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]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	10	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	インフルエンザ	20[redacted]	112	10	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	288	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	体重減少	20[redacted]	288	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	季節性アレルギー	20[redacted]	.	.	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咳嗽	20[redacted]	.	.	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	444	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	546	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	顎痛	20[redacted]	.	.	Y	Grade 1	RELATED	NOT RESOLVED	DRUG WITHDRAWN	NO ACTION TAKEN	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	下痢	20[redacted]	85	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	医療機器不具合	20[redacted]	140	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	錯乱状態	20[redacted]	.	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	失神	20[redacted]	299	1	N	Grade 2	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	腎不全	20[redacted]	366	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	節足動物咬傷	20[redacted]	306	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	体重減少	20[redacted]	401	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	430	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	結腸腺癌	20[redacted]	.	.	Y	Grade 3	RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	嘔吐	20[redacted]	30	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	リンパ球数減少	20[redacted]	31	62	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	98	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胸部不快感	20[redacted]	.	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	注射部位疼痛	20[redacted]	122	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格硬直	20[redacted]	232	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	235	1	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	注射部位内出血	20[redacted]	244	23	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節腫脹	20[redacted]	285	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血管穿刺部位内出血	20[redacted]	312	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	片耳難聴	20[redacted]	449	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯痛	20[redacted]	695	32	Y	Grade 2	RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上気道感染	20[redacted]	56	51	N	Grade 2	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	体重減少	20[redacted]	56	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	閉経後出血	20[redacted]	.	94	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	口腔咽頭痛	20[redacted]	265	10	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	注射部位疼痛	20[redacted]	275	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	湿性咳嗽	20[redacted]	446	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	468	18	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	コントロール不良の糖尿病	20[redacted]	473	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	34	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	108	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	136	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎結石症	20[redacted]	136	49	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	748	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	便秘	20[redacted]	749	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	悪心	20[redacted]	749	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肝損傷	20[redacted]	777	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	冠動脈疾患	20[redacted]	116	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	白内障	20[redacted]	179	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	眼乾燥	20[redacted]	179	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	眼感染	20[redacted]	179	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	副鼻腔炎	20[redacted]	208	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	鼻咽頭炎	20[redacted]	239	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	頚髄神経根障害	20[redacted]	460	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	椎間板突出	20[redacted]	573	120	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上腕骨骨折	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肩回旋筋腱板症候群	20[redacted]	56	73	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨壊死	20[redacted]	114	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肩回旋筋腱板修復	20[redacted]	128	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格不快感	20[redacted]	182	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯牙破折	20[redacted]	387	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	椎間板変性症	20[redacted]	444	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下痢	20[redacted]	561	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胸痛	20[redacted]	561	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	561	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	564	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋痙縮	20[redacted]	859	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	憩室炎	20[redacted]	1093	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	蜂巣炎	20[redacted]	326	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	接触性皮膚炎	20[redacted]	448	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋力低下	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	接触性皮膚炎	20[redacted]	260	48	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喀血	20[redacted]	348	7	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺腫瘤	20[redacted]	353	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	仙腸骨炎	20[redacted]	437	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	喘息	20[redacted]	205	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	265	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	喘息	20[redacted]	324	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	神経根障害	20[redacted]	.	335	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脊柱管狭窄症	20[redacted]	665	21	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	神経根障害	20[redacted]	686	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	眼乾燥	20[redacted]	89	254	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯膿瘍	20[redacted]	209	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	317	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	317	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯牙破折	20[redacted]	347	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	447	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	線維筋痛	20[redacted]	447	222	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺の良性新生物	20[redacted]	454	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	509	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	509	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低カリウム血症	20[redacted]	527	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大動脈弁狭窄	20[redacted]	527	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心膜炎	20[redacted]	530	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[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]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊椎すべり症	20[redacted]	10	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腰部脊柱管狭窄症	20[redacted]	10	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	204	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	358	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咳嗽	20[redacted]	686	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	114	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	215	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	蜂巣炎	20[redacted]	609	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	蜂巣炎	20[redacted]	705	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	下痢	20[redacted]	88	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	憩室炎	20[redacted]	98	11	N	Grade 3	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	迷路炎	20[redacted]	289	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	迷路炎	20[redacted]	303	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MULTIPLE	

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]	UNITED STATES	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	上気道感染	20[redacted]	306	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	PLACEBO		7[redacted]	F	WHITE	皮膚擦過傷	20[redacted]	27	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	PLACEBO		7[redacted]	F	WHITE	皮膚擦過傷	20[redacted]	27	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	PLACEBO		7[redacted]	F	WHITE	尾骨痛	20[redacted]	60	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	PLACEBO		7[redacted]	F	WHITE	皮膚腫瘤	20[redacted]	60	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	PLACEBO		7[redacted]	F	WHITE	うっ血性心不全	20[redacted]	70	1	N	Grade 3	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	PLACEBO		7[redacted]	F	WHITE	うっ血性心不全	20[redacted]	70	.	Y	Grade 4	RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	UNITED STATES	PLACEBO		7[redacted]	F	WHITE	悪心	20[redacted]	70	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	PLACEBO		7[redacted]	F	WHITE	高カリウム血症	20[redacted]	74	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	便秘	20[redacted]	182	1	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺炎	20[redacted]	182	9	Y	Grade 4	RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺炎	20[redacted]	182	17	N	Grade 3	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血糖	20[redacted]	182	26	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	便秘	20[redacted]	185	1	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心房細動	20[redacted]	185	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	浮腫	20[redacted]	186	1	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腹痛	20[redacted]	228	19	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低カリウム血症	20[redacted]	297	22	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肛門直腸不快感	20[redacted]	302	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腹痛	20[redacted]	302	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高脂血症	20[redacted]	303	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	便潜血陽性	20[redacted]	304	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	悪心	20[redacted]	462	101	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	精神状態変化	20[redacted]	681	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	徐脈	20[redacted]	710	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	複合アレルギー	20[redacted]	42	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	睡眠時無呼吸症候群	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性胃腸炎	20[redacted]	149	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	168	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿失禁	20[redacted]	224	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	224	6	N	Grade 1	RELATED		DOSE ALTERED OR WITHHELD	MULTIPLE	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	日常生活動作障害者	20[redacted]	224	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	橈骨骨折	20[redacted]	224	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	224	4	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	靭帯捻挫	20[redacted]	224	50	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	靭帯捻挫	20[redacted]	224	50	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	便秘	20[redacted]	225	3	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不眠症	20[redacted]	234	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咳嗽	20[redacted]	238	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	副鼻腔炎	20[redacted]	249	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	252	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	302	11	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	343	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	狭窄性腱鞘炎	20[redacted]	.	.	N	Grade 2	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	双極２型障害	20[redacted]	409	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	胃腸障害	20[redacted]	1	6	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	大腿骨骨折	20[redacted]	35	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	便秘	20[redacted]	37	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	無気肺	20[redacted]	37	4	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	不眠症	20[redacted]	41	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	胃潰瘍	20[redacted]	200	.	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	便秘	20[redacted]	.	.	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	痔核	20[redacted]	232	.	N	Grade 3	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	筋力低下	20[redacted]	.	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	真菌感染	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	足部白癬	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	304	3	Y	Grade 3	RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	上気道感染	20[redacted]	.	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	歯の脱落	20[redacted]	367	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	体位性めまい	20[redacted]	.	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	挫傷	20[redacted]	446	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	インフルエンザ様疾患	20[redacted]	456	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	呼吸困難	20[redacted]	1	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	1	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胸痛	20[redacted]	1	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃炎	20[redacted]	106	.	N	Grade 3	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	下痢	20[redacted]	119	.	N	Grade 2	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃ポリープ	20[redacted]	167	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心臓弁閉鎖不全	20[redacted]	207	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	214	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	狭心症	20[redacted]	259	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	貧血	20[redacted]	.	129	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不安定狭心症	20[redacted]	303	14	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	虚血性心筋症	20[redacted]	303	245	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	冠動脈硬化症	20[redacted]	306	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	無力症	20[redacted]	310	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	失神	20[redacted]	329	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	冠動脈疾患	20[redacted]	346	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性咽頭炎	20[redacted]	360	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不安	20[redacted]	367	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肋軟骨炎	20[redacted]	374	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	失神	20[redacted]	400	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心房細動	20[redacted]	400	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心房細動	20[redacted]	404	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脂質異常症	20[redacted]	424	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	虚血性心筋症	20[redacted]	548	158	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	虚血性心筋症	20[redacted]	706	.	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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋骨格痛	20[redacted]	73	.	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]	73	32	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	鼻咽頭炎	20[redacted]	87	7	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	変形性関節症	20[redacted]	.	240	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	アレルギー性皮膚炎	20[redacted]	130	15	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	蜂巣炎	20[redacted]	170	11	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	上腕骨骨折	20[redacted]	178	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	四肢痛	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	ウイルス性上気道感染	20[redacted]	441	9	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	高血圧	20[redacted]	480	.	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	蜂巣炎	20[redacted]	493	13	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	変形性関節症	20[redacted]	523	.	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	鼻咽頭炎	20[redacted]	532	.	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	蜂巣炎	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	頚部痛	20[redacted]	17	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	腎不全	20[redacted]	28	63	N	Grade 3	NOT RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	蕁麻疹	20[redacted]	126	64	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	不眠症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	敗血症	20[redacted]	140	15	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	動脈瘤	20[redacted]	145	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	側腹部痛	20[redacted]	230	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	筋骨格痛	20[redacted]	301	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	腎性貧血	20[redacted]	303	145	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	高カリウム血症	20[redacted]	314	134	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	蕁麻疹	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	糖尿病	20[redacted]	600	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	蜂巣炎	20[redacted]	602	9	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	糖尿病	20[redacted]	604	7	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	慢性腎臓病	20[redacted]	605	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	低血圧	20[redacted]	606	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	糖尿病	20[redacted]	611	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	過角化	20[redacted]	625	.	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	喘息クリーゼ	20[redacted]	19	29	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	ウイルス性気道感染	20[redacted]	44	4	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	喘息クリーゼ	20[redacted]	48	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	不眠症	20[redacted]	63	31	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	脂質異常症	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	感染性腸炎	20[redacted]	89	8	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	斑	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	子宮出血	20[redacted]	174	19	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	喘息	20[redacted]	181	.	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	胸痛	20[redacted]	186	.	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]	204	.	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	喘息クリーゼ	20[redacted]	228	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肺炎	20[redacted]	228	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭痛	20[redacted]	228	4	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	肺炎	20[redacted]	238	21	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	背部痛	20[redacted]	254	29	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	鼻咽頭炎	20[redacted]	302	.	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	喘息	20[redacted]	501	19	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	結膜出血	20[redacted]	530	5	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	頭痛	20[redacted]	530	3	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	鼻咽頭炎	20[redacted]	619	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性気道感染	20[redacted]	5	4	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	背部痛	20[redacted]	5	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	歯周炎	20[redacted]	98	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	錯感覚	20[redacted]	98	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	筋骨格痛	20[redacted]	101	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	四肢痛	20[redacted]	.	150	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	気道感染	20[redacted]	109	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	嚥下痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	末梢性浮腫	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	食欲減退	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性気道感染	20[redacted]	247	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性気道感染	20[redacted]	247	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	転倒	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	手骨折	20[redacted]	314	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	手骨折	20[redacted]	314	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	384	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	うつ病	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	末梢性浮腫	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	腹痛	20[redacted]	413	26	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	貧血	20[redacted]	428	149	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	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		7[redacted]	F	OTHER	四肢痛	20[redacted]	2	49	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	背部痛	20[redacted]	66	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	変形性関節症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	全身性浮腫	20[redacted]	.	79	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	高血圧クリーゼ	20[redacted]	177	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	尿路感染	20[redacted]	179	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	食中毒	20[redacted]	218	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	健忘	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	咳嗽	20[redacted]	263	141	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	眼乾燥	20[redacted]	268	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	緑内障	20[redacted]	268	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	高血圧クリーゼ	20[redacted]	270	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	下部消化管出血	20[redacted]	398	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	高血圧	20[redacted]	399	.	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	尿路感染	20[redacted]	80	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	末梢動脈血栓症	20[redacted]	96	3	Y	Grade 3	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]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	116	1	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	皮膚炎	20[redacted]	140	21	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	背部痛	20[redacted]	178	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋骨格痛	20[redacted]	180	10	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	214	.	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	背部痛	20[redacted]	214	.	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	転倒	20[redacted]	214	1	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	関節痛	20[redacted]	214	.	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	四肢損傷	20[redacted]	237	.	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	変形性脊椎症	20[redacted]	240	.	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	変形性関節症	20[redacted]	240	.	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	変形性関節症	20[redacted]	240	.	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	脊柱変形	20[redacted]	240	.	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	ウイルス性上気道感染	20[redacted]	259	9	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃腸出血	20[redacted]	267	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	痔核	20[redacted]	268	.	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	結膜出血	20[redacted]	325	9	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	皮膚炎	20[redacted]	430	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	437	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	筋痙縮	20[redacted]	35	.	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]	.	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	悲嘆反応	20[redacted]	50	.	N	Grade 3	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	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尿路感染	20[redacted]	73	8	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	.	94	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	食欲減退	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	浮動性めまい	20[redacted]	231	87	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	うつ病	20[redacted]	.	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	細菌性気管支炎	20[redacted]	357	22	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	悪心	20[redacted]	1	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	頭痛	20[redacted]	27	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	糖尿病	20[redacted]	57	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	筋肉痛	20[redacted]	81	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	肺の悪性新生物	20[redacted]	141	156	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	UNKNOWN	N
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	腸憩室	20[redacted]	159	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	臍ヘルニア	20[redacted]	159	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	蕁麻疹	20[redacted]	250	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	便秘	20[redacted]	253	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	外傷性気胸	20[redacted]	255	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	皮下気腫	20[redacted]	255	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	カテーテル留置部位疼痛	20[redacted]	256	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	変形性関節症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	薬物不耐性	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	大腸腺腫	20[redacted]	586	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	痔核	20[redacted]	586	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	変形性脊椎症	20[redacted]	599	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	腎嚢胞	20[redacted]	599	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	下痢	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	88	5	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	159	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	扁桃炎	20[redacted]	224	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	扁桃炎	20[redacted]	264	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	筋肉痛	20[redacted]	269	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	低ナトリウム血症	20[redacted]	271	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	体内異物	20[redacted]	279	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	細菌性肺炎	20[redacted]	279	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	副鼻腔ポリープ	20[redacted]	281	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	甲状腺腫	20[redacted]	281	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	急性呼吸窮迫症候群	20[redacted]	309	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	リンパ腫	20[redacted]	316	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	便秘	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	創部内臓脱出	20[redacted]	.	15	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	口腔カンジダ症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	好中球減少症	20[redacted]	.	.	N	Grade 3	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	細菌性腹膜炎	20[redacted]	.	18	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[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

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	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	
[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	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	咽喉刺激感	20[redacted]	16	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	体重減少	20[redacted]	17	217	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	胸痛	20[redacted]	17	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	気管支炎	20[redacted]	77	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	健忘	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	176	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	甲状腺機能低下症	20[redacted]	190	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	肋軟骨炎	20[redacted]	271	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	肋軟骨炎	20[redacted]	288	3	N	Grade 2	RELATED		DRUG WITHDRAWN	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	細菌性咽頭炎	20[redacted]	330	12	Y	Grade 3	RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	頭痛	20[redacted]	540	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	コントロール不良の糖尿病	20[redacted]	5	100	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	寄生虫性胃腸炎	20[redacted]	11	77	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	変形性関節症	20[redacted]	66	91	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	ウイルス性気道感染	20[redacted]	68	16	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	関節痛	20[redacted]	113	.	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	関節痛	20[redacted]	117	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性下痢	20[redacted]	154	9	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	頭痛	20[redacted]	155	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	錯感覚	20[redacted]	201	19	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	食欲減退	20[redacted]	240	98	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	不安	20[redacted]	.	89	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	腹痛	20[redacted]	255	26	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	変形性関節症	20[redacted]	338	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	子宮瘤	20[redacted]	622	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	膀胱瘤	20[redacted]	622	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	

