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭部損傷	20[redacted]	267	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	アルツハイマー型認知症	20[redacted]	423	9	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	嘔吐	20[redacted]	83	62	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	悪心	20[redacted]	83	62	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	疼痛	20[redacted]	221	85	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	皮膚炎	20[redacted]	231	28	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	580	192	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃腺癌	20[redacted]	675	97	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	691	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	気管支炎	20[redacted]	145	185	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	迷路炎	20[redacted]	374	325	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	僧帽弁疾患	20[redacted]	545	154	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	気管支炎	20[redacted]	545	154	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	698	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	OTHER	Y
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	変形性脊椎症	20[redacted]	139	168	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	206	482	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不安	20[redacted]	271	417	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	咽頭炎	20[redacted]	272	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	湿性咳嗽	20[redacted]	296	38	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	上腹部痛	20[redacted]	337	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	抑うつ症状	20[redacted]	436	252	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	副鼻腔炎	20[redacted]	537	151	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	急性呼吸不全	20[redacted]	679	9	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	多臓器不全	20[redacted]	687	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	失神	20[redacted]	15	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	胆石症	20[redacted]	16	45	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	尿路感染	20[redacted]	25	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	インフルエンザ	20[redacted]	113	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	筋力低下	20[redacted]	127	195	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	甲状腺機能低下症	20[redacted]	134	188	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	糖尿病	20[redacted]	134	188	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	関節損傷	20[redacted]	145	177	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	蜂巣炎	20[redacted]	176	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	尿路感染	20[redacted]	215	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	痙攣発作	20[redacted]	215	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	耳痛	20[redacted]	257	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	不整脈	20[redacted]	319	3	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	房室ブロック	20[redacted]	319	3	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	多臓器不全	20[redacted]	320	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	心原性ショック	20[redacted]	320	2	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	消化不良	20[redacted]	125	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	ウイルス性発疹	20[redacted]	216	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	咳嗽	20[redacted]	269	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	上部消化管出血	20[redacted]	307	39	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	深部静脈血栓症	20[redacted]	307	39	Y	Grade 5	RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	269	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	突然死	20[redacted]	.	.	Y	Grade 5	NOT RELATED	FATAL			Y
[redacted]	CZECH REPUBLIC	PLACEBO		8[redacted]	F	WHITE	結膜炎	20[redacted]	54	127	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		8[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	179	69	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	体内異物	20[redacted]	9	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	咳嗽	20[redacted]	179	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	537	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腰椎骨折	20[redacted]	551	122	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	睡眠障害	20[redacted]	552	121	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低クロール血症	20[redacted]	553	120	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	553	120	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	尿路感染	20[redacted]	556	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胸痛	20[redacted]	560	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	560	113	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低カリウム血症	20[redacted]	664	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	尿路感染	20[redacted]	664	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心房細動	20[redacted]	664	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	眼乾燥	20[redacted]	664	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	認知症	20[redacted]	664	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鉄欠乏性貧血	20[redacted]	664	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	扁桃炎	20[redacted]	670	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	口腔腫脹	20[redacted]	671	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	呼吸不全	20[redacted]	671	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	咽頭炎	20[redacted]	671	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	急性心不全	20[redacted]	672	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	22	801	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胆汁うっ滞性黄疸	20[redacted]	722	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	リンパ節症	20[redacted]	727	96	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	リンパ節症	20[redacted]	727	96	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺気腫	20[redacted]	727	96	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺腫瘤	20[redacted]	727	96	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎嚢胞	20[redacted]	727	96	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膵腺癌	20[redacted]	727	96	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺うっ血	20[redacted]	762	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻炎	20[redacted]	147	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	急性心不全	20[redacted]	229	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高尿酸血症	20[redacted]	229	492	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	突然死	20[redacted]	720	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	DENMARK	PLACEBO		6[redacted]	F	WHITE	過敏症	20[redacted]	8	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO		6[redacted]	F	WHITE	気管支炎	20[redacted]	16	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO		6[redacted]	F	WHITE	結腸直腸癌	20[redacted]	93	261	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y

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[redacted]	DENMARK	PLACEBO		6[redacted]	F	WHITE	腎機能障害	20[redacted]	93	261	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	33	645	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ	20[redacted]	152	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ	20[redacted]	176	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎機能障害	20[redacted]	184	494	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ	20[redacted]	203	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浮動性めまい	20[redacted]	.	395	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	283	395	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋攣縮	20[redacted]	366	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	錯感覚	20[redacted]	379	119	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	動悸	20[redacted]	497	181	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	死亡	20[redacted]	677	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	坐骨神経痛	20[redacted]	78	617	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	225	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	植物アレルギー	20[redacted]	474	221	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	死亡	20[redacted]	694	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	OTHER	Y
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	くも膜下出血	20[redacted]	489	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	アレルギー性皮膚炎	20[redacted]	55	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	306	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	点状出血	20[redacted]	373	225	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	多臓器不全	20[redacted]	590	8	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y

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[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	後腹膜血腫	20[redacted]	595	2	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO		6[redacted]	F	ASIAN	坐骨神経痛	20[redacted]	23	255	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		6[redacted]	F	ASIAN	上気道感染	20[redacted]	85	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		6[redacted]	F	ASIAN	上気道感染	20[redacted]	147	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		6[redacted]	F	ASIAN	帯状疱疹	20[redacted]	203	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		6[redacted]	F	ASIAN	ヘルペス後神経痛	20[redacted]	216	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO		6[redacted]	F	ASIAN	心筋梗塞	20[redacted]	277	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	HUNGARY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	くも膜下出血	20[redacted]	120	27	Y	Grade 1	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	くも膜下出血	20[redacted]	320	42	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	OTHER	Y
[redacted]	HUNGARY	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	47	64	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃炎	20[redacted]	92	91	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	創傷	20[redacted]	171	37	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃炎	20[redacted]	204	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	創傷	20[redacted]	235	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	灼熱感	20[redacted]	236	140	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	咳嗽	20[redacted]	301	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	発熱	20[redacted]	302	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	灼熱感	20[redacted]	442	151	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃炎	20[redacted]	442	151	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	脱水	20[redacted]	572	11	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N

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[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	死亡	20[redacted]	592	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	下痢	20[redacted]	88	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	下痢	20[redacted]	97	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	咳嗽	20[redacted]	120	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	糖尿病性ケトアシドーシス	20[redacted]	248	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	心肺停止	20[redacted]	249	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	咳嗽	20[redacted]	119	41	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	うっ血性心不全	20[redacted]	152	8	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	心停止	20[redacted]	15	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	172	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	うっ血性心筋症	20[redacted]	297	22	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	胃炎	20[redacted]	311	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	便秘	20[redacted]	223	196	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	水頭症	20[redacted]	390	29	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	脳出血	20[redacted]	390	29	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	多臓器不全	20[redacted]	396	23	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	肺炎	20[redacted]	396	23	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LATVIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	44	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LATVIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	慢性心不全	20[redacted]	44	111	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	慢性腎臓病	20[redacted]	44	111	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	慢性腎臓病	20[redacted]	90	65	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	高カリウム血症	20[redacted]	90	65	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	

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[redacted]	LATVIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	脳挫傷	20[redacted]	154	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心停止	20[redacted]	682	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心肺不全	20[redacted]	503	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	OTHER	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢循環不全	20[redacted]	.	98	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	便秘	20[redacted]	160	40	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭痛	20[redacted]	.	291	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	嵌頓腹部ヘルニア	20[redacted]	473	5	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心筋虚血	20[redacted]	473	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	473	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心肺不全	20[redacted]	477	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血小板増加症	20[redacted]	360	379	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下気道感染	20[redacted]	371	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鉄欠乏性貧血	20[redacted]	371	368	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	724	15	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	死亡	20[redacted]	605	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	141	15	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	215	506	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	251	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	429	292	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	突然死	20[redacted]	720	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED		Y
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	189	35	Y	Grade 3	RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	205	19	Y	Grade 3	RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	突然死	20[redacted]	223	1	Y	Grade 5	RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	肝不全	20[redacted]	100	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	肝不全	20[redacted]	193	62	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	齲歯	20[redacted]	.	153	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	貧血	20[redacted]	426	36	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	死亡	20[redacted]	461	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	せつ	20[redacted]	163	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	409	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	浮動性めまい	20[redacted]	154	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	乳癌	20[redacted]	169	.	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	肺炎	20[redacted]	90	18	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	91	17	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	気管支炎	20[redacted]	151	15	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	212	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	末梢動脈血栓症	20[redacted]	82	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	末梢動脈血栓症	20[redacted]	97	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	四肢痛	20[redacted]	102	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	処置後出血	20[redacted]	142	3	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	靭帯捻挫	20[redacted]	311	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	.	137	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	81	190	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	292	340	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	325	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	硝子体剥離	20[redacted]	360	272	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	436	196	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	小脳腫瘍	20[redacted]	519	113	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	体重減少	20[redacted]	1	236	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	呼吸困難	20[redacted]	.	79	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	無力症	20[redacted]	.	79	N	Grade 3	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心拍数増加	20[redacted]	184	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	死亡	20[redacted]	236	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	筋肉痛	20[redacted]	.	183	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	齲歯	20[redacted]	.	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	流涎過多	20[redacted]	43	149	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	そう痒症	20[redacted]	71	121	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	皮膚乾燥	20[redacted]	94	98	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	.	63	Y	Grade 5	NOT RELATED	FATAL	DRUG WITHDRAWN	MULTIPLE	Y

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	脳血管発作	20[redacted]	.	32	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	UNKNOWN	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	50	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	変形性関節症	20[redacted]	54	311	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	皮膚潰瘍	20[redacted]	.	81	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	皮膚乾燥	20[redacted]	152	122	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	疼痛	20[redacted]	177	188	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心不全	20[redacted]	195	170	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心房細動	20[redacted]	195	170	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	甲状腺新生物	20[redacted]	195	170	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	胸水	20[redacted]	195	170	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	胸膜線維症	20[redacted]	195	170	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	高血圧	20[redacted]	195	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	209	156	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	動脈硬化症	20[redacted]	209	156	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	右室機能不全	20[redacted]	209	156	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	大動脈弁閉鎖不全症	20[redacted]	209	156	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	左室機能不全	20[redacted]	209	156	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心室拡張	20[redacted]	209	156	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心房拡張	20[redacted]	209	156	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	駆出率減少	20[redacted]	209	156	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	266	99	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	皮膚炎	20[redacted]	315	50	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	死亡	20[redacted]	364	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y