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	7[redacted]	F	OTHER	筋肉痛	20[redacted]	8	36	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頚部痛	20[redacted]	96	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	便秘	20[redacted]	134	40	N	Grade 1	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋骨格痛	20[redacted]	136	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	158	26	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不眠症	20[redacted]	195	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	195	157	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不眠症	20[redacted]	326	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋痙縮	20[redacted]	346	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	細菌性肺炎	20[redacted]	429	15	Y	Grade 2	RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	非心臓性胸痛	20[redacted]	666	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	回転性めまい	20[redacted]	37	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	腎機能障害	20[redacted]	46	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	高血圧	20[redacted]	51	38	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	背部痛	20[redacted]	79	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	変形性脊椎症	20[redacted]	88	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	高血圧	20[redacted]	123	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	細菌性気管支炎	20[redacted]	147	33	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	脳血管障害	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	細菌性気道感染	20[redacted]	218	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	腎症	20[redacted]	246	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	腎盂腎杯拡張症	20[redacted]	246	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	動脈硬化症	20[redacted]	251	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	頚動脈硬化症	20[redacted]	251	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	頚動脈硬化症	20[redacted]	251	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	便秘	20[redacted]	280	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	細菌性尿路感染	20[redacted]	280	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	胃炎	20[redacted]	287	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	動脈硬化症	20[redacted]	288	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	肝石灰化	20[redacted]	288	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	腎石灰沈着症	20[redacted]	288	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	腎障害	20[redacted]	288	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	裂孔ヘルニア	20[redacted]	288	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	ウイルス性下痢	20[redacted]	318	4	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	ウイルス性下痢	20[redacted]	341	5	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	２型糖尿病	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	36	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	気道感染	20[redacted]	41	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	基底細胞癌	20[redacted]	77	256	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	皮膚有棘細胞癌	20[redacted]	77	256	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	回転性めまい	20[redacted]	137	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃食道逆流性疾患	20[redacted]	137	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃炎	20[redacted]	151	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	白内障	20[redacted]	177	505	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	188	9	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	皮下組織膿瘍	20[redacted]	221	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	緑内障	20[redacted]	224	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	20[redacted]	305	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	動物咬傷	20[redacted]	326	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	346	3	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	444	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	眼乾燥	20[redacted]	512	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	炭水化物不耐症	20[redacted]	542	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脂質異常症	20[redacted]	568	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低血糖	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	白内障	20[redacted]	681	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	感覚異常性大腿神経痛	20[redacted]	14	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	気管支炎	20[redacted]	.	.	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	鼻炎	20[redacted]	.	150	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	口腔内潰瘍形成	20[redacted]	55	6	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	椎間板障害	20[redacted]	67	.	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	口腔カンジダ症	20[redacted]	.	.	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	鼻咽頭炎	20[redacted]	91	7	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胃炎	20[redacted]	151	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	慢性腎臓病	20[redacted]	184	.	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	無力症	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	不眠症	20[redacted]	.	.	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	歯の脱落	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	頭痛	20[redacted]	293	2	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	口内炎	20[redacted]	322	18	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	気道感染	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	甲状腺機能低下症	20[redacted]	.	.	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]	89	3	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	耳鳴	20[redacted]	149	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	坐骨神経痛	20[redacted]	175	333	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	四肢痛	20[redacted]	495	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	動脈硬化症	20[redacted]	516	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	大腸潰瘍	20[redacted]	610	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	腸憩室	20[redacted]	610	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胆石症	20[redacted]	613	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	臍ヘルニア	20[redacted]	613	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	大腸潰瘍	20[redacted]	616	.	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	筋痙縮	20[redacted]	1	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	変形性脊椎症	20[redacted]	48	.	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	鼻咽頭炎	20[redacted]	125	17	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	末梢性浮腫	20[redacted]	200	.	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	関節痛	20[redacted]	209	.	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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	361	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	うつ病	20[redacted]	439	.	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	交通事故	20[redacted]	439	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢損傷	20[redacted]	439	.	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	筋力低下	20[redacted]	439	.	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	脳血腫	20[redacted]	439	63	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節損傷	20[redacted]	439	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭部損傷	20[redacted]	439	28	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	メニエール病	20[redacted]	441	64	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	末梢静脈疾患	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	硬膜下血腫	20[redacted]	502	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	502	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	下痢	20[redacted]	528	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	変形性関節症	20[redacted]	.	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不眠症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	外陰腟そう痒症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿失禁	20[redacted]	706	.	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	頭痛	20[redacted]	48	58	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	急性膵炎	20[redacted]	103	5	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	胆石症	20[redacted]	104	3	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	錯感覚	20[redacted]	145	16	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	頭痛	20[redacted]	212	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	発熱	20[redacted]	184	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	細菌性尿路感染	20[redacted]	184	20	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	262	9	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	急性中耳炎	20[redacted]	441	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高血圧	20[redacted]	448	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	525	13	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]	704	.	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	背部痛	20[redacted]	104	9	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	背部痛	20[redacted]	165	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頚部痛	20[redacted]	167	46	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	頭痛	20[redacted]	172	.	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	関節痛	20[redacted]	195	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	錯感覚	20[redacted]	213	9	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	細菌性膣炎	20[redacted]	224	17	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	膣血腫	20[redacted]	224	17	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	傾眠	20[redacted]	234	.	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	術後貧血	20[redacted]	234	42	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	筋力低下	20[redacted]	241	48	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	背部痛	20[redacted]	258	18	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	300	3	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	328	18	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	関節痛	20[redacted]	420	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	434	.	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	消化不良	20[redacted]	445	.	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		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
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	食欲減退	20[redacted]	.	.	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	筋肉痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	体重減少	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[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	7[redacted]	F	OTHER	全身性そう痒症	20[redacted]	432	.	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]	.	.	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	放線菌性肺感染	20[redacted]	.	23	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	チクングニヤウイルス感染	20[redacted]	485	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	糖尿病	20[redacted]	34	235	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	糖尿病性足病変	20[redacted]	.	.	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	心雑音	20[redacted]	217	.	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	高血圧	20[redacted]	538	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ジスキネジア	20[redacted]	.	.	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]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	糖尿病	20[redacted]	700	19	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	左脚ブロック	20[redacted]	704	.	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	心房細動	20[redacted]	708	.	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	心臓弁閉鎖不全	20[redacted]	708	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	抑うつ症状	20[redacted]	119	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	甲状腺の良性新生物	20[redacted]	120	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	甲状腺機能低下症	20[redacted]	120	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	甲状腺腫	20[redacted]	120	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃食道逆流性疾患	20[redacted]	138	93	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	変形性脊椎症	20[redacted]	232	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	変形性関節症	20[redacted]	232	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	蜂巣炎	20[redacted]	714	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[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	

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	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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	貧血	20[redacted]	1	269	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	貧血	20[redacted]	72	.	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	浮動性めまい	20[redacted]	143	6	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	ウイルス性上気道感染	20[redacted]	182	23	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	発疹	20[redacted]	211	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	217	17	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	細菌性尿路感染	20[redacted]	297	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	貧血	20[redacted]	535	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[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
[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	

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[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	PLACEBO		7[redacted]	F	OTHER	脳虚血	20[redacted]	17	.	Y	Grade 2	NOT RELATED	UNKNOWN	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	期外収縮	20[redacted]	1	94	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]	24	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	爪囲炎	20[redacted]	28	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	非心臓性胸痛	20[redacted]	41	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	腎機能障害	20[redacted]	86	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頚部痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	皮膚真菌感染	20[redacted]	114	56	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	.	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	浮動性めまい	20[redacted]	225	54	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	尿路感染	20[redacted]	342	118	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	末梢性浮腫	20[redacted]	443	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	側弯症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	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	PLACEBO	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	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	パーキンソン病	20[redacted]	677	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	体重減少	20[redacted]	725	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	糖尿病性腎症	20[redacted]	34	.	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	低血糖	20[redacted]	57	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	糖尿病	20[redacted]	145	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	蜂巣炎	20[redacted]	163	19	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	呼吸不全	20[redacted]	181	.	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	関節痛	20[redacted]	211	.	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	20[redacted]	243	.	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	高トリグリセリド血症	20[redacted]	303	.	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	動脈閉塞性疾患	20[redacted]	.	72	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	末梢動脈閉塞性疾患	20[redacted]	.	239	N	Grade 3	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	20[redacted]	331	.	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	うつ病	20[redacted]	.	.	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	低血糖	20[redacted]	375	.	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	喉頭炎	20[redacted]	544	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	末梢動脈閉塞性疾患	20[redacted]	566	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	失神	20[redacted]	668	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	668	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	下痢	20[redacted]	671	1	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	僧帽弁硬化症	20[redacted]	671	.	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	第一度房室ブロック	20[redacted]	671	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	損傷	20[redacted]	13	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	四肢痛	20[redacted]	.	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	損傷	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	傾眠	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	視力低下	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	錯感覚	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	気道感染	20[redacted]	100	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	薬物不耐性	20[redacted]	115	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[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		8[redacted]	F	OTHER	関節痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	高血圧	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	腟感染	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	細菌性肺炎	20[redacted]	430	14	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	四肢痛	20[redacted]	432	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	心拡大	20[redacted]	435	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	そう痒症	20[redacted]	440	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	無力症	20[redacted]	440	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	四肢痛	20[redacted]	56	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	60	4	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]	61	173	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	20[redacted]	77	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	204	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	創傷	20[redacted]	208	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	変形性脊椎症	20[redacted]	208	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	恥骨骨折	20[redacted]	208	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肋骨骨折	20[redacted]	208	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胸水	20[redacted]	208	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	脊椎骨折	20[redacted]	208	90	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	脛骨骨折	20[redacted]	208	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	腓骨骨折	20[redacted]	208	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	貧血	20[redacted]	208	425	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭蓋脳損傷	20[redacted]	208	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	骨盤血腫	20[redacted]	208	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	細菌性肺炎	20[redacted]	210	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	血小板減少症	20[redacted]	210	45	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	低カリウム血症	20[redacted]	211	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	低血糖	20[redacted]	211	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	心室性不整脈	20[redacted]	211	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	静脈血栓症	20[redacted]	212	86	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	心拡大	20[redacted]	213	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	細菌性気管炎	20[redacted]	213	8	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]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	高血圧	20[redacted]	213	102	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭蓋内出血	20[redacted]	289	18	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	創傷感染	20[redacted]	353	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	高血圧	20[redacted]	365	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	438	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	細菌性創感染	20[redacted]	506	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	慢性骨髄炎	20[redacted]	.	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	20[redacted]	.	260	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	過敏性腸症候群	20[redacted]	.	.	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	憩室	20[redacted]	8	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	憩室	20[redacted]	33	12	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	低カリウム血症	20[redacted]	41	4	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	低ナトリウム血症	20[redacted]	41	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	慢性腎臓病	20[redacted]	41	157	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	蛋白尿	20[redacted]	41	157	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	閉経期症状	20[redacted]	139	.	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	甲状腺機能低下症	20[redacted]	171	.	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	脂質異常症	20[redacted]	197	.	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	尿路感染	20[redacted]	236	.	N	Grade 1	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	20[redacted]	265	.	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	過敏性腸症候群	20[redacted]	496	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[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	

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[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	
[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	PLACEBO		6[redacted]	F	OTHER	腹痛	20[redacted]	34	179	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	68	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	下痢	20[redacted]	77	368	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	高血糖	20[redacted]	87	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	関節痛	20[redacted]	166	236	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	うつ病	20[redacted]	176	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	腹痛	20[redacted]	262	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	膵神経内分泌腫瘍	20[redacted]	267	30	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	膵癌	20[redacted]	289	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	脂質異常症	20[redacted]	297	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	低換気	20[redacted]	298	112	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	膝瘻	20[redacted]	298	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	貧血	20[redacted]	298	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	TRANSFUSION PERFORMED	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	電解質失調	20[redacted]	298	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	高血糖	20[redacted]	298	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	下痢	20[redacted]	301	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	肋軟骨炎	20[redacted]	311	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	離脱症候群	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	便秘	20[redacted]	324	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	側弯症	20[redacted]	324	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	虚血性大腸炎	20[redacted]	329	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	下部消化管出血	20[redacted]	331	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	下痢	20[redacted]	332	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	消化器カンジダ症	20[redacted]	332	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	胃炎	20[redacted]	332	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	腸憩室	20[redacted]	332	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	接触性皮膚炎	20[redacted]	336	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	腹痛	20[redacted]	358	2	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	糖尿病	20[redacted]	427	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	脂肪肝	20[redacted]	439	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	創離開	20[redacted]	454	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	糖尿病性ケトアシドーシス	20[redacted]	454	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	乾皮症	20[redacted]	.	.	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	高血圧	20[redacted]	35	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	注射部位内出血	20[redacted]	59	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	指変形	20[redacted]	.	.	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	ウイルス性上気道感染	20[redacted]	131	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	外陰腟そう痒症	20[redacted]	162	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	176	31	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	尿路感染	20[redacted]	235	13	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	筋痙縮	20[redacted]	246	27	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	283	1	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	顔面損傷	20[redacted]	283	33	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	334	.	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	高血圧	20[redacted]	345	.	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	高血糖	20[redacted]	360	.	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	関節痛	20[redacted]	.	.	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	健忘	20[redacted]	.	.	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	関節痛	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	7[redacted]	F	OTHER	失神	20[redacted]	686	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	悪心	20[redacted]	686	4	N	Grade 1	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]	686	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	挫傷	20[redacted]	686	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	頭痛	20[redacted]	686	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	便秘	20[redacted]	43	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	頭痛	20[redacted]	45	23	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	筋痙縮	20[redacted]	50	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	回転性めまい	20[redacted]	93	10	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	頭痛	20[redacted]	94	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高血圧	20[redacted]	94	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	下腹部痛	20[redacted]	158	33	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	筋拘縮	20[redacted]	206	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	不眠症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	背部痛	20[redacted]	511	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	上室性頻脈	20[redacted]	701	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	大動脈弁硬化症	20[redacted]	702	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	左房拡張	20[redacted]	702	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	上室性頻脈	20[redacted]	705	.	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	橈骨骨折	20[redacted]	8	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	8	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脊椎骨折	20[redacted]	8	135	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	8	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	薬物不耐性	20[redacted]	15	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	脊椎圧迫骨折	20[redacted]	27	.	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	四肢痛	20[redacted]	125	.	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	頚部痛	20[redacted]	125	36	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	手関節変形	20[redacted]	146	.	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	頚部痛	20[redacted]	203	14	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	非心臓性胸痛	20[redacted]	205	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肩回旋筋腱板症候群	20[redacted]	279	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	嚥下痛	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	7[redacted]	F	OTHER	アトピー性皮膚炎	20[redacted]	.	.	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	関節痛	20[redacted]	.	.	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	動悸	20[redacted]	16	.	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	大動脈弁閉鎖不全症	20[redacted]	85	.	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	拡張機能障害	20[redacted]	85	.	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	変形性関節症	20[redacted]	94	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	変形性関節症	20[redacted]	94	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	胃腸音異常	20[redacted]	.	.	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	甲状腺機能低下症	20[redacted]	128	.	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	慢性閉塞性肺疾患	20[redacted]	136	34	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	口内乾燥	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	8[redacted]	F	OTHER	変形性関節症	20[redacted]	168	.	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	心拡大	20[redacted]	168	.	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	慢性閉塞性肺疾患	20[redacted]	168	.	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	腱断裂	20[redacted]	.	.	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	高血圧	20[redacted]	226	15	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	慢性胃炎	20[redacted]	236	.	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	うっ血性心不全	20[redacted]	336	10	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	336	10	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	低カルシウム血症	20[redacted]	339	.	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	脳症	20[redacted]	339	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	転倒	20[redacted]	339	1	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	慢性閉塞性肺疾患	20[redacted]	342	.	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	肺高血圧症	20[redacted]	342	.	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	うっ血性心不全	20[redacted]	346	.	N	Grade 2	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]	59	14	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胆石症	20[redacted]	63	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	135	15	N	Grade 1	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]	188	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	心拡大	20[redacted]	190	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	挫傷	20[redacted]	190	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	転倒	20[redacted]	190	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	挫傷	20[redacted]	191	147	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	背部痛	20[redacted]	212	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	靭帯捻挫	20[redacted]	218	67	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	頭痛	20[redacted]	281	60	N	Grade 2	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]	.	.	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]	483	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	筋力低下	20[redacted]	484	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胃食道逆流性疾患	20[redacted]	485	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	裂孔ヘルニア	20[redacted]	485	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	糖尿病	20[redacted]	486	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	530	.	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	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	脛骨骨折	20[redacted]	44	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	腓骨骨折	20[redacted]	44	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	足骨折	20[redacted]	44	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	大腿骨骨折	20[redacted]	87	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	骨折痛	20[redacted]	87	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	慢性骨髄炎	20[redacted]	129	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	嘔吐	20[redacted]	182	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭痛	20[redacted]	183	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	貧血	20[redacted]	184	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	耳鳴	20[redacted]	200	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	動悸	20[redacted]	212	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	四肢痛	20[redacted]	363	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	無力症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	手根管症候群	20[redacted]	448	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	うつ病	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胃炎	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	164	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	細菌性尿路感染	20[redacted]	176	85	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頚部痛	20[redacted]	.	155	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	254	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頻脈性不整脈	20[redacted]	275	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	細菌性咽頭炎	20[redacted]	279	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頻脈性不整脈	20[redacted]	353	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	