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[redacted]	POLAND	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	心不全	20[redacted]	.	204	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	頭部損傷	20[redacted]	127	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	死亡	20[redacted]	211	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	胸痛	20[redacted]	80	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	死亡	20[redacted]	.	.	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	120	.	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	上腹部痛	20[redacted]	.	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	.	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	死亡	20[redacted]	.	.	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	359	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	労作性呼吸困難	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咳嗽	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	リンパ節症	20[redacted]	444	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管新生物	20[redacted]	444	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺新生物	20[redacted]	444	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺動脈血栓症	20[redacted]	444	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺転移	20[redacted]	444	.	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	OTHER	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	体重減少	20[redacted]	476	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	心筋梗塞	20[redacted]	320	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	高血圧	20[redacted]	71	183	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	下痢	20[redacted]	197	57	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	尿管穿孔	20[redacted]	213	41	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	腸管穿孔	20[redacted]	213	41	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	多臓器不全	20[redacted]	253	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	そう痒症	20[redacted]	1	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋骨格痛	20[redacted]	10	48	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	貧血	20[redacted]	177	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心不全	20[redacted]	676	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	肺炎	20[redacted]	.	.	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	UNITED STATES	PLACEBO		6[redacted]	F	WHITE	心筋梗塞	20[redacted]	175	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	大腸菌性敗血症	20[redacted]	30	24	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	糖尿病	20[redacted]	30	61	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	白質病変	20[redacted]	34	656	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	腱炎	20[redacted]	36	654	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	拡張機能障害	20[redacted]	37	653	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	40	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	譫妄	20[redacted]	40	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	変形性関節症	20[redacted]	119	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	関節痛	20[redacted]	178	512	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高血糖	20[redacted]	178	512	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	変形性関節症	20[redacted]	206	484	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	296	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	下痢	20[redacted]	300	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	不整脈	20[redacted]	307	383	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	気管支炎	20[redacted]	312	378	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高血圧性心拡大	20[redacted]	312	378	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	転倒	20[redacted]	425	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鎖骨骨折	20[redacted]	425	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	耳痛	20[redacted]	443	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	心肺停止	20[redacted]	689	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	薬物不耐性	20[redacted]	17	134	N	Grade 3	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	背部痛	20[redacted]	38	113	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	頚部痛	20[redacted]	38	113	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	死亡	20[redacted]	150	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	甲状腺機能低下症	20[redacted]	69	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	咳嗽	20[redacted]	104	94	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	糖尿病	20[redacted]	134	294	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	異常行動	20[redacted]	.	96	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	四肢損傷	20[redacted]	218	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	筋肉痛	20[redacted]	302	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	子宮腫瘤	20[redacted]	.	111	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	胆石症	20[redacted]	377	51	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	不整脈	20[redacted]	379	49	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	子宮癌	20[redacted]	415	13	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	膀胱瘤	20[redacted]	.	110	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	細菌性尿路感染	20[redacted]	74	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋骨格痛	20[redacted]	80	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	上腹部痛	20[redacted]	215	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	241	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	242	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	卵巣癌	20[redacted]	381	117	Y	Grade 4	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	心不全	20[redacted]	381	22	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	386	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	貧血	20[redacted]	387	111	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	帯状疱疹	20[redacted]	391	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	細菌性肺炎	20[redacted]	404	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	脳血管発作	20[redacted]	496	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	Y
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	背部痛	20[redacted]	58	144	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	73	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	下痢	20[redacted]	149	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	背部痛	20[redacted]	181	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	動悸	20[redacted]	186	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	187	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	四肢痛	20[redacted]	231	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	関節痛	20[redacted]	253	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	失神	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	失神	20[redacted]	347	27	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	左脚ブロック	20[redacted]	367	199	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	495	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	心不全	20[redacted]	540	26	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	腹痛	20[redacted]	540	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	三尖弁閉鎖不全症	20[redacted]	546	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	低カリウム血症	20[redacted]	546	20	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	僧帽弁閉鎖不全症	20[redacted]	546	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	大動脈弁閉鎖不全症	20[redacted]	546	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	脂肪腫	20[redacted]	546	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	腎不全	20[redacted]	546	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	凝固時間延長	20[redacted]	550	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	虚血性肝炎	20[redacted]	550	16	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肺腫瘤	20[redacted]	558	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	譫妄	20[redacted]	560	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	憩室	20[redacted]	21	227	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	肺腫瘤	20[redacted]	.	77	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	84	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	リンパ節症	20[redacted]	99	149	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	肺の悪性新生物	20[redacted]	99	149	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	OTHER	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	腎嚢胞	20[redacted]	99	149	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	腎嚢胞	20[redacted]	99	149	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	胸痛	20[redacted]	137	111	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	MEDICATION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	気管支炎	20[redacted]	165	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	僧帽弁逸脱	20[redacted]	188	60	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	脳微小血管症	20[redacted]	198	50	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	昏迷	20[redacted]	.	45	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	REMOVED FROM STUDY	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	四肢痛	20[redacted]	.	81	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	筋痙縮	20[redacted]	69	47	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	80	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	末梢性浮腫	20[redacted]	109	153	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	末梢動脈閉塞性疾患	20[redacted]	117	641	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	筋骨格痛	20[redacted]	.	88	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	好酸球増加症	20[redacted]	177	91	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高血圧	20[redacted]	243	515	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	大動脈雑音	20[redacted]	298	460	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	筋痙縮	20[redacted]	433	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	白血球増加症	20[redacted]	535	223	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高カルシウム血症	20[redacted]	537	221	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尿路感染	20[redacted]	543	16	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	下痢	20[redacted]	547	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	冠動脈疾患	20[redacted]	.	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	心拡大	20[redacted]	672	86	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胸水	20[redacted]	672	9	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	DEVICE EXPLANTATION	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	無気肺	20[redacted]	673	85	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肺扁平上皮癌	20[redacted]	673	85	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	転倒	20[redacted]	712	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	転倒	20[redacted]	717	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	下痢	20[redacted]	718	40	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO		5[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	80	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		5[redacted]	F	OTHER	四肢痛	20[redacted]	143	87	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		5[redacted]	F	OTHER	関節痛	20[redacted]	143	87	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		5[redacted]	F	OTHER	筋痙縮	20[redacted]	258	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		5[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	269	6	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		5[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	295	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		5[redacted]	F	OTHER	浮動性めまい	20[redacted]	300	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		5[redacted]	F	OTHER	細菌性気管支炎	20[redacted]	307	55	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		5[redacted]	F	OTHER	胸水	20[redacted]	313	156	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO		5[redacted]	F	OTHER	気管支癌	20[redacted]	.	118	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	PLACEBO		5[redacted]	F	OTHER	腸憩室	20[redacted]	433	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	無力症	20[redacted]	17	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	脂質異常症	20[redacted]	62	613	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋骨格痛	20[redacted]	81	47	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	113	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	外傷後疼痛	20[redacted]	187	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	転倒	20[redacted]	187	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	ウイルス性胃腸炎	20[redacted]	239	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋痙縮	20[redacted]	.	173	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	285	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	慢性胃炎	20[redacted]	342	333	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	腸憩室	20[redacted]	342	333	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	間擦疹	20[redacted]	361	314	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	転倒	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節損傷	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋骨格系損傷	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	転倒	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	不安障害	20[redacted]	523	152	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	破裂性脳動脈瘤	20[redacted]	674	10	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	関節痛	20[redacted]	19	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	アレルギー性皮膚炎	20[redacted]	21	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	84	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	損傷	20[redacted]	163	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	斑状出血	20[redacted]	163	236	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	脂質異常症	20[redacted]	218	181	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	脳血管発作	20[redacted]	218	181	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	四肢痛	20[redacted]	294	105	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	浮腫	20[redacted]	294	105	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	嘔吐	20[redacted]	302	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	嚥下障害	20[redacted]	3	460	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	全身性皮疹	20[redacted]	83	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	丘疹	20[redacted]	340	123	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	皮膚病変	20[redacted]	340	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	皮膚病変	20[redacted]	340	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	死亡	20[redacted]	462	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	そう痒症	20[redacted]	2	139	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	13	128	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	破裂性脳動脈瘤	20[redacted]	133	8	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	四肢痛	20[redacted]	2	63	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	糖尿病	20[redacted]	3	84	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	大腸菌性尿路感染	20[redacted]	114	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	高血圧	20[redacted]	116	106	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	低血糖	20[redacted]	136	2	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	筋痙縮	20[redacted]	195	27	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	脳血管発作	20[redacted]	217	5	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	23	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	四肢痛	20[redacted]	26	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	浮動性めまい	20[redacted]	26	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	創傷	20[redacted]	34	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	疲労	20[redacted]	.	107	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	.	61	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭痛	20[redacted]	.	76	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭蓋脳損傷	20[redacted]	40	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胸骨損傷	20[redacted]	86	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	錯感覚	20[redacted]	88	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	うつ病	20[redacted]	132	614	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋拘縮	20[redacted]	138	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	138	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	四肢痛	20[redacted]	177	569	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頚部痛	20[redacted]	177	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	錯感覚	20[redacted]	178	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	紅斑	20[redacted]	183	563	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	20[redacted]	189	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋痙縮	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	乾皮症	20[redacted]	309	437	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	過敏性腸症候群	20[redacted]	.	341	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	遠隔転移を伴う結腸癌	20[redacted]	511	235	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	深部静脈血栓症	20[redacted]	561	29	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肺気腫	20[redacted]	581	165	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胃腸出血	20[redacted]	706	34	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	四肢痛	20[redacted]	3	40	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	咳嗽	20[redacted]	72	342	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尿臭異常	20[redacted]	75	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	貧血	20[redacted]	89	633	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	無力症	20[redacted]	105	617	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	歯肉痛	20[redacted]	121	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	161	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性胃腸炎	20[redacted]	208	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	208	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	食欲減退	20[redacted]	256	466	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	出血性膀胱炎	20[redacted]	296	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	悪心	20[redacted]	303	151	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	口腔カンジダ症	20[redacted]	339	92	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尿路感染	20[redacted]	344	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	変形性関節症	20[redacted]	360	362	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肺腫瘤	20[redacted]	.	327	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	413	13	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	625	97	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	心筋梗塞	20[redacted]	61	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	嚢胞	20[redacted]	175	249	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	平滑筋腫	20[redacted]	175	249	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胆石症	20[redacted]	175	249	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腎症	20[redacted]	175	249	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	眼挫傷	20[redacted]	205	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	斑状出血	20[redacted]	247	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	247	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腟出血	20[redacted]	296	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹痛	20[redacted]	296	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	細菌尿	20[redacted]	364	60	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	交通事故	20[redacted]	423	1	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心肺停止	20[redacted]	423	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	Y
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	高血圧	20[redacted]	159	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	腸管虚血	20[redacted]	200	5	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性胃炎	20[redacted]	191	446	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	裂孔ヘルニア	20[redacted]	191	446	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肺炎	20[redacted]	242	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	出血性膀胱炎	20[redacted]	354	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	死亡	20[redacted]	636	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性胃炎	20[redacted]	22	9	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	緊張性膀胱	20[redacted]	.	689	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	三尖弁閉鎖不全症	20[redacted]	104	608	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	僧帽弁閉鎖不全症	20[redacted]	104	608	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肺高血圧症	20[redacted]	104	608	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧性心疾患	20[redacted]	104	608	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	潰瘍性出血	20[redacted]	418	41	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃炎	20[redacted]	418	41	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	裂孔ヘルニア	20[redacted]	418	41	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	結腸腺癌	20[redacted]	607	105	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MEDICATION TAKEN	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹膜転移	20[redacted]	607	105	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	静脈瘤性潰瘍	20[redacted]	5	101	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	血液量減少性ショック	20[redacted]	101	5	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	脂肪肝	20[redacted]	36	.	Y	Grade 1	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	胆石症	20[redacted]	44	502	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	糖尿病	20[redacted]	49	497	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	胃腺癌	20[redacted]	127	419	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	胃腸炎	20[redacted]	278	36	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	慢性胃炎	20[redacted]	345	201	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	食道静脈瘤	20[redacted]	345	201	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	胆管結石	20[redacted]	358	188	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	腸閉塞	20[redacted]	422	8	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	大腿ヘルニア	20[redacted]	423	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	消化管壊死	20[redacted]	423	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	変形性関節症	20[redacted]	63	84	N	Grade 1	RELATED		DOSE ALTERED OR WITHHELD	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋骨格痛	20[redacted]	247	342	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	気管支炎	20[redacted]	389	24	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	遠隔転移を伴う肺腺癌	20[redacted]	586	3	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	副鼻腔新生物	20[redacted]	118	36	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	腸閉塞	20[redacted]	486	18	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	呼吸窮迫	20[redacted]	502	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	腹部腫瘤	20[redacted]	502	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	消化不良	20[redacted]	358	404	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	貧血	20[redacted]	419	343	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	消化不良	20[redacted]	504	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胃腺癌	20[redacted]	652	110	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	死亡	20[redacted]	119	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	不随意性筋収縮	20[redacted]	35	120	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	錯感覚	20[redacted]	42	264	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	149	18	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	254	23	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	271	251	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	インフルエンザ	20[redacted]	411	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胃食道逆流性疾患	20[redacted]	519	210	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	回転性めまい	20[redacted]	534	195	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肺の悪性新生物	20[redacted]	697	32	Y	Grade 5	RELATED	FATAL	DOSE NOT CHANGED	OTHER	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	無力症	20[redacted]	138	84	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	無力症	20[redacted]	138	84	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	肝細胞癌	20[redacted]	197	25	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	循環虚脱	20[redacted]	345	21	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	両耳難聴	20[redacted]	14	260	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	死亡	20[redacted]	273	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	不眠症	20[redacted]	59	91	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	背部痛	20[redacted]	75	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	失禁	20[redacted]	157	75	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	失禁	20[redacted]	241	128	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	卵巣嚢胞	20[redacted]	339	30	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋痙縮	20[redacted]	72	522	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	嘔吐	20[redacted]	95	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹痛	20[redacted]	95	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	下痢	20[redacted]	153	51	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	糖尿病性ニューロパチー	20[redacted]	176	418	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	挫傷	20[redacted]	283	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	インフルエンザ	20[redacted]	343	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	便秘	20[redacted]	.	133	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	血小板減少症	20[redacted]	547	47	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高カルシウム血症	20[redacted]	547	47	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	敗血症性ショック	20[redacted]	592	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	糖尿病性ケトアシドーシス	20[redacted]	592	2	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	AMERICAN INDIAN OR ALASKA NATIVE	インフルエンザ	20[redacted]	44	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	AMERICAN INDIAN OR ALASKA NATIVE	変形性関節症	20[redacted]	282	121	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	AMERICAN INDIAN OR ALASKA NATIVE	心筋梗塞	20[redacted]	402	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	DOMINICAN REPUBLIC	PLACEBO		8[redacted]	F	BLACK OR AFRICAN AMERICAN	狭心症	20[redacted]	191	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	Y
[redacted]	DOMINICAN REPUBLIC	PLACEBO		7[redacted]	F	BLACK OR AFRICAN AMERICAN	狭心症	20[redacted]	73	6	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DOMINICAN REPUBLIC	PLACEBO		7[redacted]	F	BLACK OR AFRICAN AMERICAN	不眠症	20[redacted]	78	23	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	DOMINICAN REPUBLIC	PLACEBO		7[redacted]	F	BLACK OR AFRICAN AMERICAN	狭心症	20[redacted]	100	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO		7[redacted]	F	BLACK OR AFRICAN AMERICAN	狭心症	20[redacted]	129	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	四肢痛	20[redacted]	146	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	坐骨神経痛	20[redacted]	235	71	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	四肢痛	20[redacted]	278	248	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	ウイルス感染	20[redacted]	312	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	血圧上昇	20[redacted]	335	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	出血性卒中	20[redacted]	500	26	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	皮下組織膿瘍	20[redacted]	87	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	上腹部痛	20[redacted]	104	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	白内障	20[redacted]	148	583	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	食欲減退	20[redacted]	.	62	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	回虫症	20[redacted]	261	82	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	浮動性めまい	20[redacted]	327	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	ジアルジア症	20[redacted]	342	389	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	発熱	20[redacted]	348	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	呼吸不全	20[redacted]	729	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		8[redacted]	F	MULTIPLE	頭痛	20[redacted]	62	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		8[redacted]	F	MULTIPLE	アメーバ赤痢	20[redacted]	166	124	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		8[redacted]	F	MULTIPLE	高血圧	20[redacted]	187	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		8[redacted]	F	MULTIPLE	鼻咽頭炎	20[redacted]	230	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		8[redacted]	F	MULTIPLE	発熱	20[redacted]	264	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		8[redacted]	F	MULTIPLE	四肢痛	20[redacted]	272	18	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		8[redacted]	F	MULTIPLE	下部消化管出血	20[redacted]	288	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	関節痛	20[redacted]	53	90	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	関節痛	20[redacted]	115	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	発熱	20[redacted]	215	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	紅斑	20[redacted]	215	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	腎クレアチニン・クリアランス減少	20[redacted]	272	235	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	貧血	20[redacted]	272	235	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	裂傷	20[redacted]	290	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	皮膚感染	20[redacted]	431	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	糖尿病性ニューロパチー	20[redacted]	431	76	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	心肺停止	20[redacted]	506	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	Y
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	高血圧	20[redacted]	29	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	大動脈瘤	20[redacted]	51	562	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	頭痛	20[redacted]	53	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	インフルエンザ	20[redacted]	147	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	高血圧	20[redacted]	185	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	高血圧	20[redacted]	219	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	発熱	20[redacted]	239	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	高血圧	20[redacted]	276	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	発熱	20[redacted]	331	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	高血圧	20[redacted]	337	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	排尿困難	20[redacted]	449	66	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	呼吸困難	20[redacted]	493	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	高血圧	20[redacted]	562	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	急性心不全	20[redacted]	612	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Actual Treatment for Period 03	Actual Treatment for Period 04	Actual Treatment for Period 05	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Severity/Intensity	Causality	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	疲労	20[redacted]	3	1589	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	嚢胞	20[redacted]	172	1420	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	歯牙破折	20[redacted]	413	63	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	挫傷	20[redacted]	517	46	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	517	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	腹部不快感	20[redacted]	638	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	裂傷	20[redacted]	649	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	649	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	高血圧	20[redacted]	692	900	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	1237	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	椎間板変性症	20[redacted]	.	289	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	1343	17	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	視力低下	20[redacted]	1465	127	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	1588	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	8[redacted]	F	WHITE OR CAUCASIAN	心肺停止	20[redacted]	1588	4	Y	FATAL	NOT RELATED	DOSE NOT CHANGED	OTHER	Y
[redacted]	DENMARK	AMG 785 70 MG SC QM					7[redacted]	F	WHITE OR CAUCASIAN	そう痒症	20[redacted]	53	91	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM					7[redacted]	F	WHITE OR CAUCASIAN	上腹部痛	20[redacted]	91	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM					7[redacted]	F	WHITE OR CAUCASIAN	動脈硬化症	20[redacted]	133	2	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	DENMARK	AMG 785 70 MG SC QM					7[redacted]	F	WHITE OR CAUCASIAN	大動脈バイパス	20[redacted]-[redacted]-[redacted]	134	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	DENMARK	AMG 785 70 MG SC QM					7[redacted]	F	WHITE OR CAUCASIAN	術後イレウス	20[redacted]-[redacted]-[redacted]	136	8	Y	FATAL	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	Y
[redacted]	ARGENTINA	PLACEBO Q3M					5[redacted]	F	WHITE OR CAUCASIAN	胃炎	20[redacted]-[redacted]-[redacted]	124	236	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	ARGENTINA	PLACEBO Q3M					5[redacted]	F	WHITE OR CAUCASIAN	結腸癌	20[redacted]-[redacted]-[redacted]	329	31	Y	FATAL	NOT RELATED	DRUG WITHDRAWN	MULTIPLE	Y