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	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	375	20	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	375	.	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	気道感染	20[redacted]	22	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	47	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	72	.	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	142	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	158	21	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	ウイルス性上気道感染	20[redacted]	241	15	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	背部痛	20[redacted]	247	.	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	浮動性めまい	20[redacted]	332	1	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	好中球減少症	20[redacted]	599	127	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	貧血	20[redacted]	599	127	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	慢性閉塞性肺疾患	20[redacted]	608	.	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	大動脈硬化症	20[redacted]	618	.	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	体部白癬	20[redacted]	.	.	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	急性骨髄性白血病	20[redacted]	726	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	貧血	20[redacted]	726	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	24	23	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]	71	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	腹部膨満	20[redacted]	85	33	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭痛	20[redacted]	85	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	103	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	皮膚病変	20[redacted]	107	.	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	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	高血圧	20[redacted]	240	81	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	244	71	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	四肢損傷	20[redacted]	247	43	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]	247	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋骨格痛	20[redacted]	264	.	N	Grade 2	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]	291	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	甲状腺新生物	20[redacted]	298	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	321	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	眼瞼損傷	20[redacted]	325	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	四肢損傷	20[redacted]	358	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	転倒	20[redacted]	358	1	N	Grade 2	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]	358	.	N	Grade 2	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]	358	.	N	Grade 2	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]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	卵巣癌	20[redacted]	447	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	低クロール血症	20[redacted]	465	.	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	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	

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[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
[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	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	.	43	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋痙縮	20[redacted]	13	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	注射部位疼痛	20[redacted]	117	3	N	Grade 1	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭痛	20[redacted]	117	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	うつ病	20[redacted]	.	107	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胃炎	20[redacted]	244	39	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	6[redacted]	F	OTHER	細菌性尿路感染	20[redacted]	260	36	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	低血圧	20[redacted]	275	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	変形性脊椎症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	変形性関節症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	20[redacted]	361	4	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	361	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭痛	20[redacted]	361	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	細菌性副鼻腔炎	20[redacted]	362	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	鼓膜障害	20[redacted]	362	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	444	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋痙縮	20[redacted]	448	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胃炎	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	変形性脊椎症	20[redacted]	657	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	骨端症	20[redacted]	657	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	甲状腺機能低下症	20[redacted]	662	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	脂質異常症	20[redacted]	662	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	うつ病	20[redacted]	.	.	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	腎不全	20[redacted]	36	91	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	ウイルス性上気道感染	20[redacted]	238	9	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	心不全	20[redacted]	392	32	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	下痢	20[redacted]	398	63	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	血小板減少症	20[redacted]	402	311	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	貧血	20[redacted]	402	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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	6[redacted]	F	OTHER	電解質失調	20[redacted]	402	69	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	心臓弁閉鎖不全	20[redacted]	403	21	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肺高血圧症	20[redacted]	403	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	虚血性心筋症	20[redacted]	403	.	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	高血圧性心筋症	20[redacted]	403	.	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	慢性閉塞性肺疾患	20[redacted]	406	9	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	尿路感染	20[redacted]	408	7	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	肺炎	20[redacted]	412	67	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肺水腫	20[redacted]	414	44	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	寄生虫性胃腸炎	20[redacted]	421	14	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	高血糖	20[redacted]	423	30	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	心房細動	20[redacted]	424	12	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	尿路感染	20[redacted]	431	15	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	大動脈解離	20[redacted]	444	.	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	甲状腺機能低下症	20[redacted]	464	.	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	下痢	20[redacted]	486	4	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	慢性腎臓病	20[redacted]	548	.	N	Grade 2	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]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	下痢	20[redacted]	174	4	N	Grade 1	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]	245	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	アレルギー性皮膚炎	20[redacted]	312	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	感染による慢性閉塞性気道疾患の増悪	20[redacted]	312	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋痙縮	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	認知障害	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	20[redacted]	510	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	大動脈硬化症	20[redacted]	534	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	脊柱変形	20[redacted]	534	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	脊椎すべり症	20[redacted]	534	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肺炎	20[redacted]	616	19	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	低カリウム血症	20[redacted]	623	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	呼吸不全	20[redacted]	623	6	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	呼吸性アシドーシス	20[redacted]	623	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	気管支吸引	20[redacted]	623	6	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	薬物過敏症	20[redacted]	623	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	冠動脈疾患	20[redacted]	631	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	尿路感染	20[redacted]	709	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	31	8	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	過敏性腸症候群	20[redacted]	116	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	変形性関節症	20[redacted]	190	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	処置による疼痛	20[redacted]	197	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	手骨折	20[redacted]	234	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	234	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	250	38	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹痛	20[redacted]	279	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脂質異常症	20[redacted]	286	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃炎	20[redacted]	673	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	便秘	20[redacted]	682	.	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	アルコールによる宿酔	20[redacted]	19	3	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	四肢痛	20[redacted]	26	12	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	四肢痛	20[redacted]	178	44	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	ウイルス性上気道感染	20[redacted]	266	9	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胆石症	20[redacted]	311	10	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	急性腎不全	20[redacted]	313	5	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	起立性高血圧	20[redacted]	313	8	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	高血圧	20[redacted]	313	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	大動脈瘤	20[redacted]	315	.	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	心拡大	20[redacted]	315	.	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	薬疹	20[redacted]	317	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	変形性関節症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	白内障	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	30	4	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]	53	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不眠症	20[redacted]	76	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	82	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	148	97	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	血栓症	20[redacted]	176	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頚部痛	20[redacted]	215	35	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	221	21	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	233	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頚部痛	20[redacted]	331	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頚動脈狭窄	20[redacted]	621	18	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頚動脈閉塞	20[redacted]	621	18	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	白質脳症	20[redacted]	627	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ビタミンＢ群欠乏	20[redacted]	628	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脂質異常症	20[redacted]	628	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭蓋内動脈瘤	20[redacted]	635	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	咳嗽	20[redacted]	29	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	無力症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	20[redacted]	266	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	転倒	20[redacted]	266	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭痛	20[redacted]	273	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	歯牙破折	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋肉痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	皮膚炎	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	皮膚炎	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	急性胆嚢炎	20[redacted]	463	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	高血圧緊急症	20[redacted]	464	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	膵炎	20[redacted]	465	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	側弯症	20[redacted]	640	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	変形性脊椎症	20[redacted]	640	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	歯牙破折	20[redacted]	691	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	1	33	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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不眠症	20[redacted]	29	252	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	鼻咽頭炎	20[redacted]	74	8	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	静脈瘤	20[redacted]	116	.	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	ウイルス性上気道感染	20[redacted]	132	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	205	15	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	四肢痛	20[redacted]	275	195	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	ウイルス性上気道感染	20[redacted]	327	9	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	四肢痛	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	7[redacted]	F	OTHER	四肢痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	.	112	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	甲状腺腫	20[redacted]	359	.	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	アレルギー性皮膚炎	20[redacted]	.	.	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	肺炎	20[redacted]	538	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	587	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	臍ヘルニア	20[redacted]	588	.	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	電解質失調	20[redacted]	588	3	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	便秘	20[redacted]	590	.	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	変形性脊椎症	20[redacted]	590	.	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	肝嚢胞	20[redacted]	590	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脂肪肝	20[redacted]	590	.	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	腸憩室	20[redacted]	590	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	中足骨痛	20[redacted]	30	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	下痢	20[redacted]	91	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]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	憩室炎	20[redacted]	91	9	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	電解質失調	20[redacted]	94	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	大腸狭窄	20[redacted]	142	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	憩室	20[redacted]	142	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	痔核	20[redacted]	142	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脂質異常症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頚部痛	20[redacted]	.	337	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性下痢	20[redacted]	182	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	好中球減少症	20[redacted]	184	177	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	白血球減少症	20[redacted]	184	85	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	子宮内膜形成不全	20[redacted]	200	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	296	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	好酸球増加症	20[redacted]	360	174	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	関節痛	20[redacted]	43	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	会陰損傷	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	心不全	20[redacted]	.	.	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	耐糖能障害	20[redacted]	.	221	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	胸水	20[redacted]	65	36	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	胸膜転移	20[redacted]	91	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	不眠症	20[redacted]	98	.	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	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		6[redacted]	F	OTHER	急性呼吸窮迫症候群	20[redacted]	101	20	Y	Grade 4	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	原発性甲状腺機能低下症	20[redacted]	110	.	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	低色素性貧血	20[redacted]	112	252	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	肺高血圧症	20[redacted]	112	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	慢性胃炎	20[redacted]	113	.	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	痔核	20[redacted]	114	.	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	便秘	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	膀胱痙縮	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	好中球減少症	20[redacted]	210	65	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	白血球減少症	20[redacted]	210	65	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	ウイルス性下痢	20[redacted]	258	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	胆石症	20[redacted]	262	205	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	背部痛	20[redacted]	316	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	便秘	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	膀胱炎	20[redacted]	457	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	四肢痛	20[redacted]	464	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	急性腎不全	20[redacted]	154	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	TRANSFUSION PERFORMED	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	胃潰瘍	20[redacted]	154	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	血液量減少性ショック	20[redacted]	154	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	血液量減少性ショック	20[redacted]	154	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	TRANSFUSION PERFORMED	

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[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	貧血	20[redacted]	154	33	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	TRANSFUSION PERFORMED	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	便秘	20[redacted]	159	53	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	びらん性十二指腸炎	20[redacted]	162	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	胃潰瘍	20[redacted]	162	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	裂孔ヘルニア	20[redacted]	162	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	浮動性めまい	20[redacted]	209	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	230	8	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	頭痛	20[redacted]	99	45	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	ウイルス性上気道感染	20[redacted]	179	19	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	体重増加	20[redacted]	183	.	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	扁桃炎	20[redacted]	353	8	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	胸部不快感	20[redacted]	.	.	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	慢性気管支炎	20[redacted]	420	21	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心拡大	20[redacted]	429	.	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	高血圧	20[redacted]	429	1	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	心臓弁閉鎖不全	20[redacted]	430	.	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]	430	.	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	腎嚢胞	20[redacted]	430	.	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	慢性閉塞性肺疾患	20[redacted]	493	22	Y	Grade 3	RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	16	16	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	喘息	20[redacted]	27	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	20[redacted]	46	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肺炎	20[redacted]	69	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	上腹部痛	20[redacted]	83	106	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]	83	.	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]	83	389	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肺炎	20[redacted]	83	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	気管支拡張症	20[redacted]	85	.	N	Grade 2	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]	107	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	細菌性膣症	20[redacted]	200	21	N	Grade 1	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]	216	16	Y	Grade 3	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]	360	32	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肺炎	20[redacted]	360	32	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	低カリウム血症	20[redacted]	369	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	甲状腺新生物	20[redacted]	376	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	皮膚炎	20[redacted]	.	171	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性気管支炎	20[redacted]	63	40	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胆石症	20[redacted]	.	198	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	149	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋肉痛	20[redacted]	149	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	190	117	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	弾発指	20[redacted]	190	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	196	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	糖尿病	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	嘔吐	20[redacted]	241	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部損傷	20[redacted]	254	72	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	7[redacted]	F	OTHER	転倒	20[redacted]	254	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹痛	20[redacted]	355	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	うつ病	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	下痢	20[redacted]	390	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	上部消化管出血	20[redacted]	394	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性胃炎	20[redacted]	396	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	452	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	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	7[redacted]	F	OTHER	関節痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃食道逆流性疾患	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	7[redacted]	F	OTHER	細菌性気管支炎	20[redacted]	164	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋肉痛	20[redacted]	.	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	弾発指	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	7[redacted]	F	OTHER	背部痛	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	7[redacted]	F	OTHER	眼痛	20[redacted]	427	.	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	末梢動脈狭窄	20[redacted]	435	.	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	大動脈弁硬化症	20[redacted]	504	.	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	大動脈弁閉鎖不全症	20[redacted]	504	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	関節損傷	20[redacted]	36	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	関節痛	20[redacted]	83	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	細菌性上気道感染	20[redacted]	103	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	脂質異常症	20[redacted]	254	106	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	統合失調症	20[redacted]	335	.	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]	351	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	浮動性めまい	20[redacted]	351	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	頚動脈硬化症	20[redacted]	352	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尺骨骨折	20[redacted]	500	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	橈骨骨折	20[redacted]	500	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	転倒	20[redacted]	500	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	57	21	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻炎	20[redacted]	78	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	憩室炎	20[redacted]	102	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	細菌性尿路感染	20[redacted]	104	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	変形性関節症	20[redacted]	173	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	20[redacted]	191	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	注射部位疼痛	20[redacted]	239	2	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	299	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	335	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	449	91	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肺動脈性肺高血圧症	20[redacted]	454	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃炎	20[redacted]	454	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	.	.	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	白癬感染	20[redacted]	35	162	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	高血圧	20[redacted]	76	.	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]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	斑状出血	20[redacted]	122	44	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	関節腫脹	20[redacted]	122	52	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	静脈瘤	20[redacted]	204	6	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	背部痛	20[redacted]	224	.	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	炭水化物不耐症	20[redacted]	273	.	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	細菌性肺炎	20[redacted]	273	22	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	アレルギー性皮膚炎	20[redacted]	.	.	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	慢性胆嚢炎	20[redacted]	280	.	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	洞性徐脈	20[redacted]	280	35	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	肺線維症	20[redacted]	286	.	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	肺高血圧症	20[redacted]	286	.	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	ウイルス性上気道感染	20[redacted]	324	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	浮動性めまい	20[redacted]	446	1	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	左脚ブロック	20[redacted]	494	.	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	末梢性浮腫	20[redacted]	.	.	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	関節痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	過眠症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋肉痛	20[redacted]	.	85	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	口腔ヘルペス	20[redacted]	73	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	77	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	錯感覚	20[redacted]	77	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	好酸球増加症	20[redacted]	267	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心房細動	20[redacted]	443	48	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION 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]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	変形性脊椎症	20[redacted]	489	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	大動脈硬化症	20[redacted]	489	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	489	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	無気肺	20[redacted]	489	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心房細動	20[redacted]	490	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹痛	20[redacted]	521	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	58	16	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	ウイルス性上気道感染	20[redacted]	154	9	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肺炎	20[redacted]	.	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹部膨満	20[redacted]	1	.	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	ウイルス性咽頭炎	20[redacted]	60	2	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	鼻咽頭炎	20[redacted]	69	3	N	Grade 1	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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	84	54	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	静脈瘤	20[redacted]	86	3	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	消化不良	20[redacted]	140	43	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	195	6	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	細菌性結膜炎	20[redacted]	270	8	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	ウイルス性下痢	20[redacted]	326	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	マイコプラズマ性肺炎	20[redacted]	336	13	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧クリーゼ	20[redacted]	337	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肋軟骨炎	20[redacted]	382	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	炭水化物不耐症	20[redacted]	33	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	高血糖	20[redacted]	33	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	末梢性浮腫	20[redacted]	103	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	結膜出血	20[redacted]	116	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	頻脈	20[redacted]	148	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	197	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	細菌性気道感染	20[redacted]	197	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	甲状腺機能低下症	20[redacted]	215	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	細菌性尿路感染	20[redacted]	229	30	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	肺高血圧症	20[redacted]	255	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	気管支拡張症	20[redacted]	256	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	肝腫大	20[redacted]	256	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	腎萎縮	20[redacted]	256	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	263	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]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	細菌性尿路感染	20[redacted]	293	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	腹部膨満	20[redacted]	3	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	変形性関節症	20[redacted]	312	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	貧血	20[redacted]	359	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肋骨骨折	20[redacted]	451	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胃腸出血	20[redacted]	451	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	貧血	20[redacted]	451	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	転倒	20[redacted]	451	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	頭蓋脳損傷	20[redacted]	451	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	大脳障害	20[redacted]	452	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	心拡大	20[redacted]	452	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ヘリコバクター感染	20[redacted]	453	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性胃炎	20[redacted]	453	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	虫垂炎	20[redacted]	601	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	32	28	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	筋肉痛	20[redacted]	35	163	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	洞性徐脈	20[redacted]	89	242	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	筋肉痛	20[redacted]	106	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋骨格痛	20[redacted]	116	3	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	ウイルス性上気道感染	20[redacted]	216	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋痙縮	20[redacted]	229	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	注射部位疼痛	20[redacted]	301	3	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	頭痛	20[redacted]	345	1	N	Grade 2	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	慢性閉塞性肺疾患	20[redacted]	353	.	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	胃炎	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	7[redacted]	F	OTHER	歯周炎	20[redacted]	453	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	徐脈	20[redacted]	.	62	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低心拍出量症候群	20[redacted]	695	5	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	処置による疼痛	20[redacted]	699	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	34	4	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	細菌性副鼻腔炎	20[redacted]	37	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	115	10	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	119	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	149	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[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	7[redacted]	F	OTHER	背部痛	20[redacted]	181	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	錯感覚	20[redacted]	195	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	203	11	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低血圧	20[redacted]	209	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低血圧	20[redacted]	211	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	294	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	白内障	20[redacted]	361	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低色素性貧血	20[redacted]	494	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	創傷	20[redacted]	494	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	大脳基底核卒中	20[redacted]	494	12	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	494	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	顔面骨骨折	20[redacted]	494	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	骨折	20[redacted]	494	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	葉酸欠乏	20[redacted]	496	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	白質病変	20[redacted]	497	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頚動脈狭窄	20[redacted]	498	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頚動脈狭窄	20[redacted]	498	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	三尖弁閉鎖不全症	20[redacted]	499	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	伝導障害	20[redacted]	499	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	僧帽弁閉鎖不全症	20[redacted]	499	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	呼吸不全	20[redacted]	499	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	大動脈弁閉鎖不全症	20[redacted]	499	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	530	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	変形性脊椎症	20[redacted]	534	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	変形性脊椎症	20[redacted]	534	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	561	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尺骨骨折	20[redacted]	715	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	橈骨骨折	20[redacted]	715	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	715	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	耳鳴	20[redacted]	61	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	107	32	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]	177	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高血圧	20[redacted]	184	33	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	皮膚病変	20[redacted]	.	.	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	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	疼痛	20[redacted]	.	347	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	錯感覚	20[redacted]	328	331	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	腹痛	20[redacted]	337	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	乾皮症	20[redacted]	370	366	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	耳垢分泌過多	20[redacted]	370	366	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	心電図再分極異常	20[redacted]	401	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高血圧クリーゼ	20[redacted]	401	2	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	徐脈	20[redacted]	597	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	45	19	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	46	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	OTHER	関節損傷	20[redacted]	46	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	OTHER	関節損傷	20[redacted]	46	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	OTHER	ウイルス性上気道感染	20[redacted]	86	13	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	非心臓性胸痛	20[redacted]	86	93	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	脊椎痛	20[redacted]	135	14	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	鉄欠乏性貧血	20[redacted]	185	352	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	アレルギー性結膜炎	20[redacted]	260	366	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	265	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	下痢	20[redacted]	268	19	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	背部痛	20[redacted]	438	11	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	機能不全性子宮出血	20[redacted]	586	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	全身性そう痒症	20[redacted]	599	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	機能不全性子宮出血	20[redacted]	708	1	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	20[redacted]	717	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胃食道逆流性疾患	20[redacted]	19	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	ウイルス性咽頭炎	20[redacted]	58	8	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]	63	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肋軟骨炎	20[redacted]	85	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	90	104	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	20[redacted]	93	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	歯ぎしり	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	上部消化管出血	20[redacted]	148	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	慢性胃炎	20[redacted]	151	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	痔核	20[redacted]	152	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋肉疲労	20[redacted]	185	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	.	63	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	急性中耳炎	20[redacted]	236	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	20[redacted]	237	258	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	皮膚炎	20[redacted]	.	132	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	網膜剥離	20[redacted]	.	90	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	3	8	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	高トリグリセリド血症	20[redacted]	3	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	68	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	79	.	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	顔面損傷	20[redacted]	113	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	148	9	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	浮動性めまい	20[redacted]	240	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	ウイルス性胃腸炎	20[redacted]	288	2	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	膵炎	20[redacted]	459	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧緊急症	20[redacted]	463	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	690	.	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	擦過傷	20[redacted]	706	3	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	転倒	20[redacted]	706	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	皮膚病変	20[redacted]	2	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	11	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻出血	20[redacted]	11	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	便秘	20[redacted]	26	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	下痢	20[redacted]	32	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	便秘	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	75	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢損傷	20[redacted]	86	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	霰粒腫	20[redacted]	.	117	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	142	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	165	86	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	171	23	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	200	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	234	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	便秘	20[redacted]	240	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	軟部組織損傷	20[redacted]	250	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	斑状出血	20[redacted]	278	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	日光角化症	20[redacted]	278	463	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	流涙増加	20[redacted]	285	456	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	痔核	20[redacted]	285	456	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	296	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	血腫	20[redacted]	298	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	351	36	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	蜂巣炎	20[redacted]	356	31	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	斑状出血	20[redacted]	358	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	359	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	手根管症候群	20[redacted]	.	334	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	
[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	