Subject Identifier for the Study	Country	Actual Treatment	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	JAPAN	AMG 785 140 MG SC QM	7[redacted]	F	ASIAN	四肢痛	20[redacted]-[redacted]-[redacted]	123	310	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 140 MG SC QM	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]-[redacted]-[redacted]	270	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 140 MG SC QM	7[redacted]	F	ASIAN	急性心筋梗塞	20[redacted]-[redacted]-[redacted]	432	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	Y

Subject Identifier for the Study	Country	Actual Treatment	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	POLAND	PLACEBO 70 MG SC QM	8[redacted]	F	WHITE	四肢痛	20[redacted]-[redacted]-[redacted]	19	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO 70 MG SC QM	8[redacted]	F	WHITE	腸間膜動脈塞栓	20[redacted]-[redacted]-[redacted]	88	.	Y	Grade 3	NOT RELATED	RECOVERED/RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO 70 MG SC QM	8[redacted]	F	WHITE	死亡	20[redacted]-[redacted]-[redacted]	154	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y

Subject Identifier for the Study	Country	Actual Treatment	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	急性腎不全	20[redacted]	191	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	脱水	20[redacted]	191	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	脱水	20[redacted]	199	48	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	関節痛	20[redacted]	302	92	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	三尖弁閉鎖不全症	20[redacted]	352	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	僧帽弁石灰化	20[redacted]	352	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	352	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	大動脈弁石灰化	20[redacted]	352	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	大動脈弁閉鎖不全症	20[redacted]	352	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	左室肥大	20[redacted]	352	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	左房拡張	20[redacted]	352	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	拡張機能障害	20[redacted]	352	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	肺高血圧症	20[redacted]	352	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	尿路感染	20[redacted]	357	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	慢性心不全	20[redacted]	357	29	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	甲状腺機能低下症	20[redacted]	357	37	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	肺炎	20[redacted]	357	15	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	胸水	20[redacted]	358	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	骨髄機能不全	20[redacted]	367	27	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	肺炎	20[redacted]	372	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	胸水	20[redacted]	372	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	肺炎	20[redacted]	381	13	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	低アルブミン血症	20[redacted]	382	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	低カリウム血症	20[redacted]	383	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	骨髄性白血病	20[redacted]	385	9	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	真菌性尿路感染	20[redacted]	388	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	高ナトリウム血症	20[redacted]	389	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	出血	20[redacted]	393	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	徐脈	20[redacted]	393	1	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	7[redacted]	F	WHITE	心停止	20[redacted]	393	1	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	TPTD 20 UG SC QD	7[redacted]	F	WHITE	全身性そう痒症	20[redacted]	1	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	DENMARK	TPTD 20 UG SC QD	7[redacted]	F	WHITE	頭痛	20[redacted]	106	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	TPTD 20 UG SC QD	7[redacted]	F	WHITE	ウイルス感染	20[redacted]	120	23	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	TPTD 20 UG SC QD	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	232	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	TPTD 20 UG SC QD	7[redacted]	F	WHITE	うつ病	20[redacted]	361	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	TPTD 20 UG SC QD	7[redacted]	F	WHITE	胃腸出血	20[redacted]	369	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y

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[redacted]	RUSSIAN FEDERATION	PLACEBO	8[redacted]	M	WHITE	鼻咽頭炎	20[redacted]	274	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	RUSSIAN FEDERATION	PLACEBO	8[redacted]	M	WHITE	死亡	20[redacted]	287	1	Y	Grade 5	NOT RELATED	FATAL	DRUG WITHDRAWN	NO ACTION TAKEN	Y
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	心房粗動	20[redacted]	196	4	Y	Grade 4	NOT RELATED	RECOVERED/RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	心筋虚血	20[redacted]	196	.	N	Grade 2	NOT RELATED	NOT RECOVERED/NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	慢性心不全	20[redacted]	196	.	N	Grade 2	NOT RELATED	NOT RECOVERED/NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	上室性頻脈	20[redacted]	230	.	N	Grade 3	NOT RELATED	NOT RECOVERED/NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	心筋虚血	20[redacted]	230	12	Y	Grade 4	NOT RELATED	RECOVERED/RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	肺気腫	20[redacted]	230	.	N	Grade 1	NOT RELATED	NOT RECOVERED/NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	肺線維症	20[redacted]	230	.	N	Grade 1	NOT RELATED	NOT RECOVERED/NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	良性前立腺肥大症	20[redacted]	230	.	N	Grade 1	NOT RELATED	NOT RECOVERED/NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	僧帽弁閉鎖不全症	20[redacted]	235	.	N	Grade 1	NOT RELATED	NOT RECOVERED/NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	左房拡張	20[redacted]	235	.	N	Grade 1	NOT RELATED	NOT RECOVERED/NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	高血糖	20[redacted]	251	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	冠動脈狭窄	20[redacted]	256	2	Y	Grade 3	NOT RELATED	RECOVERED/RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	椎間板変性症	20[redacted]	256	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	狭心症	20[redacted]	256	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	脂質異常症	20[redacted]	256	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	8[redacted]	M	WHITE	死亡	20[redacted]	.	.	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	8[redacted]	M	OTHER	便秘	20[redacted]	53	75	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	8[redacted]	M	OTHER	心肺停止	20[redacted]	317	1	Y	Grade 5	NOT RELATED	FATAL	DRUG WITHDRAWN	NO ACTION TAKEN	Y

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	関節痛	20[redacted]	56	1020	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	腎不全	20[redacted]	185	906	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	関節痛	20[redacted]	1076	110	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	転倒	20[redacted]	1076	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	腎不全	20[redacted]	1091	95	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	急性肺水腫	20[redacted]	1156	30	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	高血圧	20[redacted]	1156	30	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	四肢痛	20[redacted]	47	60	N	Grade 1			DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	心筋虚血	20[redacted]	106	1	Y	Grade 5		FATAL	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	Y
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	心不全	20[redacted]	89	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	各種物質毒性	20[redacted]	92	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	腹痛	20[redacted]	152	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	高血糖	20[redacted]	372	547	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	消化不良	20[redacted]	626	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	丹毒	20[redacted]	719	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	背部痛	20[redacted]	835	84	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	嘔吐	20[redacted]	866	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	転倒	20[redacted]	915	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	橈骨骨折	20[redacted]	915	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ARGENTINA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	徐脈性不整脈	20[redacted]	917	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	筋骨格系胸痛	20[redacted]	30	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	ARGENTINA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	下痢	20[redacted]	63	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	血腫	20[redacted]	567	80	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	脳血管発作	20[redacted]	1241	11	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	ARGENTINA	ALN 70 MG PO QW		8[redacted]	F	WHITE	気管支炎	20[redacted]	351	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	ALN 70 MG PO QW		8[redacted]	F	WHITE	インフルエンザ	20[redacted]	369	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	ALN 70 MG PO QW		8[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	395	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	ALN 70 MG PO QW		8[redacted]	F	WHITE	錯乱状態	20[redacted]	447	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	BELGIUM	ALN 70 MG PO QW		8[redacted]	F	WHITE	労作性呼吸困難	20[redacted]	17	69	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	ALN 70 MG PO QW		8[redacted]	F	WHITE	浮腫	20[redacted]	23	103	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	ALN 70 MG PO QW		8[redacted]	F	WHITE	気管支炎	20[redacted]	86	40	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	ALN 70 MG PO QW		8[redacted]	F	WHITE	肺うっ血	20[redacted]	86	40	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	ALN 70 MG PO QW		8[redacted]	F	WHITE	肺水腫	20[redacted]	174	39	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	ALN 70 MG PO QW		8[redacted]	F	WHITE	気管支炎	20[redacted]	272	87	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	ALN 70 MG PO QW		8[redacted]	F	WHITE	胃腸炎	20[redacted]	276	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	ALN 70 MG PO QW		8[redacted]	F	WHITE	痛風性関節炎	20[redacted]	279	80	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	ALN 70 MG PO QW		8[redacted]	F	WHITE	腎不全	20[redacted]	283	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BELGIUM	ALN 70 MG PO QW		8[redacted]	F	WHITE	関節痛	20[redacted]	306	53	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	ALN 70 MG PO QW		8[redacted]	F	WHITE	背部痛	20[redacted]	306	53	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BELGIUM	ALN 70 MG PO QW		8[redacted]	F	WHITE	大腸菌性敗血症	20[redacted]	336	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	ALN 70 MG PO QW		8[redacted]	F	WHITE	異常感	20[redacted]	355	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y

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[redacted]	BELGIUM	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	肺炎	20[redacted]	130	23	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	脳血管発作	20[redacted]	138	15	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	BELGIUM	ALN 70 MG PO QW		7[redacted]	F	WHITE	貧血	20[redacted]	16	56	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	ALN 70 MG PO QW		7[redacted]	F	WHITE	肺炎	20[redacted]	126	8	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	肺炎	20[redacted]	14	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	関節痛	20[redacted]	139	1008	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	肺炎	20[redacted]	176	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	細菌性副鼻腔炎	20[redacted]	433	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	肺炎	20[redacted]	999	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	肺炎	20[redacted]	1143	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	細菌性肺炎	20[redacted]	111	32	Y	Grade 4	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	肺敗血症	20[redacted]	142	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	迷路炎	20[redacted]	146	671	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	筋骨格系胸痛	20[redacted]	274	595	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	急性腎障害	20[redacted]	277	89	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	低カリウム血症	20[redacted]	277	592	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	慢性腎臓病	20[redacted]	365	504	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	変形性関節症	20[redacted]	419	450	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	変形性関節症	20[redacted]	419	450	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	咳嗽	20[redacted]	433	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	うつ病	20[redacted]	724	145	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	868	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	関節痛	20[redacted]	490	144	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	変形性関節症	20[redacted]	490	144	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	虚血性脳卒中	20[redacted]	572	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	虚血性脳卒中	20[redacted]	582	52	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	高血圧	20[redacted]	178	282	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	インフルエンザ	20[redacted]	331	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	肺炎	20[redacted]	435	25	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	背部痛	20[redacted]	115	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	転倒	20[redacted]	115	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	130	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	135	7	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	肺炎	20[redacted]	135	7	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	糖尿病	20[redacted]	184	237	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	インフルエンザ	20[redacted]	212	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	四肢痛	20[redacted]	361	23	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	395	26	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	心原性ショック	20[redacted]	395	26	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	肺炎	20[redacted]	405	16	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	IV ANTIMICROBIAL TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	急性腎障害	20[redacted]	409	12	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	副鼻腔炎	20[redacted]	375	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	副鼻腔炎	20[redacted]	543	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	体位性めまい	20[redacted]	569	237	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	インフルエンザ	20[redacted]	778	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	805	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	Y
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	胸痛	20[redacted]	1	315	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	爪真菌症	20[redacted]	24	306	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	浮動性めまい	20[redacted]	25	34	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	浮動性めまい	20[redacted]	59	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	尿路感染	20[redacted]	67	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	鼓腸	20[redacted]	112	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	記憶障害	20[redacted]	192	234	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	不全単麻痺	20[redacted]	218	393	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	幻覚	20[redacted]	262	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	筋骨格痛	20[redacted]	359	48	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	無力症	20[redacted]	383	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	構語障害	20[redacted]	383	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	幻覚	20[redacted]	410	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	鼻咽頭炎	20[redacted]	479	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	無力症	20[redacted]	542	69	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	尿路感染	20[redacted]	605	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	BLACK OR AFRICAN AMERICAN	敗血症	20[redacted]	607	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	腎不全	20[redacted]	495	68	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	肺炎	20[redacted]	523	40	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	敗血症性ショック	20[redacted]	562	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	上腹部痛	20[redacted]	5	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	頻脈	20[redacted]	34	151	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	迷路炎	20[redacted]	61	110	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	血中コレステロール異常	20[redacted]	95	555	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	無力症	20[redacted]	109	166	N	Grade 2	RELATED		DRUG WITHDRAWN	OTHER	
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	疲労	20[redacted]	135	36	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	貧血	20[redacted]	158	492	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	脳血管発作	20[redacted]	646	4	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	ALN 70 MG PO QW		8[redacted]	F	WHITE	肺炎	20[redacted]	646	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	不眠症	20[redacted]	18	458	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	無感情	20[redacted]	140	336	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	嘔吐	20[redacted]	151	1	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	嘔吐	20[redacted]	185	1	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	認知症	20[redacted]	.	124	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	口腔カンジダ症	20[redacted]	441	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	急性腎障害	20[redacted]	445	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	尿路感染	20[redacted]	445	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	急性腎障害	20[redacted]	474	2	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	尿路性敗血症	20[redacted]	474	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	アルツハイマー型認知症	20[redacted]	475	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	靭帯捻挫	20[redacted]	168	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	四肢痛	20[redacted]	168	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	糖尿病	20[redacted]	180	30	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	狭心症	20[redacted]	203	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	狭心症	20[redacted]	213	7	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	BULGARIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	結腸癌	20[redacted]	154	45	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	BULGARIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	結腸癌	20[redacted]	199	5	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	リウマチ性多発筋痛	20[redacted]	67	37	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	慢性胃炎	20[redacted]	169	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	大腸ポリープ	20[redacted]	169	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	465	24	Y	Grade 4	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	BULGARIA	ALN 70 MG PO QW		6[redacted]	F	WHITE	心不全	20[redacted]	87	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BULGARIA	ALN 70 MG PO QW		6[redacted]	F	WHITE	嘔吐	20[redacted]	141	15	N	Grade 3	NOT RELATED		DOSE ALTERED OR WITHHELD	DEVICE/PROCEDURE INTERVENTION	
[redacted]	BULGARIA	ALN 70 MG PO QW		6[redacted]	F	WHITE	死亡	20[redacted]	176	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	BULGARIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	変形性関節症	20[redacted]	229	333	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BULGARIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	皮膚化学熱傷	20[redacted]	451	108	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BULGARIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	558	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	感染性皮膚炎	20[redacted]	78	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	膿皮症	20[redacted]	89	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	下腹部痛	20[redacted]	272	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	貧血	20[redacted]	355	285	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	筋痙縮	20[redacted]	414	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	下腹部痛	20[redacted]	460	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	筋痙縮	20[redacted]	547	93	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	高ビリルビン血症	20[redacted]	550	19	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	598	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	胆汁性肝硬変	20[redacted]	601	33	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	BULGARIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	胆汁性肝硬変	20[redacted]	633	7	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	CANADA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	ほてり	20[redacted]	1	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	注射部位疼痛	20[redacted]	1	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	筋痙縮	20[redacted]	68	60	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CANADA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	湿性咳嗽	20[redacted]	68	60	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	注射部位疼痛	20[redacted]	99	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	注射部位疼痛	20[redacted]	127	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	腸閉塞	20[redacted]	453	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	CANADA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	頭蓋内動脈瘤	20[redacted]	559	9	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	CANADA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	呼吸困難	20[redacted]	860	102	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CANADA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	敗血症	20[redacted]	953	9	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	CHILE	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	背部痛	20[redacted]	114	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CHILE	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	高血圧	20[redacted]	123	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CHILE	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	肝酵素上昇	20[redacted]	128	8	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	CHILE	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心筋梗塞	20[redacted]	128	8	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CHILE	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	呼吸窮迫	20[redacted]	134	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	CHILE	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	上室性期外収縮	20[redacted]	123	454	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CHILE	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	変形性関節症	20[redacted]	141	436	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CHILE	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	高血圧	20[redacted]	142	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	CHILE	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	四肢痛	20[redacted]	393	68	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CHILE	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	蜂巣炎	20[redacted]	562	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CHILE	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	死亡	20[redacted]	576	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	CHILE	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	挫傷	20[redacted]	97	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CHILE	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	膵管内乳頭粘液性腫瘍	20[redacted]	272	498	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	CHILE	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	肝損傷	20[redacted]	272	498	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	CHILE	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	骨髄増殖性新生物	20[redacted]	272	498	Y	Grade 4	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	CHILE	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	肺炎	20[redacted]	272	34	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CHILE	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	気管支炎	20[redacted]	327	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CHILE	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	変形性関節症	20[redacted]	651	44	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CHILE	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	尿路感染	20[redacted]	762	8	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CHILE	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	心停止	20[redacted]	769	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	CHILE	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	心不全	20[redacted]	769	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	無力症	20[redacted]	32	27	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	背部痛	20[redacted]	63	4	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	咳嗽	20[redacted]	91	347	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	関節痛	20[redacted]	258	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	気管支炎	20[redacted]	395	20	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	うっ血性心不全	20[redacted]	395	20	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	肺気腫	20[redacted]	395	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	心筋虚血	20[redacted]	395	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	２型糖尿病	20[redacted]	395	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	大動脈狭窄	20[redacted]	396	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	脂質異常症	20[redacted]	396	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	左室機能不全	20[redacted]	396	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	396	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	貧血	20[redacted]	397	41	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	肺炎	20[redacted]	436	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	肺炎	20[redacted]	437	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	甲状腺機能亢進症	20[redacted]	221	817	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	高血圧	20[redacted]	384	654	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	挫傷	20[redacted]	684	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	転倒	20[redacted]	684	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	四肢痛	20[redacted]	688	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	運動性低下	20[redacted]	800	238	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	認知症	20[redacted]	873	165	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	下痢	20[redacted]	998	40	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	イレウス	20[redacted]	998	18	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	腸重積症	20[redacted]	998	18	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	肺炎	20[redacted]	1025	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	肺炎	20[redacted]	1037	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	アルツハイマー型認知症	20[redacted]	.	1335	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	上気道感染	20[redacted]	138	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	回転性めまい	20[redacted]	341	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	消化不良	20[redacted]	371	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	537	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	822	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	823	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	気道感染	20[redacted]	823	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	２型糖尿病	20[redacted]	823	650	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	血腫	20[redacted]	826	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	腎症	20[redacted]	826	647	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	全身性そう痒症	20[redacted]	908	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	上気道感染	20[redacted]	931	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	尿路感染	20[redacted]	1026	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	脳血管発作	20[redacted]	1355	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	脱水	20[redacted]	1355	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	低カリウム血症	20[redacted]	1355	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	気管支炎	20[redacted]	1460	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	低血糖	20[redacted]	1462	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	頻脈	20[redacted]	1463	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	転倒	20[redacted]	1471	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	血腫	20[redacted]	1471	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	急性呼吸不全	20[redacted]	1472	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y

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[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	左室不全	20[redacted]	1472	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	便秘	20[redacted]	8	1046	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	23	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	転倒	20[redacted]	180	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	血腫	20[redacted]	180	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	転倒	20[redacted]	252	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	血腫	20[redacted]	252	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	裂傷	20[redacted]	252	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	関節痛	20[redacted]	.	354	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	下痢	20[redacted]	548	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	669	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	回転性めまい	20[redacted]	.	332	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	急性腎障害	20[redacted]	726	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	慢性呼吸不全	20[redacted]	726	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	脱水	20[redacted]	726	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	フィブリンDダイマー増加	20[redacted]	726	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	高尿酸血症	20[redacted]	726	328	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	腹圧性尿失禁	20[redacted]	726	328	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	高血圧	20[redacted]	789	265	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	尿路感染	20[redacted]	970	84	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	上室性不整脈	20[redacted]	997	57	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	胸痛	20[redacted]	997	57	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	肺高血圧症	20[redacted]	997	57	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	脂質異常症	20[redacted]	998	56	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	認知障害	20[redacted]	1008	46	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	全身健康状態低下	20[redacted]	1008	46	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	運動性低下	20[redacted]	1008	46	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	うつ病	20[redacted]	1026	28	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	うっ血性心不全	20[redacted]	1051	3	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	肺炎	20[redacted]	1051	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	振戦	20[redacted]	.	997	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	大脳動脈塞栓症	20[redacted]	433	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	歯肉出血	20[redacted]	433	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	433	618	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	処置後出血	20[redacted]	433	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	潰瘍性出血	20[redacted]	433	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	胆石症	20[redacted]	434	617	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	腟裂傷	20[redacted]	437	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	気管支炎	20[redacted]	641	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	消化不良	20[redacted]	877	174	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	多臓器機能不全症候群	20[redacted]	1050	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	異型肺炎	20[redacted]	1003	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	急性心不全	20[redacted]	1008	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	低カリウム血症	20[redacted]	1008	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW		7[redacted]	F	WHITE	尿路感染	20[redacted]	58	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW		7[redacted]	F	WHITE	疲労	20[redacted]	127	96	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW		7[redacted]	F	WHITE	大腿骨骨折	20[redacted]	220	.	Y	Grade 3	NOT RELATED	UNKNOWN	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW		7[redacted]	F	WHITE	肺塞栓症	20[redacted]	222	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	浮動性めまい	20[redacted]	196	159	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	白内障	20[redacted]	387	53	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	筋肉痛	20[redacted]	410	542	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	白内障	20[redacted]	431	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	白内障	20[redacted]	438	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	胸部損傷	20[redacted]	614	93	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	正色素性正球性貧血	20[redacted]	732	531	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	高血圧	20[redacted]	783	480	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	肋骨骨折	20[redacted]	857	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	視力低下	20[redacted]	860	403	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	背部痛	20[redacted]	941	322	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	歩行障害	20[redacted]	983	280	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	不眠症	20[redacted]	983	280	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	変形性関節症	20[redacted]	1069	194	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	無力症	20[redacted]	1096	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	転倒	20[redacted]	1096	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	回転性めまい	20[redacted]	1096	167	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	1096	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	頚動脈硬化症	20[redacted]	1118	145	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	不全単麻痺	20[redacted]	1118	145	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	頚動脈狭窄	20[redacted]	1138	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	1149	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	全身健康状態低下	20[redacted]	1160	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	貧血	20[redacted]	.	98	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	尿路感染	20[redacted]	.	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	頚動脈狭窄	20[redacted]	1166	97	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	処置後出血	20[redacted]	1167	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	褥瘡性潰瘍	20[redacted]	.	67	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	肺炎	20[redacted]	.	6	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	高血圧	20[redacted]	416	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	脳新生物	20[redacted]	727	25	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	脳新生物	20[redacted]	752	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	頚動脈硬化症	20[redacted]	64	510	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	315	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	肛門失禁	20[redacted]	322	252	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	尿失禁	20[redacted]	353	221	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	突然死	20[redacted]	573	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	血中マグネシウム減少	20[redacted]	1	37	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	胆道仙痛	20[redacted]	23	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	上腹部痛	20[redacted]	51	745	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	血中クロール減少	20[redacted]	86	99	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	血中ナトリウム減少	20[redacted]	86	99	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	変形性関節症	20[redacted]	112	62	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	咳嗽	20[redacted]	181	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	本態性高血圧症	20[redacted]	240	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	変形性関節症	20[redacted]	248	548	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	関節炎	20[redacted]	265	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	血中カリウム減少	20[redacted]	275	274	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	悪心	20[redacted]	356	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	高血圧	20[redacted]	496	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	気管支炎	20[redacted]	710	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	死亡	20[redacted]	795	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	疲労	20[redacted]	80	162	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	頭蓋内動脈瘤	20[redacted]	92	150	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	関節炎	20[redacted]	170	72	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	高血糖	20[redacted]	185	57	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	大腿骨骨折	20[redacted]	405	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	脳血管発作	20[redacted]	406	28	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	DENMARK	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	感染	20[redacted]	63	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	疲労	20[redacted]	.	450	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	創傷	20[redacted]	300	41	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	356	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	浮動性めまい	20[redacted]	634	85	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	顔面骨骨折	20[redacted]	674	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	肺炎	20[redacted]	674	43	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	失神	20[redacted]	718	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	ESTONIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	心不全	20[redacted]	61	159	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	皮膚潰瘍	20[redacted]	110	144	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	高カリウム血症	20[redacted]	125	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ESTONIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	低血糖	20[redacted]	202	33	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ESTONIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	無症候性細菌尿	20[redacted]	231	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	そう痒症	20[redacted]	385	114	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	顔面腫脹	20[redacted]	388	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	心不全	20[redacted]	407	14	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ESTONIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	慢性腎臓病	20[redacted]	448	51	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	一酸化炭素中毒	20[redacted]	498	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y