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	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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	転倒	20[redacted]	23	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	関節損傷	20[redacted]	23	27	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	痙攣発作	20[redacted]	72	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	てんかん	20[redacted]	95	4	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	筋痙縮	20[redacted]	95	.	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	背部痛	20[redacted]	170	40	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	筋痙縮	20[redacted]	228	128	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	浮動性めまい	20[redacted]	235	121	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	鼻咽頭炎	20[redacted]	332	14	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]	351	64	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	531	.	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	消化不良	20[redacted]	81	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	背部痛	20[redacted]	133	.	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]	210	.	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	脛骨骨折	20[redacted]	210	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	腓骨骨折	20[redacted]	210	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	転倒	20[redacted]	210	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	うつ病	20[redacted]	.	191	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]	251	39	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]	321	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	錯感覚	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋痙縮	20[redacted]	44	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	体重増加	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	78	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	四肢損傷	20[redacted]	86	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胃炎	20[redacted]	237	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	不安障害	20[redacted]	289	.	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]	294	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	軟部組織損傷	20[redacted]	338	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胆管結石	20[redacted]	411	25	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	膵炎	20[redacted]	427	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	歯肉障害	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	コントロール不良の糖尿病	20[redacted]	29	91	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	高血圧	20[redacted]	113	6	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	脳血管発作	20[redacted]	116	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	低カリウム血症	20[redacted]	118	14	N	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	嘔吐	20[redacted]	125	7	N	Grade 2	NOT RELATED	RESOLVED	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]	23	32	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	末梢腫脹	20[redacted]	58	27	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	8[redacted]	F	OTHER	筋拘縮	20[redacted]	104	198	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	軟部組織損傷	20[redacted]	138	89	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鼻中隔弯曲	20[redacted]	138	.	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	鼻甲介肥大	20[redacted]	138	.	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	コントロール不良の糖尿病	20[redacted]	181	.	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	関節痛	20[redacted]	198	38	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	頭痛	20[redacted]	206	4	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	細菌性膣症	20[redacted]	298	21	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	高血圧	20[redacted]	319	11	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	関節痛	20[redacted]	322	.	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	筋拘縮	20[redacted]	323	.	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	背部痛	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	8[redacted]	F	OTHER	頭部損傷	20[redacted]	707	4	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	斑状出血	20[redacted]	708	.	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	転倒	20[redacted]	708	1	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	転倒	20[redacted]	55	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	関節損傷	20[redacted]	55	.	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]	55	.	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	便秘	20[redacted]	.	121	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	尿路結石	20[redacted]	192	30	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	憩室	20[redacted]	195	.	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	高血圧	20[redacted]	199	2	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	消化不良	20[redacted]	228	33	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭痛	20[redacted]	228	60	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	背部痛	20[redacted]	247	111	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	高血圧	20[redacted]	343	198	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	咳嗽	20[redacted]	348	4	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	関節痛	20[redacted]	348	.	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	便秘	20[redacted]	349	3	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	白癬感染	20[redacted]	356	34	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	背部痛	20[redacted]	358	63	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]	426	85	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	転倒	20[redacted]	426	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	転倒	20[redacted]	510	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	関節損傷	20[redacted]	510	8	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	外傷後疼痛	20[redacted]	582	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	転倒	20[redacted]	582	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	関節脱臼	20[redacted]	582	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	13	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	末梢性浮腫	20[redacted]	39	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹痛	20[redacted]	39	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	コントロール不良の糖尿病	20[redacted]	114	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	蛋白尿	20[redacted]	114	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	149	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	消化不良	20[redacted]	180	81	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	258	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹部膨満	20[redacted]	271	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	406	9	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃腸炎	20[redacted]	435	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	蛋白尿	20[redacted]	644	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	排尿困難	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	7[redacted]	F	OTHER	血管穿刺部位出血	20[redacted]	3	6	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	血小板減少症	20[redacted]	5	264	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	狭心症	20[redacted]	75	.	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	頭位性回転性めまい	20[redacted]	.	64	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	緊張性頭痛	20[redacted]	105	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頻脈	20[redacted]	116	2	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	歯肉出血	20[redacted]	237	1	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	ウイルス性胃腸炎	20[redacted]	261	5	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	脂質異常症	20[redacted]	261	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	264	11	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	頻脈	20[redacted]	325	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	血腫	20[redacted]	399	52	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	裂傷	20[redacted]	399	11	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	転倒	20[redacted]	399	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	上室性頻脈	20[redacted]	427	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	上室性頻脈	20[redacted]	515	1	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	心房細動	20[redacted]	721	4	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	細菌性膀胱炎	20[redacted]	17	25	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	関節痛	20[redacted]	24	122	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	便秘	20[redacted]	54	92	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	TRANSFUSION PERFORMED	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	回転性めまい	20[redacted]	86	15	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	頭痛	20[redacted]	86	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	疲労	20[redacted]	.	121	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性気道感染	20[redacted]	117	29	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]	124	33	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	不眠症	20[redacted]	146	.	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]	232	97	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	錯感覚	20[redacted]	244	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	帯状疱疹	20[redacted]	288	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	289	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	うっ血性心不全	20[redacted]	291	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性胃腸炎	20[redacted]	301	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	第一度房室ブロック	20[redacted]	301	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	うっ血性心不全	20[redacted]	.	48	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]	374	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	筋痙縮	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	うっ血性心不全	20[redacted]	463	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	斑状皮疹	20[redacted]	481	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	甲状腺機能低下症	20[redacted]	639	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	電解質失調	20[redacted]	666	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尿路感染	20[redacted]	668	11	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	急性腎不全	20[redacted]	668	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	末梢動脈閉塞性疾患	20[redacted]	683	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[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	ウイルス性上気道感染	20[redacted]	.	.	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	腹部膨満	20[redacted]	159	140	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	末梢性浮腫	20[redacted]	180	119	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	細菌性尿路感染	20[redacted]	203	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	乾皮症	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	7[redacted]	F	OTHER	無力症	20[redacted]	.	204	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	錯感覚	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	7[redacted]	F	OTHER	うっ血性心不全	20[redacted]	262	37	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	血小板減少症	20[redacted]	265	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	慢性閉塞性肺疾患	20[redacted]	270	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	血腫	20[redacted]	270	23	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	270	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹腔内血腫	20[redacted]	271	25	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	疼痛	20[redacted]	291	.	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	うっ血性心不全	20[redacted]	311	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	311	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	701	.	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	20[redacted]	717	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	乾皮症	20[redacted]	28	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	胃炎	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	腱炎	20[redacted]	121	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	133	57	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	健忘	20[redacted]	175	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	アレルギー性結膜炎	20[redacted]	194	27	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	滑液嚢腫	20[redacted]	207	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	多形性神経膠芽細胞腫	20[redacted]	284	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	転倒	20[redacted]	284	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性気道感染	20[redacted]	27	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋痙縮	20[redacted]	53	135	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	歯の脱落	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	189	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃炎	20[redacted]	325	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃腸炎	20[redacted]	628	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肺炎	20[redacted]	630	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低カルシウム血症	20[redacted]	631	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃炎	20[redacted]	22	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	53	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	重複感染	20[redacted]	53	23	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	83	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	貧血	20[redacted]	91	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹痛	20[redacted]	106	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹痛	20[redacted]	326	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	耳垢栓塞	20[redacted]	363	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	604	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	616	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	コントロール不良の糖尿病	20[redacted]	618	70	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	貧血	20[redacted]	618	103	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	牛乳不耐症	20[redacted]	19	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	顔面浮腫	20[redacted]	25	3	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	四肢痛	20[redacted]	75	39	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	ウイルス性上気道感染	20[redacted]	114	11	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	ウイルス性上気道感染	20[redacted]	219	24	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	第７脳神経麻痺	20[redacted]	337	4	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	頚動脈硬化症	20[redacted]	338	.	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	高血圧性血管障害	20[redacted]	338	.	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	ウイルス性上気道感染	20[redacted]	533	.	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	低血圧	20[redacted]	629	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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	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	
[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	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	13	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	52	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	56	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	咽頭炎	20[redacted]	83	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	咽頭炎	20[redacted]	134	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	205	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	213	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	回転性めまい	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	咽頭炎	20[redacted]	237	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脂漏性角化症	20[redacted]	267	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	注射部位内出血	20[redacted]	268	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	269	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻出血	20[redacted]	269	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脂質異常症	20[redacted]	274	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	挫傷	20[redacted]	296	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ヘルペス後神経痛	20[redacted]	380	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	耳帯状疱疹	20[redacted]	400	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肺炎	20[redacted]	517	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	519	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	520	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	536	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	703	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	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	7[redacted]	F	OTHER	筋拘縮	20[redacted]	10	.	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	頭部損傷	20[redacted]	53	12	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	細菌性尿路感染	20[redacted]	61	74	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脂質異常症	20[redacted]	61	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	144	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	156	31	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肺高血圧症	20[redacted]	186	.	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	ウイルス性上気道感染	20[redacted]	308	30	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	悪心	20[redacted]	673	1	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	気管支炎	20[redacted]	715	65	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胃炎	20[redacted]	2	65	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	回転性めまい	20[redacted]	9	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	9	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	細菌性中耳炎	20[redacted]	38	40	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭痛	20[redacted]	72	32	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	中耳炎	20[redacted]	147	36	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	眼充血	20[redacted]	205	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋肉痛	20[redacted]	220	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭痛	20[redacted]	235	78	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	回転性めまい	20[redacted]	265	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭痛	20[redacted]	341	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	四肢損傷	20[redacted]	348	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	蜂巣炎	20[redacted]	380	14	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	41	40	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]	.	46	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	腹痛	20[redacted]	89	3	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	血管炎	20[redacted]	199	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	208	2	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	空腹時血中ブドウ糖不良	20[redacted]	309	611	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	ウイルス性上気道感染	20[redacted]	446	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	胃炎	20[redacted]	.	364	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	一過性脳虚血発作	20[redacted]	697	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	貧血	20[redacted]	698	222	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[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	

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[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	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	85	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	110	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	機能不全性子宮出血	20[redacted]	129	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢損傷	20[redacted]	201	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢損傷	20[redacted]	201	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節損傷	20[redacted]	201	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃炎	20[redacted]	202	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	蟯虫症	20[redacted]	228	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃炎	20[redacted]	231	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	狭窄性腱鞘炎	20[redacted]	234	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高コレステロール血症	20[redacted]	235	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	全身性そう痒症	20[redacted]	365	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃腸出血	20[redacted]	430	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃ポリープ	20[redacted]	437	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	473	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	回転性めまい	20[redacted]	502	70	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	非心臓性胸痛	20[redacted]	506	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	便秘	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	