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[redacted]	FRANCE	ALN 70 MG PO QW		6[redacted]	F	WHITE	多汗症	20[redacted]	.	57	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	FRANCE	ALN 70 MG PO QW		6[redacted]	F	WHITE	末梢性浮腫	20[redacted]	138	501	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	FRANCE	ALN 70 MG PO QW		6[redacted]	F	WHITE	糖尿病	20[redacted]	183	92	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	FRANCE	ALN 70 MG PO QW		6[redacted]	F	WHITE	尿路感染	20[redacted]	183	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	FRANCE	ALN 70 MG PO QW		6[redacted]	F	WHITE	糖尿病	20[redacted]	275	364	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	FRANCE	ALN 70 MG PO QW		6[redacted]	F	WHITE	殺人	20[redacted]	638	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	GERMANY	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	死亡	20[redacted]	47	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	GERMANY	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	上気道感染	20[redacted]	27	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	トランスアミナーゼ上昇	20[redacted]	100	772	N	Grade 2	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	GERMANY	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	末梢性浮腫	20[redacted]	366	506	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GERMANY	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	腓骨骨折	20[redacted]	529	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	GERMANY	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	脛骨骨折	20[redacted]	529	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	GERMANY	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	脊椎すべり症	20[redacted]	677	195	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	GERMANY	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	変形性関節症	20[redacted]	733	139	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	GERMANY	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	食道腺癌	20[redacted]	799	73	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	GERMANY	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	食道腺癌	20[redacted]	871	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	GREECE	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	筋肉痛	20[redacted]	123	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GREECE	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	背部痛	20[redacted]	204	95	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GREECE	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	２型糖尿病	20[redacted]	901	105	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GREECE	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	冠動脈疾患	20[redacted]	1005	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	GREECE	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	高血圧	20[redacted]	204	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GREECE	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	下部消化管出血	20[redacted]	804	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	GREECE	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	1002	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	GREECE	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	心肺不全	20[redacted]	220	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	GREECE	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	肺炎	20[redacted]	220	2	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	ASIAN	齲歯	20[redacted]	380	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	ASIAN	心筋梗塞	20[redacted]	518	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	HUNGARY	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	顔面骨骨折	20[redacted]	531	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	大動脈瘤破裂	20[redacted]	631	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	HUNGARY	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	大腿骨骨折	20[redacted]	250	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	脳血管発作	20[redacted]	475	4	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	顔面骨骨折	20[redacted]	475	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	貧血	20[redacted]	477	2	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	心停止	20[redacted]	478	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	HUNGARY	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	脳硬化症	20[redacted]	3	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	大腿骨骨折	20[redacted]	62	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	心不全	20[redacted]	127	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	HUNGARY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	筋力低下	20[redacted]	92	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	うつ病	20[redacted]	225	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	パーキンソン病	20[redacted]	225	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	無力症	20[redacted]	232	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	脳動脈硬化症	20[redacted]	246	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	HUNGARY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	大脳萎縮	20[redacted]	246	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	高血圧	20[redacted]	247	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	虚血性脳梗塞	20[redacted]	247	19	Y	Grade 5	NOT RELATED	FATAL	DRUG WITHDRAWN	MULTIPLE	Y
[redacted]	HUNGARY	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	高血圧	20[redacted]	576	256	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	646	186	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	大脳萎縮	20[redacted]	785	47	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	785	.	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	HUNGARY	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	精神障害	20[redacted]	785	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	橈骨骨折	20[redacted]	785	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	サンバーン	20[redacted]	785	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HUNGARY	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	尺骨骨折	20[redacted]	785	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HUNGARY	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	尿失禁	20[redacted]	813	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HUNGARY	ALN 70 MG PO QW		7[redacted]	F	WHITE	貧血	20[redacted]	29	288	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	ALN 70 MG PO QW		7[redacted]	F	WHITE	動脈硬化症	20[redacted]	141	176	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	ALN 70 MG PO QW		7[redacted]	F	WHITE	高血圧	20[redacted]	141	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	ALN 70 MG PO QW		7[redacted]	F	WHITE	失神	20[redacted]	198	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	ALN 70 MG PO QW		7[redacted]	F	WHITE	心房細動	20[redacted]	283	34	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	HUNGARY	ALN 70 MG PO QW		7[redacted]	F	WHITE	うつ病	20[redacted]	283	34	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	ALN 70 MG PO QW		7[redacted]	F	WHITE	筋緊張低下	20[redacted]	283	34	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	ALN 70 MG PO QW		7[redacted]	F	WHITE	倦怠感	20[redacted]	283	34	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	HUNGARY	ALN 70 MG PO QW		7[redacted]	F	WHITE	循環虚脱	20[redacted]	309	8	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	HUNGARY	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	大腿骨骨折	20[redacted]	134	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	心筋梗塞	20[redacted]	1044	3	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	HUNGARY	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	肋骨骨折	20[redacted]	532	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	心肺不全	20[redacted]	1142	3	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	HUNGARY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心房細動	20[redacted]	86	112	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	突然死	20[redacted]	197	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	OTHER	Y
[redacted]	ITALY	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	子宮癌	20[redacted]	.	482	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ITALY	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	骨盤血腫	20[redacted]	877	8	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ITALY	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	子宮癌	20[redacted]	.	54	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	LATVIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	59	5	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	LATVIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	気管支炎	20[redacted]	359	159	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	心不全	20[redacted]	365	153	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	呼吸不全	20[redacted]	517	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	LITHUANIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	膝蓋骨骨折	20[redacted]	677	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	LITHUANIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	挫傷	20[redacted]	759	114	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	齲歯	20[redacted]	975	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	不眠症	20[redacted]	1184	40	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	LITHUANIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	感情障害	20[redacted]	1208	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	虚血性ニューロパチー	20[redacted]	1208	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	創傷	20[redacted]	1208	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	うっ血性心不全	20[redacted]	1223	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	ストーマ閉塞	20[redacted]	123	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	尿路性敗血症	20[redacted]	123	8	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	昏睡	20[redacted]	129	2	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	出血性びらん性胃炎	20[redacted]	129	2	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	水腎症	20[redacted]	129	2	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	イレウス	20[redacted]	129	2	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	多臓器機能不全症候群	20[redacted]	129	2	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	肺炎	20[redacted]	129	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW		8[redacted]	F	OTHER	コントロール不良の糖尿病	20[redacted]	35	320	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW		8[redacted]	F	OTHER	脳血管発作	20[redacted]	168	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	MEXICO	ALN 70 MG PO QW		8[redacted]	F	OTHER	うっ血性心不全	20[redacted]	334	21	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	MEXICO	ALN 70 MG PO QW		8[redacted]	F	OTHER	脳血管発作	20[redacted]	334	21	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	MEXICO	ALN 70 MG PO QW		8[redacted]	F	OTHER	慢性腎臓病	20[redacted]	334	21	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	下痢	20[redacted]	93	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	尿路感染	20[redacted]	190	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	脊椎痛	20[redacted]	685	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	股関節部骨折	20[redacted]	968	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	肺炎	20[redacted]	972	4	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	敗血症	20[redacted]	974	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	帯状疱疹	20[redacted]	272	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	胃炎	20[redacted]	733	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	気管支炎	20[redacted]	741	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	745	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED		Y
[redacted]	MEXICO	ALN 70 MG PO QW		8[redacted]	F	WHITE	脳血管発作	20[redacted]	367	2	Y	Grade 5	RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	MEXICO	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	肺炎	20[redacted]	28	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	MEXICO	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	第３度熱傷	20[redacted]	190	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	MEXICO	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	背部痛	20[redacted]	377	464	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	MEXICO	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	うっ血性心不全	20[redacted]	829	12	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	MEXICO	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	尿路性敗血症	20[redacted]	45	7	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MEDICATION TAKEN	Y
[redacted]	MEXICO	ALN 70 MG PO QW		7[redacted]	F	OTHER	心筋梗塞	20[redacted]	378	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	MEXICO	ALN 70 MG PO QW		9[redacted]	F	OTHER	呼吸性アシドーシス	20[redacted]	246	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	MEXICO	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	大腿骨骨折	20[redacted]	493	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	MEXICO	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	膀胱出血	20[redacted]	553	43	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N

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[redacted]	MEXICO	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	肺炎	20[redacted]	582	14	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	MEXICO	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	心原性ショック	20[redacted]	595	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	569	330	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	899	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	末梢性浮腫	20[redacted]	98	467	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	糖尿病性足病変	20[redacted]	250	315	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	肺炎	20[redacted]	564	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	MEXICO	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	うつ病	20[redacted]	253	56	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	変形性関節症	20[redacted]	312	136	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	失神	20[redacted]	362	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	MEXICO	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	尿路感染	20[redacted]	362	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	MEXICO	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	肺線維症	20[redacted]	372	76	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	偽膜性大腸炎	20[redacted]	407	41	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	MEXICO	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	下咽頭癌	20[redacted]	535	142	Y	Grade 5	RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	神経炎	20[redacted]	20	48	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	小発作てんかん	20[redacted]	34	610	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	リンパ節症	20[redacted]	114	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	下痢	20[redacted]	117	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	湿疹	20[redacted]	149	169	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	心雑音	20[redacted]	157	487	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	胃炎	20[redacted]	246	110	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	骨挫傷	20[redacted]	290	76	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	心因性結腸炎	20[redacted]	420	224	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	低ナトリウム血症	20[redacted]	547	97	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	背部痛	20[redacted]	567	77	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	MEXICO	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	肺炎	20[redacted]	638	6	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	NETHERLANDS	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	イレウス	20[redacted]	603	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	NETHERLANDS	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	イレウス	20[redacted]	603	7	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	NETHERLANDS	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	敗血症性ショック	20[redacted]	607	3	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	IV ANTIBIOTICS TAKEN	N
[redacted]	NETHERLANDS	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	イレウス	20[redacted]	616	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	NEW ZEALAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	26	7	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	NEW ZEALAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	虚血性心筋症	20[redacted]	26	7	Y	Grade 4	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	NEW ZEALAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心室性頻脈	20[redacted]	26	7	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	NEW ZEALAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	肝転移	20[redacted]	27	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	NORWAY	ALN 70 MG PO QW		8[redacted]	F	WHITE	腹部膨満	20[redacted]	70	23	N	Grade 1	RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	NORWAY	ALN 70 MG PO QW		8[redacted]	F	WHITE	突然死	20[redacted]	187	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	NORWAY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	咳嗽	20[redacted]	.	442	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	NORWAY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	注射部位炎症	20[redacted]	118	3	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	NORWAY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	軟部組織腫瘤	20[redacted]	118	3	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	NORWAY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	疲労	20[redacted]	.	230	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	NORWAY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	高血圧	20[redacted]	237	230	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	NORWAY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	.	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	NORWAY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	遠隔転移を伴う肺腺癌	20[redacted]	350	117	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	腹痛	20[redacted]	15	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	注射部位疼痛	20[redacted]	54	2	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	体重減少	20[redacted]	54	225	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	73	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	うつ病	20[redacted]	134	728	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	高血圧	20[redacted]	187	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	貧血	20[redacted]	280	80	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	喘息	20[redacted]	294	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	肺炎	20[redacted]	294	15	Y	Grade 4	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	変形性関節症	20[redacted]	418	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	変形性関節症	20[redacted]	723	139	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	尿路感染	20[redacted]	723	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心房細動	20[redacted]	794	24	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	慢性気管支炎	20[redacted]	794	68	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心不全	20[redacted]	794	24	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	肺炎	20[redacted]	794	24	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	うっ血性心不全	20[redacted]	854	8	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	食欲亢進	20[redacted]	.	218	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	体位性めまい	20[redacted]	21	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	挫傷	20[redacted]	36	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	リンパ腫	20[redacted]	.	196	N	Grade 3	NOT RELATED		DRUG WITHDRAWN	DEVICE/PROCEDURE INTERVENTION	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	皮膚炎	20[redacted]	120	114	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	末梢性浮腫	20[redacted]	120	93	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	処置による疼痛	20[redacted]	164	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	蜂巣炎	20[redacted]	200	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	非ホジキンリンパ腫	20[redacted]	200	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	消化不良	20[redacted]	205	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	帯状疱疹	20[redacted]	212	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	非ホジキンリンパ腫	20[redacted]	224	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	敗血症性ショック	20[redacted]	231	3	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	萎縮性外陰腟炎	20[redacted]	53	213	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	性器脱	20[redacted]	53	213	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	食欲減退	20[redacted]	130	136	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	小腸癌	20[redacted]	130	136	Y	Grade 5	NOT RELATED	FATAL	DRUG WITHDRAWN	MULTIPLE	Y
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	先天性嚢胞性腎疾患	20[redacted]	173	93	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	肝包虫症	20[redacted]	173	93	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	裂孔ヘルニア	20[redacted]	173	93	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	痔核	20[redacted]	183	83	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	貧血	20[redacted]	191	75	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	尿路感染	20[redacted]	195	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	十二指腸潰瘍	20[redacted]	198	68	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	胃炎	20[redacted]	198	68	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	気管支炎	20[redacted]	24	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	右脚ブロック	20[redacted]	27	106	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	上室性期外収縮	20[redacted]	27	167	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	不眠症	20[redacted]	42	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	気管支炎	20[redacted]	91	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	下痢	20[redacted]	93	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	低ナトリウム血症	20[redacted]	98	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	肺感染	20[redacted]	190	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	PERU	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	肺線維症	20[redacted]	190	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	便秘	20[redacted]	48	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	変形性関節症	20[redacted]	80	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	変形性関節症	20[redacted]	112	63	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	肺動脈性肺高血圧症	20[redacted]	131	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	下痢	20[redacted]	138	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	変形性関節症	20[redacted]	179	25	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	下痢	20[redacted]	296	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	尿路感染	20[redacted]	320	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	高血圧	20[redacted]	387	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	尿路感染	20[redacted]	438	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	死亡	20[redacted]	699	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	下痢	20[redacted]	49	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	手根管症候群	20[redacted]	70	24	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	下痢	20[redacted]	164	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	下痢	20[redacted]	243	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	便秘	20[redacted]	262	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	腱炎	20[redacted]	302	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	錯感覚	20[redacted]	322	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	気管支炎	20[redacted]	410	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	肝胆道系癌	20[redacted]	492	36	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	肝胆道系癌	20[redacted]	528	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	うつ病	20[redacted]	7	98	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	頚部痛	20[redacted]	22	45	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	尿路感染	20[redacted]	65	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	82	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	挫傷	20[redacted]	90	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	頚部痛	20[redacted]	112	87	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	不眠症	20[redacted]	338	104	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	浮腫	20[redacted]	409	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	PERU	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	肺線維症	20[redacted]	441	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MEDICATION TAKEN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	気管支炎	20[redacted]	10	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	転倒	20[redacted]	53	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	558	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	うつ病	20[redacted]	.	216	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	認知症	20[redacted]	.	94	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	肺炎	20[redacted]	1162	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	POLAND	ALN 70 MG PO QW		6[redacted]	F	WHITE	貧血	20[redacted]	33	833	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	POLAND	ALN 70 MG PO QW		6[redacted]	F	WHITE	血尿	20[redacted]	33	833	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	POLAND	ALN 70 MG PO QW		6[redacted]	F	WHITE	腎盂の悪性新生物	20[redacted]	67	799	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW		6[redacted]	F	WHITE	尿管癌	20[redacted]	.	719	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW		6[redacted]	F	WHITE	膀胱癌第４期	20[redacted]	.	353	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW		6[redacted]	F	WHITE	上気道感染	20[redacted]	642	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW		6[redacted]	F	WHITE	死亡	20[redacted]	866	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	高血圧	20[redacted]	40	589	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	362	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	心房細動	20[redacted]	392	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	低カリウム血症	20[redacted]	392	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	洞結節機能不全	20[redacted]	480	149	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	心タンポナーデ	20[redacted]	628	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	悪性新生物	20[redacted]	65	202	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	肛門癌	20[redacted]	190	77	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MEDICATION TAKEN	Y
[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	慢性腎臓病	20[redacted]	228	39	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	28	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	尿路感染	20[redacted]	257	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	背部痛	20[redacted]	.	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	椎間板障害	20[redacted]	515	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	心不全	20[redacted]	.	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	死亡	20[redacted]	635	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	上気道感染	20[redacted]	44	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	四肢損傷	20[redacted]	427	30	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	肺炎	20[redacted]	1173	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	心肺不全	20[redacted]	1176	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	挫傷	20[redacted]	169	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	喀痰増加	20[redacted]	236	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	尿路感染	20[redacted]	258	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心不全	20[redacted]	302	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	痔核	20[redacted]	143	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	無力症	20[redacted]	272	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	関節痛	20[redacted]	413	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	関節痛	20[redacted]	413	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	腹痛	20[redacted]	565	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	腎結石症	20[redacted]	583	299	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	腎嚢胞	20[redacted]	583	299	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	耳感染	20[redacted]	822	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	咽頭炎	20[redacted]	822	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	咳嗽	20[redacted]	834	48	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	悪性新生物	20[redacted]	862	20	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	心筋梗塞	20[redacted]	867	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	心房細動	20[redacted]	87	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	気管支炎	20[redacted]	87	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	心筋梗塞	20[redacted]	87	8	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	心筋虚血	20[redacted]	87	949	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	尿路感染	20[redacted]	87	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	挫傷	20[redacted]	137	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	老人性難聴	20[redacted]	183	853	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	細菌性気管支炎	20[redacted]	338	50	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	食欲減退	20[redacted]	609	427	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	死亡	20[redacted]	1035	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	呼吸困難	20[redacted]	54	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	呼吸困難	20[redacted]	82	141	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	気管支炎	20[redacted]	210	27	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	細菌性気管支炎	20[redacted]	265	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	300	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	細菌性気管支炎	20[redacted]	321	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	呼吸困難	20[redacted]	337	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	448	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	白内障	20[redacted]	.	904	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	網膜剥離	20[redacted]	.	319	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	呼吸困難	20[redacted]	534	23	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	601	828	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	膀胱炎	20[redacted]	629	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	気管支炎	20[redacted]	674	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	細菌性気管支炎	20[redacted]	748	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	下痢	20[redacted]	758	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	心嚢液貯留	20[redacted]	791	464	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	813	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	867	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	不眠症	20[redacted]	874	48	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	乳頭障害	20[redacted]	1043	386	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	気管支炎	20[redacted]	1066	27	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	呼吸困難	20[redacted]	1122	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	呼吸困難	20[redacted]	1187	5	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	呼吸困難	20[redacted]	1204	4	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	1249	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	靭帯捻挫	20[redacted]	1289	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	1323	6	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	1360	7	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	呼吸不全	20[redacted]	1395	33	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	心不全	20[redacted]	1408	20	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	血尿	20[redacted]	1411	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	心原性ショック	20[redacted]	1427	1	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	心不全	20[redacted]	1428	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	心原性ショック	20[redacted]	1428	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	呼吸不全	20[redacted]	1428	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	挫傷	20[redacted]	30	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	転倒	20[redacted]	30	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	転倒	20[redacted]	232	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	血腫	20[redacted]	232	32	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	喘息	20[redacted]	454	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	肺炎	20[redacted]	454	22	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	気管支炎	20[redacted]	575	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	細菌性気管支炎	20[redacted]	634	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	死亡	20[redacted]	.	.	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	出血性卒中	20[redacted]	112	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	貧血	20[redacted]	65	254	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	下腹部痛	20[redacted]	73	54	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	筋骨格痛	20[redacted]	120	199	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	結腸腺癌	20[redacted]	264	54	Y	Grade 4	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	腹膜出血	20[redacted]	304	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	肺炎	20[redacted]	309	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	胃腸吻合部漏出	20[redacted]	310	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	腹膜炎	20[redacted]	314	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	結腸腺癌	20[redacted]	318	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	咳嗽	20[redacted]	52	24	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	ボディ・マス・インデックス増加	20[redacted]	185	182	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	心房細動	20[redacted]	.	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	胆石症	20[redacted]	216	.	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	下気道感染	20[redacted]	237	27	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	上気道感染	20[redacted]	356	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	限局性感染	20[redacted]	425	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	創傷	20[redacted]	425	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	452	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	気管支炎	20[redacted]	460	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	慢性心不全	20[redacted]	460	4	Y	Grade 3	RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	慢性心不全	20[redacted]	465	6	Y	Grade 3	RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	心房細動	20[redacted]	542	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	567	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	急性左室不全	20[redacted]	673	8	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	類上皮性中皮腫	20[redacted]	706	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	大腿骨骨折	20[redacted]	870	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	死亡	20[redacted]	899	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	ALN 70 MG PO QW		7[redacted]	F	WHITE	心タンポナーデ	20[redacted]	.	23	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	ALN 70 MG PO QW		7[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	.	31	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW		7[redacted]	F	WHITE	完全房室ブロック	20[redacted]	329	10	Y	Grade 4	RELATED	RESOLVED		HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	ALN 70 MG PO QW		7[redacted]	F	WHITE	循環虚脱	20[redacted]	335	12	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW		7[redacted]	F	WHITE	貧血	20[redacted]	338	5	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	TRANSFUSION PERFORMED	
[redacted]	POLAND	ALN 70 MG PO QW		7[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	347	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW		7[redacted]	F	WHITE	肺炎	20[redacted]	348	5	Y	Grade 5	RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	死亡	20[redacted]	646	1	Y	Grade 5	RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	29	8	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	上腕骨骨折	20[redacted]	90	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	創傷	20[redacted]	90	179	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	213	8	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	背部痛	20[redacted]	543	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	気管支炎	20[redacted]	543	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	悪性新生物	20[redacted]	543	14	Y	Grade 5	RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	22	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	そう痒症	20[redacted]	50	60	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	爪破損	20[redacted]	129	212	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	440	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	嚥下障害	20[redacted]	855	64	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	有害事象	20[redacted]	918	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	24	16	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	筋痙縮	20[redacted]	79	34	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	脱毛症	20[redacted]	133	335	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	下痢	20[redacted]	268	28	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	下部消化管出血	20[redacted]	281	187	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	子宮頚部癌第４期	20[redacted]	336	132	Y	Grade 5	RELATED	FATAL	DOSE ALTERED OR WITHHELD	MULTIPLE	Y
[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	腸憩室	20[redacted]	358	110	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	上室性期外収縮	20[redacted]	358	110	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	胆石症	20[redacted]	359	109	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	WHITE	心停止	20[redacted]	630	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	悪性黒色腫	20[redacted]	511	392	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	553	350	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	背部痛	20[redacted]	.	217	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	心停止	20[redacted]	902	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	急性胆嚢炎	20[redacted]	237	6	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	心不全	20[redacted]	226	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	循環虚脱	20[redacted]	11	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	変形性関節症	20[redacted]	52	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	肺炎	20[redacted]	463	43	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	死亡	20[redacted]	533	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	上腹部痛	20[redacted]	42	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	関節痛	20[redacted]	525	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	上腹部痛	20[redacted]	647	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	697	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	960	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	上腹部痛	20[redacted]	1053	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	1088	119	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	高コレステロール血症	20[redacted]	1092	115	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	死亡	20[redacted]	1206	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	背部痛	20[redacted]	759	83	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	872	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	993	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	背部痛	20[redacted]	1085	138	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	死亡	20[redacted]	1222	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	関節痛	20[redacted]	175	41	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	関節痛	20[redacted]	540	145	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	頭痛	20[redacted]	595	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	死亡	20[redacted]	684	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	悪心	20[redacted]	536	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	貧血	20[redacted]	550	34	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	無力症	20[redacted]	567	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	死亡	20[redacted]	583	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	便秘	20[redacted]	474	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	発疹	20[redacted]	638	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	背部痛	20[redacted]	673	41	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	死亡	20[redacted]	856	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	胆管炎	20[redacted]	528	74	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	死亡	20[redacted]	601	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	ALN 70 MG PO QW		8[redacted]	F	WHITE	死亡	20[redacted]	221	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	ALN 70 MG PO QW		7[redacted]	F	WHITE	高血圧	20[redacted]	217	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	ALN 70 MG PO QW		7[redacted]	F	WHITE	心肺不全	20[redacted]	226	3	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	突然死	20[redacted]	.	.	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	慢性心不全	20[redacted]	6	730	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	肺水腫	20[redacted]	6	8	Y	Grade 4	RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	意識消失	20[redacted]	31	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	意識消失	20[redacted]	71	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	脳血管発作	20[redacted]	713	22	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	脳血管発作	20[redacted]	735	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	ROMANIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	心筋症	20[redacted]	70	926	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	尿路感染	20[redacted]	.	38	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	992	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	排尿困難	20[redacted]	29	413	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	脳血管発作	20[redacted]	309	23	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	脳血管発作	20[redacted]	437	5	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	肺炎	20[redacted]	73	29	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	狭心症	20[redacted]	102	730	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	冠動脈疾患	20[redacted]	102	730	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	脳症	20[redacted]	102	27	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	高血圧	20[redacted]	102	730	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	高血圧	20[redacted]	102	730	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	102	730	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	僧帽弁逸脱	20[redacted]	102	730	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	前庭性運動失調	20[redacted]	102	27	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	慢性心不全	20[redacted]	120	712	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	120	712	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	三尖弁閉鎖不全症	20[redacted]	120	712	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	坐骨神経痛	20[redacted]	197	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	狭心症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	無力症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	心拍数不整	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	白内障	20[redacted]	253	579	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	近視	20[redacted]	253	579	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	狭心症	20[redacted]	347	485	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	静脈瘤	20[redacted]	347	485	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	甲状腺腫	20[redacted]	350	482	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	慢性腎盂腎炎	20[redacted]	350	482	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	腎嚢胞	20[redacted]	350	482	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	脳動脈硬化症	20[redacted]	663	169	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	胸痛	20[redacted]	663	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	脂質異常症	20[redacted]	663	169	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	左室肥大	20[redacted]	663	169	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	骨端症	20[redacted]	663	14	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	膀胱炎	20[redacted]	676	45	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	背部痛	20[redacted]	796	10	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	829	3	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	左室不全	20[redacted]	831	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	低体温	20[redacted]	701	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	RUSSIAN FEDERATION	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	死亡	20[redacted]	959	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	皮膚真菌感染	20[redacted]	39	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	背部痛	20[redacted]	116	614	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	腓骨骨折	20[redacted]	175	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	気道感染	20[redacted]	342	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	浮動性めまい	20[redacted]	352	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	RUSSIAN FEDERATION	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	インフルエンザ	20[redacted]	727	3	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	OTHER	Y
[redacted]	SLOVAKIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	食欲減退	20[redacted]	97	560	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	SLOVAKIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	回転性めまい	20[redacted]	305	352	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SLOVAKIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	関節腫脹	20[redacted]	333	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SLOVAKIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	高血圧	20[redacted]	511	40	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SLOVAKIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	肺炎	20[redacted]	651	7	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	急性心不全	20[redacted]	136	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	閉塞性気道障害	20[redacted]	137	300	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	140	297	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	便秘	20[redacted]	158	50	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	大動脈瘤破裂	20[redacted]	358	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	大動脈瘤	20[redacted]	360	77	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	交通事故	20[redacted]	436	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	浮動性めまい	20[redacted]	.	845	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	頭痛	20[redacted]	60	76	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	尿路感染	20[redacted]	77	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	筋骨格痛	20[redacted]	101	126	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	尿路感染	20[redacted]	130	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	筋痙縮	20[redacted]	175	713	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	下痢	20[redacted]	221	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	胃腸音異常	20[redacted]	224	184	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	関節痛	20[redacted]	225	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	健忘	20[redacted]	257	631	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	気管支炎	20[redacted]	285	18	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	低血圧	20[redacted]	547	341	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	筋骨格系胸痛	20[redacted]	688	45	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	転倒	20[redacted]	714	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	うっ血性心不全	20[redacted]	809	79	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	挫傷	20[redacted]	123	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	気管支炎	20[redacted]	268	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	下痢	20[redacted]	551	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	大腿骨骨折	20[redacted]	612	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N