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	便秘	20[redacted]	.	415	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	高血圧	20[redacted]	33	36	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	背部痛	20[redacted]	.	49	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	ウイルス性上気道感染	20[redacted]	51	18	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	リンパ節症	20[redacted]	77	161	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	低ナトリウム血症	20[redacted]	77	18	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	感覚鈍麻	20[redacted]	79	312	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	穿刺部位反応	20[redacted]	86	5	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	紅斑	20[redacted]	118	15	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	紅斑	20[redacted]	118	15	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	紅斑	20[redacted]	150	16	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	紅斑	20[redacted]	150	16	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	全身性そう痒症	20[redacted]	155	244	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	注射部位紅斑	20[redacted]	178	4	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	紅斑	20[redacted]	178	4	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	脂質異常症	20[redacted]	197	.	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	眼瞼浮腫	20[redacted]	199	92	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	嘔吐	20[redacted]	216	7	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	筋痙縮	20[redacted]	249	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	注射部位紅斑	20[redacted]	280	5	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	注射部位紅斑	20[redacted]	300	4	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	注射部位紅斑	20[redacted]	300	4	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	蜂巣炎	20[redacted]	307	10	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	筋痙縮	20[redacted]	314	110	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	紅斑	20[redacted]	335	3	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	注射部位炎症	20[redacted]	360	4	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	筋痙縮	20[redacted]	363	61	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	胃食道逆流性疾患	20[redacted]	.	.	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	肋軟骨炎	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低血糖	20[redacted]	14	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	食中毒	20[redacted]	18	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	疼痛	20[redacted]	85	122	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	食中毒	20[redacted]	107	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	便秘	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	116	27	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肛門直腸不快感	20[redacted]	119	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	過敏性腸症候群	20[redacted]	119	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	171	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	上腹部痛	20[redacted]	172	60	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	日光角化症	20[redacted]	178	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	白癬感染	20[redacted]	.	91	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脂質異常症	20[redacted]	238	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	293	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	429	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	急性中耳炎	20[redacted]	436	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	挫傷	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[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	7[redacted]	F	OTHER	嵌頓臍径ヘルニア	20[redacted]	669	71	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胸痛	20[redacted]	723	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	18	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	20[redacted]	18	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	感覚鈍麻	20[redacted]	83	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	20[redacted]	85	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	損傷	20[redacted]	117	2	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]	117	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	挫傷	20[redacted]	118	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	20[redacted]	197	86	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃炎	20[redacted]	253	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心房細動	20[redacted]	412	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	副鼻腔炎	20[redacted]	415	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	415	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心房細動	20[redacted]	423	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	損傷	20[redacted]	716	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	716	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	機能不全性子宮出血	20[redacted]	29	.	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	尿路感染	20[redacted]	94	110	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	関節痛	20[redacted]	139	.	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	出血性膀胱炎	20[redacted]	161	43	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	関節痛	20[redacted]	165	29	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	四肢痛	20[redacted]	179	117	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	血尿	20[redacted]	204	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	左脚ブロック	20[redacted]	224	.	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	嘔吐	20[redacted]	264	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	黄疸	20[redacted]	267	19	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	変形性関節症	20[redacted]	285	.	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	尿路感染	20[redacted]	302	29	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	関節痛	20[redacted]	320	.	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	呼吸困難	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	8[redacted]	F	OTHER	心不全	20[redacted]	420	.	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	鉄欠乏性貧血	20[redacted]	532	.	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	低血圧	20[redacted]	539	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尿路感染	20[redacted]	539	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性腎臓病	20[redacted]	539	11	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	背部痛	20[redacted]	543	.	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	背部痛	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	8[redacted]	F	OTHER	肺うっ血	20[redacted]	656	6	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	末梢性浮腫	20[redacted]	696	.	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	耐糖能障害	20[redacted]	727	.	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	ウイルス性上気道感染	20[redacted]	4	30	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	咳嗽	20[redacted]	41	50	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	20[redacted]	41	10	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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	寝汗	20[redacted]	.	120	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	慢性気管支炎	20[redacted]	133	33	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	152	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	X線異常	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	7[redacted]	F	OTHER	慢性気管支炎	20[redacted]	190	21	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	胆石症	20[redacted]	190	.	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	心障害	20[redacted]	191	.	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	頭痛	20[redacted]	210	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肺性心	20[redacted]	403	25	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	496	.	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	転倒	20[redacted]	496	1	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	鼻咽頭炎	20[redacted]	496	.	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]	52	18	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	便秘	20[redacted]	80	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	背部痛	20[redacted]	109	6	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	背部痛	20[redacted]	141	.	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	ウイルス性上気道感染	20[redacted]	190	6	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	背部痛	20[redacted]	200	21	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	足底筋膜炎	20[redacted]	246	.	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	ウイルス性胃腸炎	20[redacted]	274	2	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	関節痛	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	脛骨骨折	20[redacted]	696	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	腓骨骨折	20[redacted]	696	.	Y	Grade 3	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]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	転倒	20[redacted]	696	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	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	
[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

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	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	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	12	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋肉痛	20[redacted]	33	325	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	静脈瘤	20[redacted]	84	52	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	90	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	血管浮腫	20[redacted]	141	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	末梢性浮腫	20[redacted]	172	84	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	うっ血性心不全	20[redacted]	199	57	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	末梢性浮腫	20[redacted]	256	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胸部損傷	20[redacted]	275	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	296	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	305	121	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	咳嗽	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	3	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	急性心不全	20[redacted]	11	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	咳嗽	20[redacted]	.	181	N	Grade 1	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]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	無気肺	20[redacted]	79	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	四肢痛	20[redacted]	85	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	頭痛	20[redacted]	122	96	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	高血糖	20[redacted]	182	.	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	ウイルス性上気道感染	20[redacted]	183	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	ウイルス性胃腸炎	20[redacted]	194	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	308	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	下腹部痛	20[redacted]	28	5	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]	28	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	120	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	突然視力消失	20[redacted]	161	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	20[redacted]	273	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不眠症	20[redacted]	305	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	325	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	機能不全性子宮出血	20[redacted]	361	352	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	卵巣腺腫	20[redacted]	392	336	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	アレルギー性皮膚炎	20[redacted]	590	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹痛	20[redacted]	735	67	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	虫垂炎	20[redacted]	12	3	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頚部痛	20[redacted]	72	91	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	消化不良	20[redacted]	110	43	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]	157	27	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	236	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	筋骨格痛	20[redacted]	183	90	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	左室肥大	20[redacted]	195	.	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]	219	32	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	不眠症	20[redacted]	341	31	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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[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	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	嘔吐	20[redacted]	620	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	変形性関節症	20[redacted]	.	.	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	関節損傷	20[redacted]	710	.	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	転倒	20[redacted]	717	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	四肢痛	20[redacted]	27	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	湿性咳嗽	20[redacted]	40	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	四肢痛	20[redacted]	41	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	浮動性めまい	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	腹痛	20[redacted]	90	10	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	筋骨格系胸痛	20[redacted]	96	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	軟部組織損傷	20[redacted]	96	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	咳嗽	20[redacted]	127	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	軟部組織損傷	20[redacted]	129	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	腹痛	20[redacted]	176	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胃炎	20[redacted]	.	165	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]	187	177	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	加齢黄斑変性	20[redacted]	253	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	脂質異常症	20[redacted]	357	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	翼状片	20[redacted]	365	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	脊柱後弯症	20[redacted]	365	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	上腹部痛	20[redacted]	414	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	486	6	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]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	関節痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	上腹部痛	20[redacted]	706	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	706	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	低酸素症	20[redacted]	717	4	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	低血糖	20[redacted]	237	1	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	糖尿病性腎症	20[redacted]	267	.	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	低血糖	20[redacted]	532	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	尿路感染	20[redacted]	724	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	糖尿病	20[redacted]	724	.	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	尿路感染	20[redacted]	746	18	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	
[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	

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[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	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋拘縮	20[redacted]	14	90	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	静脈瘤	20[redacted]	19	68	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	肛門そう痒症	20[redacted]	28	69	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	鼻出血	20[redacted]	91	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	嵌頓臍ヘルニア	20[redacted]	99	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	処置による頭痛	20[redacted]	101	3	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	無力症	20[redacted]	260	177	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	腹部膨満	20[redacted]	264	158	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	憩室炎	20[redacted]	281	.	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	子宮平滑筋腫	20[redacted]	303	.	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	肝嚢胞	20[redacted]	303	.	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	胆管結石	20[redacted]	360	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	処置による疼痛	20[redacted]	369	5	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	上腹部痛	20[redacted]	433	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋肉痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	13	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	18	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	全身性そう痒症	20[redacted]	.	121	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	歯痛	20[redacted]	95	50	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	105	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	117	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	歯牙破折	20[redacted]	117	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼡径部痛	20[redacted]	134	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋肉痛	20[redacted]	165	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼡径部痛	20[redacted]	173	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	174	78	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	咳嗽	20[redacted]	195	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	20[redacted]	282	107	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	322	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	乳癌第２期	20[redacted]	430	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	30	12	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]	34	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	細菌性尿路感染	20[redacted]	64	63	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	皮膚炎	20[redacted]	74	244	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	91	32	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]	94	.	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]	97	18	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]	105	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胃炎	20[redacted]	121	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	筋損傷	20[redacted]	177	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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	高カリウム血症	20[redacted]	269	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	呼吸困難	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	変形性関節症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胃炎	20[redacted]	.	74	N	Grade 1	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]	506	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	背部痛	20[redacted]	621	.	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	関節損傷	20[redacted]	33	26	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	アレルギー性鼻炎	20[redacted]	135	19	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]	159	3	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	背部痛	20[redacted]	196	.	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	口腔ヘルペス	20[redacted]	267	18	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	片頭痛	20[redacted]	269	1	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	胃炎	20[redacted]	308	11	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	甲状腺機能低下症	20[redacted]	452	135	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	頚部痛	20[redacted]	452	1	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	胃腸炎	20[redacted]	481	32	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	甲状腺機能低下症	20[redacted]	587	.	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	過敏性腸症候群	20[redacted]	635	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	食道静脈瘤	20[redacted]	78	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	食道静脈瘤出血	20[redacted]	103	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[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

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	7[redacted]	F	OTHER	頭痛	20[redacted]	88	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	咳嗽	20[redacted]	91	45	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	ウイルス性上気道感染	20[redacted]	187	15	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	胃食道逆流性疾患	20[redacted]	197	10	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	嵌入爪	20[redacted]	228	131	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	糖尿病	20[redacted]	233	.	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	ウイルス性上気道感染	20[redacted]	369	8	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	糖尿病性代謝代償不全	20[redacted]	516	20	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	顔面損傷	20[redacted]	48	60	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	抑うつ気分	20[redacted]	76	101	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	細菌性関節炎	20[redacted]	153	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	顔面損傷	20[redacted]	232	.	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	尿路感染	20[redacted]	237	45	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	斑状出血	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	7[redacted]	F	OTHER	胸痛	20[redacted]	680	30	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	肋軟骨炎	20[redacted]	10	3	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	37	.	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	背部痛	20[redacted]	48	240	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	61	1	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	靭帯捻挫	20[redacted]	61	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	回転性めまい	20[redacted]	91	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	109	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	167	17	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	頭痛	20[redacted]	168	4	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	転倒	20[redacted]	220	1	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	関節損傷	20[redacted]	220	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋痙縮	20[redacted]	249	70	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	斑状出血	20[redacted]	634	32	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	皮膚擦過傷	20[redacted]	634	8	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	転倒	20[redacted]	634	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	四肢損傷	20[redacted]	28	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	血腫	20[redacted]	28	17	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	軟部組織損傷	20[redacted]	31	14	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	関節損傷	20[redacted]	31	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	背部痛	20[redacted]	88	7	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	上腹部痛	20[redacted]	109	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	高血圧	20[redacted]	146	29	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	爪の皮膚糸状菌症	20[redacted]	166	314	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	倦怠感	20[redacted]	176	8	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	注射部位疼痛	20[redacted]	176	8	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	倦怠感	20[redacted]	207	8	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	注射部位疼痛	20[redacted]	207	8	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	注射部位疼痛	20[redacted]	207	8	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION 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]	237	20	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	倦怠感	20[redacted]	238	8	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	注射部位疼痛	20[redacted]	238	8	N	Grade 1	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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	注射部位疼痛	20[redacted]	238	8	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	倦怠感	20[redacted]	267	8	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	注射部位疼痛	20[redacted]	267	8	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	注射部位疼痛	20[redacted]	267	8	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	注射部位疼痛	20[redacted]	299	7	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	胆石症	20[redacted]	373	12	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	血管穿刺部位出血	20[redacted]	28	8	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	高血圧	20[redacted]	78	41	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	肺炎	20[redacted]	88	31	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	糖尿病	20[redacted]	97	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不眠症	20[redacted]	103	60	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	丹毒	20[redacted]	154	33	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	背部痛	20[redacted]	155	196	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	コントロール不良の糖尿病	20[redacted]	268	.	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	ウイルス性上気道感染	20[redacted]	444	18	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	632	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[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	

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	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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	屈折障害	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	眼運動障害	20[redacted]	76	.	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	背部痛	20[redacted]	80	32	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	筋肉疲労	20[redacted]	.	290	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	各種物質毒性	20[redacted]	138	5	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	鼻咽頭炎	20[redacted]	138	21	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	軟部組織損傷	20[redacted]	239	3	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]	267	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	労作性呼吸困難	20[redacted]	305	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	心不全	20[redacted]	361	5	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	虚血性脳卒中	20[redacted]	502	14	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	歯肉炎	20[redacted]	114	4	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	肺炎	20[redacted]	204	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肺うっ血	20[redacted]	331	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	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	歯痛	20[redacted]	659	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[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]	711	5	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	7[redacted]	F	OTHER	頭痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	20	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NON-IV ANTIMICROBIAL TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	嘔吐	20[redacted]	42	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	気管支炎	20[redacted]	63	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	93	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肺炎	20[redacted]	230	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	上腹部痛	20[redacted]	.	55	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	317	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	歯牙破折	20[redacted]	339	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部損傷	20[redacted]	412	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	412	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	443	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尺骨骨折	20[redacted]	476	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	橈骨骨折	20[redacted]	476	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋萎縮	20[redacted]	476	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	476	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胆道仙痛	20[redacted]	.	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胆石症	20[redacted]	506	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心房細動	20[redacted]	579	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心房細動	20[redacted]	581	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	歯痛	20[redacted]	651	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	炭水化物不耐症	20[redacted]	.	.	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	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	静脈瘤	20[redacted]	76	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	うっ血性心不全	20[redacted]	95	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不眠症	20[redacted]	165	185	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	179	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	静脈瘤	20[redacted]	.	61	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	橈骨骨折	20[redacted]	416	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	416	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	血栓性静脈炎	20[redacted]	683	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	変形性関節症	20[redacted]	11	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	頚部痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胃炎	20[redacted]	18	68	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	外陰腟そう痒症	20[redacted]	42	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高血圧	20[redacted]	53	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	乳房痛	20[redacted]	85	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	四肢痛	20[redacted]	103	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	頭痛	20[redacted]	104	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	背部痛	20[redacted]	108	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	顔面浮腫	20[redacted]	177	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	202	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	上腹部痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	筋痙縮	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	皮膚刺激	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鼻部不快感	20[redacted]	302	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	歯牙破折	20[redacted]	332	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	斑状出血	20[redacted]	361	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	第７脳神経麻痺	20[redacted]	442	.	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]	635	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肺うっ血	20[redacted]	662	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	上腹部痛	20[redacted]	32	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	耳不快感	20[redacted]	36	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	47	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	69	60	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	114	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脊椎痛	20[redacted]	124	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	154	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	20[redacted]	223	129	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	326	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節損傷	20[redacted]	326	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋痙縮	20[redacted]	443	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	446	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋痙縮	20[redacted]	471	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	508	17	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	錯感覚	20[redacted]	.	170	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	115	119	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	多尿	20[redacted]	147	341	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋骨格痛	20[redacted]	153	96	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	記憶障害	20[redacted]	.	302	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	186	302	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	細菌性結膜炎	20[redacted]	306	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋痙縮	20[redacted]	462	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	白質脳症	20[redacted]	487	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	虚血性脳卒中	20[redacted]	487	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	虚血性脳卒中	20[redacted]	487	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脳血管発作	20[redacted]	500	.	N	Grade 3	NOT RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	注射部位内出血	20[redacted]	32	15	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	鼻咽頭炎	20[redacted]	85	8	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	鼻咽頭炎	20[redacted]	146	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	軟部組織損傷	20[redacted]	292	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	292	1	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	気管支炎	20[redacted]	380	11	N	Grade 1	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]	520	22	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	転倒	20[redacted]	520	1	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	高血圧クリーゼ	20[redacted]	577	71	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	術後創感染	20[redacted]	635	46	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	218	30	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	尿路感染	20[redacted]	24	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	口内乾燥	20[redacted]	140	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	眼球乾燥症	20[redacted]	140	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	脂漏性皮膚炎	20[redacted]	165	35	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	帯状疱疹	20[redacted]	221	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	シェーグレン症候群	20[redacted]	235	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	深部静脈血栓症	20[redacted]	263	17	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		7[redacted]	F	OTHER	胃ポリープ	20[redacted]	267	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	穿孔性虫垂炎	20[redacted]	90	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	大腿骨頚部骨折	20[redacted]	168	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	高血圧	20[redacted]	159	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[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	PLACEBO		6[redacted]	F	OTHER	胆石症	20[redacted]	.	151	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	小腸癒	20[redacted]	234	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	胆石症	20[redacted]	234	1	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	N
[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	末梢性浮腫	20[redacted]	62	4	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	表皮内悪性黒色腫	20[redacted]	526	139	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	6[redacted]	F	OTHER	転倒	20[redacted]	.	.	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	頚部損傷	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	白内障	20[redacted]	.	.	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	虫垂炎	20[redacted]	484	3	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	甲状腺新生物	20[redacted]	.	.	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	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	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	錯感覚	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	胸痛	20[redacted]	128	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	甲状腺新生物	20[redacted]	147	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	心筋梗塞	20[redacted]	234	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	うつ病	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	不安定狭心症	20[redacted]	293	9	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	尿路感染	20[redacted]	114	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	尿路性敗血症	20[redacted]	128	20	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	酸消化性障害	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	144	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	急性心筋梗塞	20[redacted]	715	32	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性心不全	20[redacted]	717	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性腎臓病	20[redacted]	717	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	不安定狭心症	20[redacted]	45	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	下痢	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	8[redacted]	F	OTHER	四肢痛	20[redacted]	.	.	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	多発ニューロパチー	20[redacted]	77	.	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	神経根障害	20[redacted]	77	.	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	腹痛	20[redacted]	317	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	動脈硬化症	20[redacted]	320	.	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	憩室	20[redacted]	320	.	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	脂肪肝	20[redacted]	320	.	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	腎嚢胞	20[redacted]	320	.	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	白内障	20[redacted]	334	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	喘息	20[redacted]	87	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	挫傷	20[redacted]	132	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	子宮内膜腺癌	20[redacted]	78	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	貧血	20[redacted]	29	354	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	急性胆嚢炎	20[redacted]	61	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胆石症	20[redacted]	61	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	N