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[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	悪心	20[redacted]	618	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	回転性めまい	20[redacted]	618	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	尿路感染	20[redacted]	890	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	抑うつ症状	20[redacted]	897	378	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	Ｂ細胞性リンパ腫	20[redacted]	1088	187	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	ホジキン病	20[redacted]	.	122	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	肺炎	20[redacted]	1168	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	手骨折	20[redacted]	1174	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	恥骨骨折	20[redacted]	1174	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	腎感染	20[redacted]	.	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	肺炎	20[redacted]	.	62	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	深部静脈血栓症	20[redacted]	1226	49	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	下痢	20[redacted]	1233	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	褥瘡性潰瘍	20[redacted]	.	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	帯状疱疹	20[redacted]	.	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	便秘	20[redacted]	.	1290	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	末梢腫脹	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	咳嗽	20[redacted]	274	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	334	.	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	尺骨骨折	20[redacted]	334	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	うっ血性心不全	20[redacted]	.	716	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	心筋虚血	20[redacted]	807	484	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	腎不全	20[redacted]	1277	15	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	敗血症性ショック	20[redacted]	1277	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	褥瘡性潰瘍	20[redacted]	1278	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	鼻漏	20[redacted]	.	755	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	筋痙縮	20[redacted]	.	298	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	急性胆嚢炎	20[redacted]	.	63	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	高血圧	20[redacted]	.	145	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	胆石症	20[redacted]	637	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	胃腸炎	20[redacted]	758	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	腹部膿瘍	20[redacted]	769	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	褥瘡性潰瘍	20[redacted]	769	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	穿孔性消化性潰瘍	20[redacted]	769	11	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	ほてり	20[redacted]	2	237	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	背部痛	20[redacted]	81	921	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	尿路感染	20[redacted]	177	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	肺炎	20[redacted]	213	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	単純ヘルペス	20[redacted]	441	561	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	ほてり	20[redacted]	.	519	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	回転性めまい	20[redacted]	.	519	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	511	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	下気道感染	20[redacted]	629	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	アレルギー性結膜炎	20[redacted]	645	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	皮膚炎	20[redacted]	645	357	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	軟部組織損傷	20[redacted]	659	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	化学物質アレルギー	20[redacted]	740	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	関節痛	20[redacted]	827	175	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	突然死	20[redacted]	1001	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	292	.	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	292	.	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	便秘	20[redacted]	.	180	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	169	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	低血圧	20[redacted]	169	21	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	尿路感染	20[redacted]	171	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	大腿骨骨折	20[redacted]	525	.	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	心房細動	20[redacted]	526	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	肺炎	20[redacted]	526	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	褥瘡性潰瘍	20[redacted]	528	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	529	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	心筋症	20[redacted]	532	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	SOUTH AFRICA	ALN 70 MG PO QW		7[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	65	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW		7[redacted]	F	WHITE	軟部組織損傷	20[redacted]	65	165	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW		7[redacted]	F	WHITE	便秘	20[redacted]	66	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW		7[redacted]	F	WHITE	悪心	20[redacted]	161	69	Y	Grade 3	RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW		7[redacted]	F	WHITE	嘔吐	20[redacted]	161	69	Y	Grade 3	RELATED	RESOLVED	DRUG WITHDRAWN	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW		7[redacted]	F	WHITE	脳血管発作	20[redacted]	226	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	上気道感染	20[redacted]	48	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	下痢	20[redacted]	89	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	下気道感染	20[redacted]	283	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	血便排泄	20[redacted]	297	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	副鼻腔炎	20[redacted]	456	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	筋痙縮	20[redacted]	553	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	狭心症	20[redacted]	.	252	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	心臓弁膜疾患	20[redacted]	.	238	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	甲状腺の良性新生物	20[redacted]	614	219	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	頭痛	20[redacted]	614	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	肺高血圧症	20[redacted]	614	219	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	高血糖	20[redacted]	818	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	多臓器機能不全症候群	20[redacted]	819	14	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	WHITE	褥瘡性潰瘍	20[redacted]	826	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	高血圧	20[redacted]	62	670	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	腎機能障害	20[redacted]	93	274	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	痛風	20[redacted]	457	275	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	食欲減退	20[redacted]	528	204	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	過敏性腸症候群	20[redacted]	540	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	死亡	20[redacted]	731	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	腎機能障害	20[redacted]	97	87	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	高血圧	20[redacted]	183	365	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	急性冠動脈症候群	20[redacted]	227	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	胃食道逆流性疾患	20[redacted]	228	80	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	疲労	20[redacted]	358	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	大動脈狭窄	20[redacted]	359	311	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	心房細動	20[redacted]	359	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	非心臓性胸痛	20[redacted]	359	1	N	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	UNKNOWN	N
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	脳血管発作	20[redacted]	659	11	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	蜂巣炎	20[redacted]	661	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	背部痛	20[redacted]	22	539	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	高血圧	20[redacted]	89	241	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	胃腸炎	20[redacted]	377	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	脱水	20[redacted]	427	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SOUTH AFRICA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	WHITE	死亡	20[redacted]	560	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	咳嗽	20[redacted]	49	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	皮膚病変	20[redacted]	87	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	末梢腫脹	20[redacted]	151	698	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	副鼻腔炎	20[redacted]	185	637	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SOUTH AFRICA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	WHITE	良性髄膜腫	20[redacted]	826	23	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	SWEDEN	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	苔癬様角化症		609	609	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	SWEDEN	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	腎感染	20[redacted]	391	373	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	SWEDEN	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	扁平上皮癌	20[redacted]	593	71	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	SWEDEN	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	低カリウム血症	20[redacted]	757	117	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWEDEN	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	頭蓋内出血	20[redacted]	873	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	SWEDEN	ALN 70 MG PO QW		7[redacted]	F	WHITE	尿路感染	20[redacted]	351	5	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWEDEN	ALN 70 MG PO QW		7[redacted]	F	WHITE	閉塞性気道障害	20[redacted]	398	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED		Y
[redacted]	TURKEY	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	疲労	20[redacted]	1	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	TURKEY	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	不安	20[redacted]	36	554	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	TURKEY	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	膀胱炎	20[redacted]	252	6	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	TURKEY	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	起立性低血圧	20[redacted]	320	270	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	TURKEY	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	死亡	20[redacted]	589	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	食欲減退	20[redacted]	21	415	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	発熱	20[redacted]	21	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	骨痛	20[redacted]	54	382	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	発熱	20[redacted]	54	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	呼吸障害	20[redacted]	54	382	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	細菌性耳感染	20[redacted]	69	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	四肢痛	20[redacted]	103	333	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	関節腫脹	20[redacted]	111	325	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	口腔咽頭痛	20[redacted]	301	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	発熱	20[redacted]	301	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	呼吸困難	20[redacted]	404	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	WHITE	肺炎	20[redacted]	435	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	背部痛	20[redacted]	1	1152	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	注射部位疼痛	20[redacted]	1	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	悪寒	20[redacted]	30	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	注射部位疼痛	20[redacted]	30	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	頭痛	20[redacted]	93	1	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	注射部位疼痛	20[redacted]	119	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	発疹	20[redacted]	192	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	注射部位疼痛	20[redacted]	210	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	腹痛	20[redacted]	253	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	肉離れ	20[redacted]	300	853	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	不安	20[redacted]	540	613	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	認知症	20[redacted]	633	520	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	副鼻腔炎	20[redacted]	643	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	UNITED STATES	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	WHITE	死亡	20[redacted]	1152	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	下痢	20[redacted]	41	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	憩室	20[redacted]	42	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	浮動性めまい	20[redacted]	.	96	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	筋痙縮	20[redacted]	141	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	急性心筋梗塞	20[redacted]	175	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	27	39	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	左脚ブロック	20[redacted]	86	862	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	うっ血性心不全	20[redacted]	86	62	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	肺水腫	20[redacted]	86	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	脂質異常症	20[redacted]	87	861	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	細菌性肺炎	20[redacted]	140	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	うっ血性心不全	20[redacted]	151	797	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心室性期外収縮	20[redacted]	238	33	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心不全	20[redacted]	399	13	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	不眠症	20[redacted]	408	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	僧帽弁閉鎖不全症	20[redacted]	408	540	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	肺高血圧症	20[redacted]	408	540	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	三尖弁閉鎖不全症	20[redacted]	408	540	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心不全	20[redacted]	471	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	気管支炎	20[redacted]	569	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	背部痛	20[redacted]	587	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	587	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	代謝障害	20[redacted]	718	230	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	挫傷	20[redacted]	819	129	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	頭蓋脳損傷	20[redacted]	819	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	鼻出血	20[redacted]	819	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	顔面骨骨折	20[redacted]	819	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	手骨折	20[redacted]	819	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	頭部損傷	20[redacted]	819	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心不全	20[redacted]	827	120	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	貧血	20[redacted]	828	120	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	うっ血性心筋症	20[redacted]	828	120	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	低クロール血症	20[redacted]	828	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	低ナトリウム血症	20[redacted]	828	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	925	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	頚部損傷	20[redacted]	925	23	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心不全	20[redacted]	947	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	22	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	76	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	四肢痛	20[redacted]	145	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	四肢痛	20[redacted]	152	23	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	細菌性気管支炎	20[redacted]	154	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	末梢静脈疾患	20[redacted]	269	723	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	関節痛	20[redacted]	289	703	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	四肢痛	20[redacted]	298	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	関節痛	20[redacted]	.	559	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	胃炎	20[redacted]	541	61	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	627	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	急性心筋梗塞	20[redacted]	687	15	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	収縮機能障害	20[redacted]	690	302	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心不全	20[redacted]	701	291	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	尿路感染	20[redacted]	701	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	冠動脈疾患	20[redacted]	702	290	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	急性心筋梗塞	20[redacted]	809	8	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	裂孔ヘルニア	20[redacted]	809	183	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	貧血	20[redacted]	810	182	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	低ナトリウム血症	20[redacted]	810	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	低血圧	20[redacted]	810	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	代謝性アシドーシス	20[redacted]	810	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心不全	20[redacted]	813	176	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	僧帽弁閉鎖不全症	20[redacted]	813	179	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	三尖弁閉鎖不全症	20[redacted]	813	179	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心不全	20[redacted]	817	76	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	胸水	20[redacted]	817	175	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	肺高血圧症	20[redacted]	817	175	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	左室拡張	20[redacted]	819	173	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	筋骨格痛	20[redacted]	956	36	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	血尿	20[redacted]	988	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	尿路感染	20[redacted]	989	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	関節痛	20[redacted]	25	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	74	450	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	譫妄	20[redacted]	74	2	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	細菌性肺炎	20[redacted]	74	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	尿路感染	20[redacted]	74	6	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	過敏性腸症候群	20[redacted]	.	156	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	末梢性浮腫	20[redacted]	105	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	顔面損傷	20[redacted]	319	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	319	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	過敏性腸症候群	20[redacted]	331	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心不全	20[redacted]	340	184	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	慢性腎臓病	20[redacted]	340	184	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	背部痛	20[redacted]	353	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	353	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	背部痛	20[redacted]	400	124	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	徐脈	20[redacted]	403	121	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	四肢静脈血栓症	20[redacted]	403	121	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	下痢	20[redacted]	472	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	死亡	20[redacted]	523	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y