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胃炎	20[redacted]	118	.	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	裂孔ヘルニア	20[redacted]	118	.	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	不眠症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION 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	
[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	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	ヘリコバクター性胃炎	20[redacted]	29	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	尿路感染	20[redacted]	75	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	甲状腺嚢腫	20[redacted]	80	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	狭窄性腱鞘炎	20[redacted]	82	58	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節損傷	20[redacted]	140	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	腹痛	20[redacted]	200	57	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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	6[redacted]	F	OTHER	閉塞性胆石症	20[redacted]	200	57	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	消化不良	20[redacted]	292	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	過敏性腸症候群	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	筋骨格系胸痛	20[redacted]	533	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	高血圧	20[redacted]	677	56	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	インフルエンザ様疾患	20[redacted]	29	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	280	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊柱損傷	20[redacted]	280	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節損傷	20[redacted]	280	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節損傷	20[redacted]	280	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節損傷	20[redacted]	280	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	281	5	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	292	11	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節脱臼	20[redacted]	320	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	437	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	蜂巣炎	20[redacted]	177	24	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[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	8[redacted]	F	OTHER	インフルエンザ	20[redacted]	92	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	急性心筋梗塞	20[redacted]	104	5	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	下痢	20[redacted]	451	3	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]	496	5	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	関節痛	20[redacted]	545	.	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	関節痛	20[redacted]	672	.	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	尿路感染	20[redacted]	703	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	回転性めまい	20[redacted]	7	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脳虚血	20[redacted]	689	5	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[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]	696	.	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	心房拡張	20[redacted]	696	.	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	心房細動	20[redacted]	710	.	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	緊張性頭痛	20[redacted]	762	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧クリーゼ	20[redacted]	762	1	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	インフルエンザ様疾患	20[redacted]	771	.	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	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	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	慢性Ｃ型肝炎	20[redacted]	121	.	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	Ｃ型肝炎	20[redacted]	121	9	Y	Grade 1	NOT RELATED	RESOLVED	DRUG WITHDRAWN	NO ACTION TAKEN	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	大腿骨頚部骨折	20[redacted]	276	.	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	貧血	20[redacted]	276	94	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	処置による低血圧	20[redacted]	279	2	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[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	
[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	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	アメーバ性大腸炎	20[redacted]	336	7	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	20[redacted]	536	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	体部白癬	20[redacted]	207	.	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	肺炎	20[redacted]	418	29	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	63	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肺炎	20[redacted]	488	15	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	創傷	20[redacted]	223	154	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	蜂巣炎	20[redacted]	695	13	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	四肢損傷	20[redacted]	29	2	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	恥骨骨折	20[redacted]	29	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	頭蓋脳損傷	20[redacted]	29	2	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	心不全	20[redacted]	269	49	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	インフルエンザ様疾患	20[redacted]	403	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腓骨骨折	20[redacted]	359	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不安定狭心症	20[redacted]	425	7	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	425	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心不全	20[redacted]	425	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心筋虚血	20[redacted]	425	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	急性冠動脈症候群	20[redacted]	671	7	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[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		7[redacted]	F	OTHER	ウイルス性肝炎	20[redacted]	182	.	Y	Grade 1	RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	OTHER	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	四肢痛	20[redacted]	1	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	頭痛	20[redacted]	1	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尿路感染	20[redacted]	2	26	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肩回旋筋腱板症候群	20[redacted]	51	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尿路感染	20[redacted]	.	111	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	発疹	20[redacted]	154	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	眼瞼内反	20[redacted]	224	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	睫毛乱生	20[redacted]	224	311	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	インフルエンザ	20[redacted]	248	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	細菌性気管支炎	20[redacted]	281	36	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	460	20	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	細菌性耳感染	20[redacted]	460	29	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	回転性めまい	20[redacted]	462	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	低ナトリウム血症	20[redacted]	463	76	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	甲状腺機能低下症	20[redacted]	464	453	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尿路感染	20[redacted]	582	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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	腎嚢胞	20[redacted]	597	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	扁桃炎	20[redacted]	724	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	7	33	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	感染性下痢	20[redacted]	41	82	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	回転性めまい	20[redacted]	61	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	大腸ポリープ	20[redacted]	137	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	嘔吐	20[redacted]	148	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	徐脈	20[redacted]	181	183	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	インフルエンザ	20[redacted]	242	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脳血管発作	20[redacted]	288	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	298	20	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	横隔膜障害	20[redacted]	328	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	坐骨神経痛	20[redacted]	356	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃腸炎	20[redacted]	418	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	回転性めまい	20[redacted]	501	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	501	41	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脂肪肝	20[redacted]	518	.	N	Grade 2	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃腸炎	20[redacted]	.	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	719	148	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	上腹部痛	20[redacted]	732	2	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	限局性感染	20[redacted]	53	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	末端部黒子様黒色腫	20[redacted]	144	147	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高トリグリセリド血症	20[redacted]	207	175	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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	術後創合併症	20[redacted]	225	139	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	細菌重複感染	20[redacted]	227	20	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	処置による疼痛	20[redacted]	274	257	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	インフルエンザ	20[redacted]	287	19	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	細菌性外耳炎	20[redacted]	298	117	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	徐脈	20[redacted]	332	50	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]	368	.	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	結膜炎	20[redacted]	419	.	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	心雑音	20[redacted]	445	.	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	末端部黒子様黒色腫	20[redacted]	574	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	SURGICAL INTERVENTION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胃腸炎	20[redacted]	623	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	電解質失調	20[redacted]	624	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	ヘルペス眼感染	20[redacted]	188	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	出血性胃潰瘍	20[redacted]	247	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	錯感覚	20[redacted]	11	23	N	Grade 1	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	306	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	チアノーゼ	20[redacted]	321	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脂質異常症	20[redacted]	456	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	インフルエンザ	20[redacted]	514	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	薬物性肝障害	20[redacted]	537	54	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	扁桃炎	20[redacted]	715	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	6	88	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	63	68	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肺障害	20[redacted]	117	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高カリウム血症	20[redacted]	134	58	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	回転性めまい	20[redacted]	175	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	末梢性浮腫	20[redacted]	219	230	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	296	35	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	303	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	擦過傷	20[redacted]	380	32	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]	380	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	380	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	失神	20[redacted]	418	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性上気道感染	20[redacted]	448	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心不全	20[redacted]	584	60	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	一過性脳虚血発作	20[redacted]	628	1	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	滑液包炎	20[redacted]	80	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	回転性めまい	20[redacted]	112	41	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	112	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	131	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低血糖	20[redacted]	136	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	外傷後疼痛	20[redacted]	147	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	皮膚損傷	20[redacted]	147	87	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	顔面痛	20[redacted]	184	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	インフルエンザ	20[redacted]	204	37	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	細菌性気管支炎	20[redacted]	205	54	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	糖尿病性腎症	20[redacted]	229	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	細菌性尿路感染	20[redacted]	252	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	269	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腎機能障害	20[redacted]	277	144	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	大脳萎縮	20[redacted]	307	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	閉塞隅角緑内障	20[redacted]	347	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	動悸	20[redacted]	535	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低血糖	20[redacted]	551	90	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	アレルギー性鼻炎	20[redacted]	582	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性副鼻腔炎	20[redacted]	582	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	下痢	20[redacted]	15	3	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	背部痛	20[redacted]	22	2	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	左脚ブロック	20[redacted]	64	.	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	左脚ブロック	20[redacted]	96	.	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	軟部組織損傷	20[redacted]	120	16	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	転倒	20[redacted]	120	1	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	不安定狭心症	20[redacted]	180	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	甲状腺機能低下症	20[redacted]	196	143	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	不安定狭心症	20[redacted]	217	21	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	232	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	発熱	20[redacted]	236	1	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	狭心症	20[redacted]	238	339	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高コレステロール血症	20[redacted]	324	.	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]	345	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	２型糖尿病	20[redacted]	364	.	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	肋軟骨炎	20[redacted]	572	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	背部痛	20[redacted]	16	57	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	黄疸尿	20[redacted]	16	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	転倒	20[redacted]	23	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	関節損傷	20[redacted]	23	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	基底細胞癌	20[redacted]	.	212	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	滑液嚢腫	20[redacted]	172	461	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	皮膚損傷	20[redacted]	211	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胸部損傷	20[redacted]	211	52	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	転倒	20[redacted]	211	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	右室肥大	20[redacted]	296	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	右脚ブロック	20[redacted]	296	.	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]	303	197	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	腹痛	20[redacted]	303	197	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	心雑音	20[redacted]	332	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高血圧	20[redacted]	365	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	低血糖	20[redacted]	444	1	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]	445	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	結膜の悪性新生物	20[redacted]	469	150	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	トランスアミナーゼ上昇	20[redacted]	561	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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	甲状腺腫	20[redacted]	723	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	無力症	20[redacted]	45	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不安	20[redacted]	135	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	インフルエンザ	20[redacted]	184	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性下痢	20[redacted]	184	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	無力症	20[redacted]	274	2	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	無力症	20[redacted]	274	2	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	非心臓性胸痛	20[redacted]	324	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不安障害	20[redacted]	388	170	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	精神病性障害	20[redacted]	558	81	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	硬膜下血腫	20[redacted]	569	22	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	体重減少	20[redacted]	619	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	便秘	20[redacted]	624	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃炎	20[redacted]	631	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	精神病性障害	20[redacted]	639	.	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	斑状出血	20[redacted]	34	10	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]	34	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	出血性皮膚潰瘍	20[redacted]	159	1	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	感染性皮膚潰瘍	20[redacted]	159	10	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	軟部組織損傷	20[redacted]	190	51	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	転倒	20[redacted]	190	1	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	狭窄性腱鞘炎	20[redacted]	238	332	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	8[redacted]	F	OTHER	下痢	20[redacted]	322	4	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	関節痛	20[redacted]	351	.	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	関節痛	20[redacted]	431	.	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	インフルエンザ	20[redacted]	538	22	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	出血性卒中	20[redacted]	603	119	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	半盲	20[redacted]	603	.	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	高血圧	20[redacted]	603	119	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	高血圧緊急症	20[redacted]	603	20	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	UNKNOWN	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	下痢	20[redacted]	640	62	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	老視	20[redacted]	694	.	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	第２度熱傷	20[redacted]	30	31	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	緊張性頭痛	20[redacted]	58	291	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	転倒	20[redacted]	76	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	末梢性浮腫	20[redacted]	106	43	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	男性型多毛症	20[redacted]	106	53	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	170	1	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	空腹時血中ブドウ糖不良	20[redacted]	190	86	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	胃炎	20[redacted]	215	1	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	血管穿刺部位内出血	20[redacted]	215	15	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	甲状腺機能低下症	20[redacted]	222	689	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃炎	20[redacted]	229	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胸部損傷	20[redacted]	292	64	N	Grade 2	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	転倒	20[redacted]	292	1	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	転倒	20[redacted]	297	1	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	関節損傷	20[redacted]	297	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	口内乾燥	20[redacted]	537	.	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	徐脈	20[redacted]	545	366	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	多発性外傷	20[redacted]	622	9	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肋骨骨折	20[redacted]	622	.	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	肺挫傷	20[redacted]	622	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脛骨骨折	20[redacted]	622	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腓骨骨折	20[redacted]	622	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低酸素症	20[redacted]	624	.	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	骨折の遷延治癒	20[redacted]	625	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	便秘	20[redacted]	626	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低カリウム血症	20[redacted]	628	3	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	貧血	20[redacted]	628	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	TRANSFUSION PERFORMED	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脊椎骨折	20[redacted]	629	.	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	高血圧	20[redacted]	629	90	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	伝音難聴	20[redacted]	.	173	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	便秘	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	耳垢分泌過多	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	末梢性浮腫	20[redacted]	4	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	緊張性頭痛	20[redacted]	117	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	擦過傷	20[redacted]	127	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	127	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性咽頭炎	20[redacted]	186	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	206	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肛門周囲痛	20[redacted]	212	51	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肋軟骨炎	20[redacted]	218	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	直腸出血	20[redacted]	236	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	痔核	20[redacted]	278	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	甲状腺機能低下症	20[redacted]	290	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	333	35	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	顎下腺腫大	20[redacted]	352	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭位性回転性めまい	20[redacted]	396	93	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	抜歯	20[redacted]	437	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	555	176	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	変形性脊椎症	20[redacted]	664	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	椎間板変性症	20[redacted]	664	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低ナトリウム血症	20[redacted]	683	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	20[redacted]	683	14	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	下痢	20[redacted]	703	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低ナトリウム血症	20[redacted]	707	9	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低ナトリウム血症	20[redacted]	716	.	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	インフルエンザ	20[redacted]	238	16	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	アレルギー性結膜炎	20[redacted]	262	30	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	便秘	20[redacted]	404	71	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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	6[redacted]	F	OTHER	肺炎	20[redacted]	440	20	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	痔核	20[redacted]	453	.	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	鼻出血	20[redacted]	661	244	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	接触性皮膚炎	20[redacted]	13	51	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	20[redacted]	76	63	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	咽喉乾燥	20[redacted]	94	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭位性回転性めまい	20[redacted]	115	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	基底細胞癌	20[redacted]	.	458	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	高コレステロール血症	20[redacted]	238	353	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	接触性皮膚炎	20[redacted]	240	37	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	外陰腟そう痒症	20[redacted]	243	44	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	視力障害	20[redacted]	272	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	消化不良	20[redacted]	298	127	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	尿路感染	20[redacted]	308	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	腟感染	20[redacted]	308	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	345	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	.	104	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	舌炎	20[redacted]	420	66	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	皮膚炎	20[redacted]	534	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	接触性皮膚炎	20[redacted]	539	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	腟感染	20[redacted]	714	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	浮動性めまい	20[redacted]	144	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	便秘	20[redacted]	167	2	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	脂質異常症	20[redacted]	177	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	四肢損傷	20[redacted]	180	1	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]	180	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	軟部組織損傷	20[redacted]	224	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	転倒	20[redacted]	224	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	細菌性胃腸炎	20[redacted]	273	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	椎間板障害	20[redacted]	288	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	316	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	くも膜下出血	20[redacted]	436	21	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	創傷	20[redacted]	436	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	回転性めまい	20[redacted]	436	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	外傷後頭痛	20[redacted]	436	41	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	外傷性難聴	20[redacted]	436	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	損傷	20[redacted]	436	36	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	硬膜下血腫	20[redacted]	436	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胸部損傷	20[redacted]	436	53	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	角膜白斑	20[redacted]	436	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭蓋骨骨折	20[redacted]	436	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	顔面損傷	20[redacted]	436	118	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	下痢	20[redacted]	45	4	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脂質異常症	20[redacted]	61	.	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	緊張性頭痛	20[redacted]	95	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性下痢	20[redacted]	113	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	便秘	20[redacted]	132	128	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	尿閉	20[redacted]	132	114	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	片麻痺	20[redacted]	132	180	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低酸素症	20[redacted]	140	408	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心室性不整脈	20[redacted]	141	.	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	敗血症性ショック	20[redacted]	141	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	IV ANTIMICROBIAL TAKEN	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	155	6	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	心筋虚血	20[redacted]	157	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	心臓内血栓	20[redacted]	157	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	下痢	20[redacted]	222	2	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	徐脈	20[redacted]	332	.	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	気管支炎	20[redacted]	442	12	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	寄生虫感染	20[redacted]	501	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋肉内出血	20[redacted]	563	16	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	凝固時間延長	20[redacted]	566	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	TRANSFUSION PERFORMED	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	右脚ブロック	20[redacted]	52	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	左脚ブロック	20[redacted]	52	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	103	380	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	転倒	20[redacted]	103	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節脱臼	20[redacted]	103	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	日光黒子	20[redacted]	.	455	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	皮膚乳頭腫	20[redacted]	.	455	N	Grade 2	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	高血圧	20[redacted]	182	62	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	斜頚	20[redacted]	207	29	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	20[redacted]	277	26	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	尺骨骨折	20[redacted]	324	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	橈骨骨折	20[redacted]	324	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	324	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	333	113	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	背部痛	20[redacted]	520	196	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	変形性関節症	20[redacted]	153	187	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	インフルエンザ	20[redacted]	226	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	悪性黒子	20[redacted]	227	209	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胃炎	20[redacted]	236	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	移植片合併症	20[redacted]	367	363	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	387	221	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	インフルエンザ	20[redacted]	433	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	四肢損傷	20[redacted]	465	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	バルサルバ法	20[redacted]	19	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	回転性めまい	20[redacted]	19	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腹痛	20[redacted]	19	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	軟部組織損傷	20[redacted]	27	35	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	過敏性腸症候群	20[redacted]	45	316	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	110	155	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧クリーゼ	20[redacted]	182	120	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃腸炎	20[redacted]	212	10	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	深部静脈血栓症	20[redacted]	314	176	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃腸炎	20[redacted]	314	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	回転性めまい	20[redacted]	440	30	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胸部損傷	20[redacted]	444	41	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	444	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	アトピー性皮膚炎	20[redacted]	.	219	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	489	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	過敏性腸症候群	20[redacted]	.	68	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	軟部組織損傷	20[redacted]	628	8	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]	628	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	外陰腟真菌感染	20[redacted]	.	201	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鼻出血	20[redacted]	68	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鼻出血	20[redacted]	76	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	背部痛	20[redacted]	115	187	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高トリグリセリド血症	20[redacted]	157	325	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	細菌性結膜炎	20[redacted]	166	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胸痛	20[redacted]	240	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	耳垢分泌過多	20[redacted]	301	52	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	聴力低下	20[redacted]	301	52	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	斑状出血	20[redacted]	307	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	転倒	20[redacted]	307	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	関節痛	20[redacted]	325	185	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	収縮機能障害	20[redacted]	411	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	裂傷	20[redacted]	442	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	転倒	20[redacted]	442	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性気管支炎	20[redacted]	.	99	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	脂質異常症	20[redacted]	481	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	眼乾燥	20[redacted]	527	199	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	眼瞼損傷	20[redacted]	675	51	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	転倒	20[redacted]	675	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	顔面損傷	20[redacted]	675	51	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	細菌性膣症	20[redacted]	704	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	静脈瘤	20[redacted]	704	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鼻乾燥	20[redacted]	704	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	発疹	20[redacted]	719	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	便秘	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	錐体外路障害	20[redacted]	.	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	うつ病	20[redacted]	89	85	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	大動脈弁閉鎖不全症	20[redacted]	118	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	心室肥大	20[redacted]	118	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	うつ病	20[redacted]	174	22	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	仮性認知症	20[redacted]	174	22	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	振戦	20[redacted]	185	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	大うつ病	20[redacted]	281	27	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	振戦	20[redacted]	281	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	血便排泄	20[redacted]	293	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	卵巣嚢胞	20[redacted]	342	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	憩室	20[redacted]	348	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	痔核	20[redacted]	348	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	20[redacted]	528	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	インフルエンザ	20[redacted]	556	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	末梢動脈閉塞性疾患	20[redacted]	643	.	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	尿路感染	20[redacted]	9	285	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	変形性関節症	20[redacted]	11	.	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	軟部組織損傷	20[redacted]	21	9	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	転倒	20[redacted]	21	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	インフルエンザ	20[redacted]	140	33	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	筋痙縮	20[redacted]	.	55	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	萎縮性外陰腟炎	20[redacted]	173	.	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	不眠症	20[redacted]	179	263	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	大動脈弁閉鎖不全症	20[redacted]	272	.	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	心臓弁硬化症	20[redacted]	272	.	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	白血球減少症	20[redacted]	273	102	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	尿路感染	20[redacted]	307	8	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	尿路感染	20[redacted]	307	.	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	慢性胃炎	20[redacted]	317	.	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	三尖弁閉鎖不全症	20[redacted]	451	.	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	肺動脈性肺高血圧症	20[redacted]	451	.	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]	.	.	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	脂質異常症	20[redacted]	531	.	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	傾眠	20[redacted]	584	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	尿路感染	20[redacted]	584	9	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	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	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	頚髄神経根障害	20[redacted]	.	.	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	うつ病	20[redacted]	67	68	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	嘔吐	20[redacted]	115	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	本態性振戦	20[redacted]	.	218	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	軟部組織損傷	20[redacted]	130	58	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	転倒	20[redacted]	130	1	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	平衡障害	20[redacted]	183	107	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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	軟部組織損傷	20[redacted]	205	22	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]	205	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	放屁	20[redacted]	248	98	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	耳垢栓塞	20[redacted]	268	74	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	関節痛	20[redacted]	279	56	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	末梢性浮腫	20[redacted]	342	18	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	眼瞼浮腫	20[redacted]	342	18	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	足部白癬	20[redacted]	468	73	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	発熱	20[redacted]	473	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	背部痛	20[redacted]	525	.	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	インフルエンザ	20[redacted]	537	6	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	非心臓性胸痛	20[redacted]	682	10	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	684	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	頭痛	20[redacted]	686	3	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	非心臓性胸痛	20[redacted]	692	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	足部白癬	20[redacted]	44	113	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	背部痛	20[redacted]	105	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	異汗性湿疹	20[redacted]	180	11	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]	221	54	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	皮膚真菌感染	20[redacted]	266	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	虫垂炎	20[redacted]	299	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	処置による疼痛	20[redacted]	301	60	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	咳嗽	20[redacted]	310	51	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	甲状腺機能低下症	20[redacted]	314	73	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	鼻出血	20[redacted]	357	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	高コレステロール血症	20[redacted]	363	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	ウイルス性胃腸炎	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	動物咬傷	20[redacted]	435	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	歯科補てつ物装着	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	436	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	頭痛	20[redacted]	486	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	甲状腺機能低下症	20[redacted]	519	182	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	手骨折	20[redacted]	606	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	720	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	上部消化管出血	20[redacted]	396	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	上部消化管出血	20[redacted]	404	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	扁平上皮癌	20[redacted]	217	179	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	UNKNOWN	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	198	.	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	背部痛	20[redacted]	252	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	咳嗽	20[redacted]	276	.	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	脂質異常症	20[redacted]	276	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	276	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	動脈硬化症	20[redacted]	309	21	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	上室性頻脈	20[redacted]	208	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尿路感染	20[redacted]	208	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尿路感染	20[redacted]	243	9	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	狭心症	20[redacted]	481	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[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	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	気管支炎	20[redacted]	411	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	下痢	20[redacted]	53	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	肺新生物	20[redacted]	265	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	136	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	234	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	254	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	一過性精神病	20[redacted]	88	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腎嚢胞	20[redacted]	233	.	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	低血糖	20[redacted]	704	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	痔核	20[redacted]	411	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	憩室炎	20[redacted]	422	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胃炎	20[redacted]	422	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	化生	20[redacted]	425	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胃腸出血	20[redacted]	457	11	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	貧血	20[redacted]	459	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	TRANSFUSION PERFORMED	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肺腫瘤	20[redacted]	707	16	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	憩室	20[redacted]	60	3	Y	Grade 3	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	複視	20[redacted]	174	8	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	脳血管発作	20[redacted]	498	18	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尿路感染	20[redacted]	505	11	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	エンテロバクター性菌血症	20[redacted]	506	10	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性腎臓病	20[redacted]	122	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	急性心筋梗塞	20[redacted]	293	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	急性心筋梗塞	20[redacted]	375	5	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	腱炎	20[redacted]	179	.	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	尿路感染	20[redacted]	282	42	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	胃炎	20[redacted]	282	42	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	結腸腺癌	20[redacted]	392	25	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	齲歯	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	7[redacted]	F	OTHER	便秘	20[redacted]	90	.	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	直腸出血	20[redacted]	90	.	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	失神	20[redacted]	207	10	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	破裂性脳動脈瘤	20[redacted]	710	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃炎	20[redacted]	14	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肩回旋筋腱板症候群	20[redacted]	72	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	急性心筋梗塞	20[redacted]	216	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		8[redacted]	F	OTHER	慢性腎臓病	20[redacted]	100	.	Y	Grade 4	RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	65	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	65	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低カリウム血症	20[redacted]	66	26	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	恥骨骨折	20[redacted]	123	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	123	1	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭蓋脳損傷	20[redacted]	138	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	141	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	537	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃腺癌	20[redacted]	314	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	上室性頻脈	20[redacted]	494	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低カルシウム血症	20[redacted]	494	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	失神	20[redacted]	494	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	汎血球減少症	20[redacted]	494	.	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	うっ血性心不全	20[redacted]	167	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	便秘	20[redacted]	64	.	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	皮膚潰瘍	20[redacted]	100	63	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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	ブドウ球菌感染	20[redacted]	162	59	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	コントロール不良の糖尿病	20[redacted]	611	9	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肺塞栓症	20[redacted]	611	9	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	深部静脈血栓症	20[redacted]	614	6	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	糖尿病性ニューロパチー	20[redacted]	618	.	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	慢性閉塞性肺疾患	20[redacted]	21	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	糖尿病	20[redacted]	21	.	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	高血圧	20[redacted]	21	.	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	胃炎	20[redacted]	316	.	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	慢性閉塞性肺疾患	20[redacted]	451	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肺性心	20[redacted]	451	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	乳房の上皮内癌	20[redacted]	267	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性腎臓病	20[redacted]	99	.	Y	Grade 4	RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	血栓性静脈炎	20[redacted]	2	8	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[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	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	気管支炎	20[redacted]	63	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	うっ血性心不全	20[redacted]	104	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	104	8	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肺炎	20[redacted]	104	8	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	121	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	脳血管発作	20[redacted]	511	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高コレステロール血症	20[redacted]	512	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	左房拡張	20[redacted]	519	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	90	19	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		7[redacted]	F	OTHER	肺の悪性新生物	20[redacted]	90	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胆石症	20[redacted]	575	48	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	小腸穿孔	20[redacted]	622	7	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	尿路感染	20[redacted]	291	6	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	尿路感染	20[redacted]	666	18	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	上腕骨骨折	20[redacted]	598	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尿路感染	20[redacted]	162	4	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肺炎	20[redacted]	345	6	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	心房細動	20[redacted]	495	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	僧帽弁閉鎖不全症	20[redacted]	497	.	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	心室肥大	20[redacted]	497	.	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	肺高血圧症	20[redacted]	497	.	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	高血圧	20[redacted]	1	210	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	喉頭炎	20[redacted]	111	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高血圧	20[redacted]	650	4	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	701	4	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	びらん性胃炎	20[redacted]	44	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	消化不良	20[redacted]	44	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	足骨折	20[redacted]	97	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	胃腺癌	20[redacted]	710	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	三叉神経痛	20[redacted]	176	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	悪性黒色腫	20[redacted]	347	29	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	遠隔転移を伴う悪性黒色腫	20[redacted]	648	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高血圧	20[redacted]	728	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	耳鳴	20[redacted]	28	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	咽頭炎	20[redacted]	51	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	58	.	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]	86	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	多発性外傷	20[redacted]	86	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	消化不良	20[redacted]	119	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	198	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	失神	20[redacted]	681	6	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	急性胆嚢炎	20[redacted]	178	6	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[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