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[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	低アルブミン血症	20[redacted]	.	262	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	口腔ヘルペス	20[redacted]	18	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	鼻部損傷	20[redacted]	27	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	胃炎	20[redacted]	107	877	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	感染性皮膚潰瘍	20[redacted]	120	74	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	結膜炎	20[redacted]	139	23	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	232	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	アレルギー性鼻炎	20[redacted]	246	77	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	抑うつ気分を伴う適応障害	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	背部痛	20[redacted]	267	717	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	脊柱前弯症	20[redacted]	271	713	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	脊椎すべり症	20[redacted]	271	713	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	脊椎すべり症	20[redacted]	271	713	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	静脈瘤性潰瘍	20[redacted]	305	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	転倒	20[redacted]	311	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	肋軟骨炎	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	過敏症	20[redacted]	446	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	496	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	609	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	関節痛	20[redacted]	619	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	転倒	20[redacted]	619	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	食欲減退	20[redacted]	.	244	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	転倒	20[redacted]	763	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	四肢痛	20[redacted]	763	221	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	尿路結石	20[redacted]	773	211	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	780	204	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	四肢痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	低アルブミン血症	20[redacted]	803	181	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	気管支炎	20[redacted]	903	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	蜂巣炎	20[redacted]	903	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	尿路感染	20[redacted]	903	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	頚部腫瘤	20[redacted]	906	78	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	貧血	20[redacted]	910	74	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	感染性皮膚潰瘍	20[redacted]	975	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	心不全	20[redacted]	979	5	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	979	5	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	僧帽弁閉鎖不全症	20[redacted]	979	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	肺高血圧症	20[redacted]	979	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	慢性腎臓病	20[redacted]	980	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	肺水腫	20[redacted]	981	3	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	関節痛	20[redacted]	4	89	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	メラノサイト性母斑	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	背部痛	20[redacted]	55	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	皮膚炎	20[redacted]	109	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	109	12	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	高血圧	20[redacted]	149	668	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	消化不良	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	うつ病	20[redacted]	.	96	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	転倒	20[redacted]	415	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	四肢損傷	20[redacted]	415	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	眼外傷	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	転倒	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	転倒	20[redacted]	544	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	頭部損傷	20[redacted]	544	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	638	40	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	四肢痛	20[redacted]	669	148	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	気管支癌	20[redacted]	.	108	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	便秘	20[redacted]	.	108	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	無力症	20[redacted]	754	63	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	下部消化管出血	20[redacted]	786	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	肝転移	20[redacted]	790	27	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	胸水	20[redacted]	790	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	気管支癌	20[redacted]	816	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	四肢痛	20[redacted]	.	432	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	錯感覚	20[redacted]	.	340	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	乾癬	20[redacted]	299	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	皮膚潰瘍	20[redacted]	322	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	肺炎	20[redacted]	477	27	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	494	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	肺炎	20[redacted]	508	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	21	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	心房頻脈	20[redacted]	57	783	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	過敏性腸症候群	20[redacted]	.	117	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	鼻炎	20[redacted]	.	776	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	胃食道逆流性疾患	20[redacted]	123	158	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	関節痛	20[redacted]	.	533	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	外傷性肺損傷	20[redacted]	311	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	腹痛	20[redacted]	324	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	肺扁平上皮癌	20[redacted]	344	496	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	貧血	20[redacted]	352	488	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	皮膚炎	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	441	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	硝子体出血	20[redacted]	441	122	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	539	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	浮動性めまい	20[redacted]	.	259	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	663	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	695	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	大腿骨骨折	20[redacted]	695	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	関節損傷	20[redacted]	695	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	肺炎	20[redacted]	778	21	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	慢性腎臓病	20[redacted]	781	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	冠動脈硬化症	20[redacted]	782	58	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	譫妄	20[redacted]	786	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	不眠症	20[redacted]	786	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	便秘	20[redacted]	823	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	誤嚥性肺炎	20[redacted]	823	17	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	鉄欠乏性貧血	20[redacted]	825	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	12	23	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	12	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	咳嗽	20[redacted]	.	528	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	無力症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	食欲減退	20[redacted]	.	72	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	食欲減退	20[redacted]	.	408	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	発熱	20[redacted]	207	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	223	24	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	動脈硬化症	20[redacted]	239	331	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	心拡大	20[redacted]	239	55	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	甲状腺腫	20[redacted]	240	330	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	特発性肺線維症	20[redacted]	240	330	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	心不全	20[redacted]	293	277	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	肺炎	20[redacted]	351	19	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	貧血	20[redacted]	361	24	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	高カリウム血症	20[redacted]	361	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	肺高血圧症	20[redacted]	363	207	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	475	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	565	5	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	筋拘縮	20[redacted]	47	729	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	背部痛	20[redacted]	58	718	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	筋力低下	20[redacted]	66	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	四肢痛	20[redacted]	101	675	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	筋痙縮	20[redacted]	109	667	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	胆管拡張	20[redacted]	249	527	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	肝障害	20[redacted]	249	527	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	健忘	20[redacted]	.	517	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	心電図再分極異常	20[redacted]	259	517	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	不眠症	20[redacted]	289	487	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	軟部組織損傷	20[redacted]	321	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	胃炎	20[redacted]	403	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	胃炎	20[redacted]	572	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	胃炎	20[redacted]	596	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	598	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	胃炎	20[redacted]	701	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	胃炎	20[redacted]	753	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	急性心筋梗塞	20[redacted]	775	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	変形性関節症	20[redacted]	6	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	変形性関節症	20[redacted]	6	1216	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	斑状出血	20[redacted]	79	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	下痢	20[redacted]	85	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	気管支炎	20[redacted]	105	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	脂質異常症	20[redacted]	199	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	眼そう痒症	20[redacted]	202	49	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	腹痛	20[redacted]	324	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	下痢	20[redacted]	370	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	筋骨格痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	430	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	頭部損傷	20[redacted]	430	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	四肢損傷	20[redacted]	430	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	478	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	間擦疹	20[redacted]	532	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	変形性関節症	20[redacted]	600	622	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	631	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	四肢損傷	20[redacted]	631	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	尿路感染	20[redacted]	703	20	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	四肢痛	20[redacted]	.	515	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	血小板減少症	20[redacted]	724	48	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	筋痙縮	20[redacted]	746	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	923	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	細菌性肺炎	20[redacted]	923	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	せつ	20[redacted]	1035	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	アレルギー性皮膚炎	20[redacted]	1049	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	気管支炎	20[redacted]	1170	52	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	出血性卒中	20[redacted]	1205	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	出血性卒中	20[redacted]	1213	9	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	痙攣発作	20[redacted]	1213	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	尿路感染	20[redacted]	1213	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	出血性卒中	20[redacted]	1216	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	低カリウム血症	20[redacted]	1217	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	２型糖尿病	20[redacted]	1219	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	心肺停止	20[redacted]	1221	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	顔面麻痺	20[redacted]	25	80	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	35	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	背部痛	20[redacted]	109	967	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	114	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	肺炎	20[redacted]	238	9	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	321	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	肺炎	20[redacted]	573	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	抑うつ気分	20[redacted]	.	445	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	変形性関節症	20[redacted]	744	332	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	781	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心不全	20[redacted]	1073	3	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	ALN 70 MG PO QW		8[redacted]	F	OTHER	頚部痛	20[redacted]	25	44	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW		8[redacted]	F	OTHER	聴力低下	20[redacted]	38	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	ALN 70 MG PO QW		8[redacted]	F	OTHER	静脈瘤	20[redacted]	46	23	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW		8[redacted]	F	OTHER	インフルエンザ	20[redacted]	64	5	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	転倒	20[redacted]	81	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	関節損傷	20[redacted]	81	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	背部痛	20[redacted]	88	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	転倒	20[redacted]	180	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	関節損傷	20[redacted]	180	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	片頭痛	20[redacted]	269	33	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	多尿	20[redacted]	282	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	不眠症	20[redacted]	301	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	変形性関節症	20[redacted]	.	576	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	転倒	20[redacted]	430	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	関節損傷	20[redacted]	430	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	咳嗽	20[redacted]	528	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	転倒	20[redacted]	646	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	頭部損傷	20[redacted]	646	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	四肢損傷	20[redacted]	646	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	転倒	20[redacted]	677	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	脊柱損傷	20[redacted]	677	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	咳嗽	20[redacted]	710	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	筋痙縮	20[redacted]	754	216	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	816	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	食中毒	20[redacted]	860	25	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	慢性気管支炎	20[redacted]	879	91	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	静脈炎	20[redacted]	892	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	胃腸炎	20[redacted]	894	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	気管支炎	20[redacted]	930	40	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	OTHER	血腫	20[redacted]	413	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	OTHER	消化不良	20[redacted]	646	240	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	OTHER	尿路感染	20[redacted]	646	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	OTHER	扁平上皮癌	20[redacted]	737	149	Y	Grade 3	RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	6[redacted]	F	OTHER	扁平上皮癌	20[redacted]	737	149	Y	Grade 5	RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	血圧上昇	20[redacted]	1	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	血圧上昇	20[redacted]	126	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	下痢	20[redacted]	243	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	貧血	20[redacted]	256	48	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	高血圧	20[redacted]	438	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	慢性腎臓病	20[redacted]	556	330	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心筋梗塞	20[redacted]	598	8	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	変形性関節症	20[redacted]	710	69	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	変形性関節症	20[redacted]	814	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	筋骨格痛	20[redacted]	846	40	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	大腿骨頚部骨折	20[redacted]	882	.	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N

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[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	肺塞栓症	20[redacted]	882	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	心筋虚血	20[redacted]	209	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	尿路感染	20[redacted]	212	64	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	心房細動	20[redacted]	234	10	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	死亡	20[redacted]	451	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	水頭症	20[redacted]	426	10	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	失神	20[redacted]	89	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	手骨折	20[redacted]	414	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	脳血管発作	20[redacted]	949	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	呼吸停止	20[redacted]	949	3	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	大動脈瘤	20[redacted]	87	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	うつ病	20[redacted]	250	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	自殺既遂	20[redacted]	284	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	完全房室ブロック	20[redacted]	313	21	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	医療機器機能不良	20[redacted]	313	21	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	高血圧	20[redacted]	333	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	死亡	20[redacted]	.	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y

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[redacted]	COLOMBIA	ALN 70 MG PO QW		6[redacted]	F	MULTIPLE	耳鳴	20[redacted]	29	81	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW		6[redacted]	F	MULTIPLE	突然死	20[redacted]	109	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	インフルエンザ	20[redacted]	61	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	背部痛	20[redacted]	200	362	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	大動脈狭窄	20[redacted]	223	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	脳虚血	20[redacted]	223	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	貧血	20[redacted]	276	286	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心不全	20[redacted]	557	5	Y	Grade 4	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心筋梗塞	20[redacted]	557	5	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	インフルエンザ	20[redacted]	305	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	大腿骨頚部骨折	20[redacted]	518	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	7[redacted]	F	OTHER	死亡	20[redacted]	661	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	OTHER	頚部痛	20[redacted]	530	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	OTHER	白血球減少症	20[redacted]	733	115	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	ALN 70 MG PO QW	ALN 70 MG PO QW	6[redacted]	F	OTHER	死亡	20[redacted]	847	1	Y	Grade 4	NOT RELATED	FATAL	DOSE NOT CHANGED	REMOVED FROM STUDY	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	15	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	41	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	筋骨格痛	20[redacted]	.	653	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	転倒	20[redacted]	176	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	死亡	20[redacted]	819	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	四肢痛	20[redacted]	.	533	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	浮動性めまい	20[redacted]	.	220	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	接触皮膚炎	20[redacted]	231	439	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	不整脈	20[redacted]	238	432	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	328	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	静脈瘤性潰瘍	20[redacted]	.	136	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	552	21	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	背部痛	20[redacted]	563	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	末梢性浮腫	20[redacted]	569	25	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	596	10	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	658	12	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	上気道感染	20[redacted]	25	67	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	低アルブミン血症	20[redacted]	261	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	丘疹性皮疹	20[redacted]	331	33	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	天疱瘡	20[redacted]	338	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	運動低下	20[redacted]	526	108	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	突然死	20[redacted]	633	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	DOMINICAN REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	貧血	20[redacted]	28	141	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	高血糖	20[redacted]	87	98	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	そう痒症	20[redacted]	96	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	背部痛	20[redacted]	189	711	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	DOMINICAN REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	切開部位感染	20[redacted]	259	641	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	高カルシウム血症	20[redacted]	274	91	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DOMINICAN REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	血小板減少症	20[redacted]	274	273	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DOMINICAN REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	結膜出血	20[redacted]	445	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	憩室	20[redacted]	456	444	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	下部消化管出血	20[redacted]	457	6	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DOMINICAN REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	低ナトリウム血症	20[redacted]	546	188	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	BLACK OR AFRICAN AMERICAN	死亡	20[redacted]	899	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	BLACK OR AFRICAN AMERICAN	上気道感染	20[redacted]	29	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	BLACK OR AFRICAN AMERICAN	上気道感染	20[redacted]	105	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	BLACK OR AFRICAN AMERICAN	膣出血	20[redacted]	.	464	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	BLACK OR AFRICAN AMERICAN	腹痛	20[redacted]	183	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	BLACK OR AFRICAN AMERICAN	上気道感染	20[redacted]	198	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	BLACK OR AFRICAN AMERICAN	子宮頸部扁平上皮癌	20[redacted]	261	325	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	OTHER	N
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	BLACK OR AFRICAN AMERICAN	黄疸	20[redacted]	443	143	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	BLACK OR AFRICAN AMERICAN	うつ病	20[redacted]	545	41	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	BLACK OR AFRICAN AMERICAN	貧血	20[redacted]	555	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	BLACK OR AFRICAN AMERICAN	低カルシウム血症	20[redacted]	555	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	BLACK OR AFRICAN AMERICAN	低ナトリウム血症	20[redacted]	555	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	BLACK OR AFRICAN AMERICAN	リンパ球減少症	20[redacted]	555	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	BLACK OR AFRICAN AMERICAN	好中球増加症	20[redacted]	555	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	BLACK OR AFRICAN AMERICAN	子宮頸部扁平上皮癌	20[redacted]	585	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	骨痛	20[redacted]	34	11	N	Grade 3	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	うつ病	20[redacted]	34	21	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	末梢性浮腫	20[redacted]	34	30	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	背部痛	20[redacted]	88	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	背部痛	20[redacted]	144	653	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	尿路感染	20[redacted]	210	2	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	死亡	20[redacted]	796	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	GUATEMALA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	脳虚血	20[redacted]	722	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	GUATEMALA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	栄養障害	20[redacted]	488	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	下痢	20[redacted]	37	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	血管浮腫	20[redacted]	85	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	便秘	20[redacted]	127	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	胃炎	20[redacted]	127	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	インフルエンザ	20[redacted]	142	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	動脈瘤	20[redacted]	220	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	背部痛	20[redacted]	220	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	坐骨神経痛	20[redacted]	220	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	関節痛	20[redacted]	245	36	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	下痢	20[redacted]	245	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	脳血管障害	20[redacted]	310	55	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	胃炎	20[redacted]	336	29	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	大腿骨頚部骨折	20[redacted]	389	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	7[redacted]	F	OTHER	上室性不整脈	20[redacted]	414	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	GUATEMALA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	急性心筋梗塞	20[redacted]	27	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	排尿困難	20[redacted]	84	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	CULTURE TAKEN	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	口腔カンジダ症	20[redacted]	178	335	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	上腹部痛	20[redacted]	335	178	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	便秘	20[redacted]	335	178	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	結腸腺癌	20[redacted]	373	140	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	GUATEMALA	AMG 785 210 MG SC QM	ALN 70 MG PO QW	8[redacted]	F	OTHER	外科手術	20[redacted]	512	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	GUATEMALA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	気管支炎	20[redacted]	156	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NON-IV ANTIMICROBIAL TAKEN	
[redacted]	GUATEMALA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心房粗動	20[redacted]	270	348	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GUATEMALA	ALN 70 MG PO QW	ALN 70 MG PO QW	8[redacted]	F	OTHER	心障害	20[redacted]	617	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	GUATEMALA	ALN 70 MG PO QW		8[redacted]	F	OTHER	子宮頚部癌	20[redacted]	43	101	Y	Grade 4	NOT RELATED	UNKNOWN	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	GUATEMALA	ALN 70 MG PO QW		8[redacted]	F	OTHER	白血球増加症	20[redacted]	82	62	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	

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[redacted]	GUATEMALA	ALN 70 MG PO QW		8[redacted]	F	OTHER	子宮頚部癌	20[redacted]	143	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	GUATEMALA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	大腿骨骨折	20[redacted]	57	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	GUATEMALA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	肺炎	20[redacted]	134	28	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y