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	腹部膨満	20[redacted]	1	31	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	大腸菌性尿路感染	20[redacted]	45	49	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	眼瞼浮腫	20[redacted]	323	69	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	医療機器合併症	20[redacted]	349	11	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	譫妄	20[redacted]	386	15	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	皮膚障害	20[redacted]	32	242	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	顔面損傷	20[redacted]	46	83	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	ウイルス性下痢	20[redacted]	155	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	回転性めまい	20[redacted]	165	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	皮膚損傷	20[redacted]	214	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	四肢痛	20[redacted]	336	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	関節痛	20[redacted]	430	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	表皮内悪性黒色腫	20[redacted]	559	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肩回旋筋腱板症候群	20[redacted]	166	.	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	緊張性頭痛	20[redacted]	229	94	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	歯の脱落	20[redacted]	675	1	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	高コレステロール血症	20[redacted]	695	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[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	
[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	8[redacted]	F	OTHER	インフルエンザ	20[redacted]	11	13	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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	関節痛	20[redacted]	54	52	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	咳嗽	20[redacted]	107	397	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	筋骨格痛	20[redacted]	143	.	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	高トリグリセリド血症	20[redacted]	148	.	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	甲状腺機能低下症	20[redacted]	169	.	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	脂質異常症	20[redacted]	169	.	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	発疹	20[redacted]	218	79	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	インフルエンザ	20[redacted]	359	19	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	高尿酸血症	20[redacted]	644	.	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	鼻出血	20[redacted]	708	1	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	トランスアミナーゼ上昇	20[redacted]	728	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	耳垢栓塞	20[redacted]	1	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	伝音難聴	20[redacted]	7	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	鼓膜穿孔	20[redacted]	7	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋骨格痛	20[redacted]	38	36	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	73	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	高血圧	20[redacted]	86	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不眠症	20[redacted]	99	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	20[redacted]	122	63	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	インフルエンザ	20[redacted]	230	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	回転性めまい	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低カリウム血症	20[redacted]	711	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低ナトリウム血症	20[redacted]	711	3	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	難聴	20[redacted]	14	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胃腸出血	20[redacted]	55	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	びらん性食道炎	20[redacted]	56	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胃粘膜紅斑	20[redacted]	56	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	関節痛	20[redacted]	221	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	嘔吐	20[redacted]	277	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	トランスアミナーゼ上昇	20[redacted]	279	12	Y	Grade 3	RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	下痢	20[redacted]	337	9	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胃腸出血	20[redacted]	337	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	貧血	20[redacted]	339	46	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	譫妄	20[redacted]	341	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	憩室	20[redacted]	372	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	痔核	20[redacted]	372	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	大腸炎	20[redacted]	374	.	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	咳嗽	20[redacted]	37	.	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	アレルギー性結膜炎	20[redacted]	119	28	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	腹痛	20[redacted]	119	67	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	嘔吐	20[redacted]	177	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	腹痛	20[redacted]	177	3	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	脂肪肝	20[redacted]	178	.	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	四肢痛	20[redacted]	256	.	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	消化不良	20[redacted]	.	.	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	筋痙縮	20[redacted]	72	522	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[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	PLACEBO		6[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	11	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	変形性脊椎症	20[redacted]	20	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	心臓弁膜疾患	20[redacted]	31	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	心臓弁閉鎖不全	20[redacted]	31	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	高血圧性心疾患	20[redacted]	31	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	僧帽弁逸脱	20[redacted]	47	53	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	僧帽弁閉鎖不全症	20[redacted]	47	53	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	大動脈弁閉鎖不全症	20[redacted]	47	53	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	肺高血圧症	20[redacted]	47	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	インフルエンザ	20[redacted]	53	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	心臓弁閉鎖不全	20[redacted]	82	26	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	大動脈狭窄	20[redacted]	83	17	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	下痢	20[redacted]	85	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	基底細胞癌	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	N
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	回転性めまい	20[redacted]	186	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	失神	20[redacted]	186	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	インフルエンザ	20[redacted]	260	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	胸痛	20[redacted]	298	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	側弯症	20[redacted]	330	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	胆道気腫	20[redacted]	330	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	脂肪肝	20[redacted]	330	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	腎結石症	20[redacted]	330	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	気管支炎	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	脂質異常症	20[redacted]	439	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	三尖弁閉鎖不全症	20[redacted]	510	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	COLOMBIA	PLACEBO		6[redacted]	F	OTHER	大動脈硬化症	20[redacted]	510	.	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	AMERICAN INDIAN OR ALASKA NATIVE	高コレステロール血症	20[redacted]	35	56	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	AMERICAN INDIAN OR ALASKA NATIVE	回転性めまい	20[redacted]	136	1	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	AMERICAN INDIAN OR ALASKA NATIVE	高血圧	20[redacted]	302	.	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	AMERICAN INDIAN OR ALASKA NATIVE	失神	20[redacted]	477	1	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	AMERICAN INDIAN OR ALASKA NATIVE	ウイルス感染	20[redacted]	685	.	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	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]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	AMERICAN INDIAN OR ALASKA NATIVE	感染性皮膚潰瘍	20[redacted]	360	124	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	COLOMBIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	AMERICAN INDIAN OR ALASKA NATIVE	静脈瘤性潰瘍	20[redacted]	520	.	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	WHITE	子宮頚管ポリープ	20[redacted]	22	20	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	口腔咽頭痛	20[redacted]	124	6	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	WHITE	関節痛	20[redacted]	186	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	WHITE	胸痛	20[redacted]	241	3	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	WHITE	背部痛	20[redacted]	264	45	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	WHITE	四肢痛	20[redacted]	294	140	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	WHITE	四肢痛	20[redacted]	294	140	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	WHITE	末梢性浮腫	20[redacted]	294	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	WHITE	末梢性浮腫	20[redacted]	294	36	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	WHITE	発熱	20[redacted]	294	3	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	WHITE	上腹部痛	20[redacted]	.	.	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	WHITE	歯牙破折	20[redacted]	357	1	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	WHITE	総蛋白増加	20[redacted]	371	.	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]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	433	29	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	WHITE	背部痛	20[redacted]	526	15	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	BLACK OR AFRICAN AMERICAN	頭部損傷	20[redacted]	77	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	高血圧	20[redacted]	77	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	外傷後頭痛	20[redacted]	78	15	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	BLACK OR AFRICAN AMERICAN	浮動性めまい	20[redacted]	78	15	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	BLACK OR AFRICAN AMERICAN	高グロブリン血症	20[redacted]	90	130	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	BLACK OR AFRICAN AMERICAN	高ビリルビン血症	20[redacted]	90	93	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	BLACK OR AFRICAN AMERICAN	出血性卒中	20[redacted]	91	218	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	高血糖	20[redacted]	93	90	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	BLACK OR AFRICAN AMERICAN	筋骨格痛	20[redacted]	129	210	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	BLACK OR AFRICAN AMERICAN	耳鳴	20[redacted]	181	.	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	BLACK OR AFRICAN AMERICAN	浮動性めまい	20[redacted]	202	47	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	BLACK OR AFRICAN AMERICAN	口内乾燥	20[redacted]	278	156	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	BLACK OR AFRICAN AMERICAN	浮動性めまい	20[redacted]	339	125	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	BLACK OR AFRICAN AMERICAN	筋力低下	20[redacted]	339	95	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	BLACK OR AFRICAN AMERICAN	高血糖	20[redacted]	371	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	回転性めまい	20[redacted]	463	.	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	BLACK OR AFRICAN AMERICAN	口内乾燥	20[redacted]	.	.	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	BLACK OR AFRICAN AMERICAN	蛋白尿	20[redacted]	603	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[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	AMG 785 210 MG SC QM		6[redacted]	F	BLACK OR AFRICAN AMERICAN	脂肪肝	20[redacted]	25	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	BLACK OR AFRICAN AMERICAN	トランスアミナーゼ上昇	20[redacted]	33	296	Y	Grade 3	RELATED	RESOLVED	DRUG WITHDRAWN	OTHER	N
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	BLACK OR AFRICAN AMERICAN	高トリグリセリド血症	20[redacted]	146	183	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	BLACK OR AFRICAN AMERICAN	眼痛	20[redacted]	167	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	BLACK OR AFRICAN AMERICAN	熱感	20[redacted]	232	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	BLACK OR AFRICAN AMERICAN	発熱	20[redacted]	242	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	BLACK OR AFRICAN AMERICAN	食欲減退	20[redacted]	242	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	BLACK OR AFRICAN AMERICAN	裂傷	20[redacted]	282	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	BLACK OR AFRICAN AMERICAN	熱感	20[redacted]	298	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	BLACK OR AFRICAN AMERICAN	疼痛	20[redacted]	298	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	BLACK OR AFRICAN AMERICAN	関節痛	20[redacted]	339	6	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	BLACK OR AFRICAN AMERICAN	インフルエンザ	20[redacted]	28	66	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	BLACK OR AFRICAN AMERICAN	転倒	20[redacted]	65	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	関節痛	20[redacted]	65	52	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	BLACK OR AFRICAN AMERICAN	血小板数増加	20[redacted]	95	.	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	BLACK OR AFRICAN AMERICAN	背部痛	20[redacted]	.	209	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	BLACK OR AFRICAN AMERICAN	インフルエンザ	20[redacted]	134	8	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	BLACK OR AFRICAN AMERICAN	アメーバ症	20[redacted]	168	11	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	インフルエンザ	20[redacted]	201	4	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	BLACK OR AFRICAN AMERICAN	発熱	20[redacted]	201	4	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	BLACK OR AFRICAN AMERICAN	発熱	20[redacted]	238	4	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	BLACK OR AFRICAN AMERICAN	関節痛	20[redacted]	238	4	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	BLACK OR AFRICAN AMERICAN	咳嗽	20[redacted]	.	65	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	BLACK OR AFRICAN AMERICAN	咽喉刺激感	20[redacted]	256	.	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	BLACK OR AFRICAN AMERICAN	斑	20[redacted]	276	.	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	BLACK OR AFRICAN AMERICAN	発熱	20[redacted]	295	3	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	BLACK OR AFRICAN AMERICAN	腹部膨満	20[redacted]	306	166	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	BLACK OR AFRICAN AMERICAN	非心臓性胸痛	20[redacted]	330	149	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	BLACK OR AFRICAN AMERICAN	白血球数増加	20[redacted]	375	.	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	BLACK OR AFRICAN AMERICAN	白内障手術	20[redacted]	466	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	眼刺激	20[redacted]	520	195	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	BLACK OR AFRICAN AMERICAN	上気道感染	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[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	
[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	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	消化器痛	20[redacted]	88	413	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	筋骨格痛	20[redacted]	143	92	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	憩室炎	20[redacted]	162	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	アレルギー性鼻炎	20[redacted]	199	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	橈骨骨折	20[redacted]	363	.	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	回転性めまい	20[redacted]	367	178	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	大腿骨骨折	20[redacted]	101	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	滑液包炎	20[redacted]	191	47	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	発熱	20[redacted]	270	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	帯状疱疹	20[redacted]	301	15	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	鼻咽頭炎	20[redacted]	698	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	脳血管発作	20[redacted]	112	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	末梢性浮腫	20[redacted]	164	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	関節痛	20[redacted]	314	.	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	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	変形性脊椎症	20[redacted]	512	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	変形性関節症	20[redacted]	512	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[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	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	腸閉塞	20[redacted]	126	18	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	術後創感染	20[redacted]	133	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	嘔吐	20[redacted]	137	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	深部静脈血栓症	20[redacted]	162	557	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	インフルエンザ	20[redacted]	241	67	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	発熱	20[redacted]	349	3	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	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	

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	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	
[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	高血圧	20[redacted]	47	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	出血性貧血	20[redacted]	52	48	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	関節痛	20[redacted]	85	134	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	インフルエンザ	20[redacted]	122	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	インフルエンザ	20[redacted]	196	10	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]	304	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	霧視	20[redacted]	334	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	不眠症	20[redacted]	347	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	MULTIPLE	筋痙縮	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	咳嗽	20[redacted]	29	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	尿路感染	20[redacted]	65	121	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	喘息	20[redacted]	105	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	ジアルジア症	20[redacted]	180	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	肝酵素上昇	20[redacted]	274	88	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	

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	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	アレルギー性皮膚炎	20[redacted]	66	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	２型糖尿病	20[redacted]	98	79	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	高血圧	20[redacted]	121	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	腎クレアチニン・クリアランス減少	20[redacted]	176	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	貧血	20[redacted]	176	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	水腎杯	20[redacted]	225	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	脳振盪	20[redacted]	233	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	浮動性めまい	20[redacted]	250	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	糖尿病	20[redacted]	359	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	高血圧	20[redacted]	359	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	高血圧	20[redacted]	539	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	小脳虚血	20[redacted]	621	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[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	

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[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	
[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
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	高血圧クリーゼ	20[redacted]	146	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	急性心筋梗塞	20[redacted]	152	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	左室機能不全	20[redacted]	154	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	心臓弁膜疾患	20[redacted]	154	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	発熱	20[redacted]	213	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	関節痛	20[redacted]	230	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	ウイルス感染	20[redacted]	307	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	浮動性めまい	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	MULTIPLE	失神	20[redacted]	311	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	

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	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	四肢痛	20[redacted]	77	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	筋痙縮	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	喉頭炎	20[redacted]	314	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	アレルギー性鼻炎	20[redacted]	349	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DOMINICAN REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	MULTIPLE	寛骨臼骨折	20[redacted]	396	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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 Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	BLACK OR AFRICAN AMERICAN	呼吸困難	20[redacted]-[redacted]-[redacted]	162	28	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	BLACK OR AFRICAN AMERICAN	四肢痛	20[redacted]-[redacted]-[redacted]	171	19	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	BLACK OR AFRICAN AMERICAN	甲状腺腺腫	20[redacted]-[redacted]-[redacted]	180	58	N	MILD	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	BLACK OR AFRICAN AMERICAN	挫傷	20[redacted]-[redacted]-[redacted]	327	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	BLACK OR AFRICAN AMERICAN	心雑音	20[redacted]-[redacted]-[redacted]	366	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	BLACK OR AFRICAN AMERICAN	呼吸困難	20[redacted]-[redacted]-[redacted]	439	13	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	尿路感染	20[redacted]-[redacted]-[redacted]	40	8	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	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	腹部圧痛	20[redacted]-[redacted]-[redacted]	94	67	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	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	関節痛	20[redacted]-[redacted]-[redacted]	94	29	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	尿路感染	20[redacted]-[redacted]-[redacted]	147	9	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	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	尿路感染	20[redacted]-[redacted]-[redacted]	241	9	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	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	蕁麻疹	20[redacted]-[redacted]-[redacted]	272	3	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	副鼻腔炎に伴う頭痛	20[redacted]-[redacted]-[redacted]	420	8	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	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	背部痛	20[redacted]-[redacted]-[redacted]	420	106	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	眼圧上昇	20[redacted]-[redacted]-[redacted]	584	56	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	副鼻腔炎	20[redacted]-[redacted]-[redacted]	638	9	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	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	ヘリコバクター感染	20[redacted]-[redacted]-[redacted]	666	10	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	小腸閉塞	20[redacted]-[redacted]-[redacted]	772	3	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	非心臓性胸痛	20[redacted]-[redacted]-[redacted]	772	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	上気道感染	20[redacted]-[redacted]-[redacted]	1218	14	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	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	HISPANIC OR LATINO	上気道感染	20[redacted]-[redacted]-[redacted]	1440	106	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	上気道感染	20[redacted]	206	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	アナフィラキシー反応	20[redacted]	351	2	Y	LIFE THREATENING	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	麦粒腫	20[redacted]	399	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	尾骨痛	20[redacted]	650	16	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	650	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	眼挫傷	20[redacted]	813	2	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	耳鳴	20[redacted]	814	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位反応	20[redacted]	1125	3	N	MODERATE	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位疼痛	20[redacted]	1125	3	N	MODERATE	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位紅斑	20[redacted]	1125	3	N	MODERATE	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位蕁麻疹	20[redacted]	1125	3	N	MODERATE	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位反応	20[redacted]	1154	2	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位蕁麻疹	20[redacted]	1154	2	N	MODERATE	RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	インフルエンザ	20[redacted]	1248	10	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位疼痛	20[redacted]	1258	2	N	MODERATE	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位疼痛	20[redacted]	1275	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	処置による疼痛	20[redacted]	613	30	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	皮膚真菌感染	20[redacted]	779	24	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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 Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]-[redacted]-[redacted]	817	6	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	冠動脈疾患	20[redacted]-[redacted]-[redacted]	1692	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	心筋梗塞	20[redacted]-[redacted]-[redacted]	1692	4	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC Q3M					6[redacted]	F	HISPANIC OR LATINO	乳腺腺腫	20[redacted]-[redacted]-[redacted]	183	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 210 MG SC Q3M					6[redacted]	F	HISPANIC OR LATINO	急性リンパ性白血病	20[redacted]-[redacted]-[redacted]	183	.	Y	SEVERE	NOT RELATED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC Q3M					6[redacted]	F	HISPANIC OR LATINO	非心臓性胸痛	20[redacted]-[redacted]-[redacted]	183	4	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC Q3M					6[redacted]	F	HISPANIC OR LATINO	汎血球減少症	20[redacted]-[redacted]-[redacted]	214	2	Y	LIFE THREATENING	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			6[redacted]	F	WHITE OR CAUCASIAN	肩回旋筋腱板症候群	20[redacted]-[redacted]-[redacted]	110	41	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	UNITED STATES	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			6[redacted]	F	WHITE OR CAUCASIAN	処置による疼痛	20[redacted]-[redacted]-[redacted]	150	38	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			6[redacted]	F	WHITE OR CAUCASIAN	穿孔性虫垂炎	20[redacted]-[redacted]-[redacted]	559	6	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			6[redacted]	F	WHITE OR CAUCASIAN	感音性難聴	20[redacted]-[redacted]-[redacted]	780	.	N	MILD	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	疲労	20[redacted]-[redacted]-[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]-[redacted]-[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]-[redacted]-[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]-[redacted]-[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]-[redacted]-[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]-[redacted]-[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]-[redacted]-[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]-[redacted]-[redacted]	649	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	N

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	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]	UNITED STATES	AMG 785 140 MG SC QM					8[redacted]	F	WHITE OR CAUCASIAN	注射部位疼痛	20[redacted]	1	4	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM					8[redacted]	F	WHITE OR CAUCASIAN	注射部位紅斑	20[redacted]	1	4	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM					8[redacted]	F	WHITE OR CAUCASIAN	疲労	20[redacted]	2	5	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM					8[redacted]	F	WHITE OR CAUCASIAN	洞結節機能不全	20[redacted]	54	124	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM					8[redacted]	F	WHITE OR CAUCASIAN	胸痛	20[redacted]	54	38	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM					8[redacted]	F	WHITE OR CAUCASIAN	頻脈	20[redacted]	54	23	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM					8[redacted]	F	WHITE OR CAUCASIAN	うっ血性心不全	20[redacted]	72	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM					8[redacted]	F	WHITE OR CAUCASIAN	失神	20[redacted]	139	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM					8[redacted]	F	WHITE OR CAUCASIAN	三尖弁閉鎖不全症	20[redacted]	177	.	N	SEVERE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	低血圧	20[redacted]	6	3	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	筋痙縮	20[redacted]	11	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	体液貯留	20[redacted]	16	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	浮動性めまい	20[redacted]	16	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	交通事故	20[redacted]-[redacted]-[redacted]	76	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	卵管炎	20[redacted]-[redacted]-[redacted]	76	43	Y	MILD	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	挫傷	20[redacted]-[redacted]-[redacted]	76	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	挫傷	20[redacted]-[redacted]-[redacted]	76	15	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]-[redacted]-[redacted]	76	8	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]-[redacted]-[redacted]	89	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]-[redacted]-[redacted]	89	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	貧血	20[redacted]-[redacted]-[redacted]	119	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	血尿	20[redacted]-[redacted]-[redacted]	121	2	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	胃食道逆流性疾患	20[redacted]-[redacted]-[redacted]	162	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	歯膿瘍	20[redacted]-[redacted]-[redacted]	201	36	N	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	歯膿瘍	20[redacted]-[redacted]-[redacted]	201	82	N	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	ヘルニア	20[redacted]-[redacted]-[redacted]	349	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	口唇損傷	20[redacted]-[redacted]-[redacted]	349	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	挫傷	20[redacted]-[redacted]-[redacted]	349	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	皮膚擦過傷	20[redacted]-[redacted]-[redacted]	349	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]-[redacted]-[redacted]	349	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	N
[redacted]	UNITED STATES	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	関節腫脹	20[redacted]-[redacted]-[redacted]	349	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	筋骨格痛	20[redacted]-[redacted]-[redacted]	14	92	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]-[redacted]-[redacted]	14	92	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	そう痒症	20[redacted]-[redacted]-[redacted]	15	119	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N

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 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	処置による低血圧	20[redacted]-[redacted]-[redacted]	24	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	痔核	20[redacted]-[redacted]-[redacted]	24	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	胃炎	20[redacted]-[redacted]-[redacted]	24	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	裂孔ヘルニア	20[redacted]-[redacted]-[redacted]	24	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	小結節	20[redacted]-[redacted]-[redacted]	33	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]-[redacted]-[redacted]	47	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	裂傷	20[redacted]-[redacted]-[redacted]	61	39	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	小結節	20[redacted]-[redacted]-[redacted]	99	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	小結節	20[redacted]-[redacted]-[redacted]	106	69	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]-[redacted]-[redacted]	119	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	小結節	20[redacted]-[redacted]-[redacted]	124	53	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	脊椎炎	20[redacted]-[redacted]-[redacted]	124	249	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	筋力低下	20[redacted]-[redacted]-[redacted]	145	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	小結節	20[redacted]-[redacted]-[redacted]	176	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	浮動性めまい	20[redacted]-[redacted]-[redacted]	238	50	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	高カルシウム血症	20[redacted]-[redacted]-[redacted]	245	31	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	神経圧迫	20[redacted]-[redacted]-[redacted]	309	64	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	脊柱管狭窄症	20[redacted]-[redacted]-[redacted]	309	.	N	MODERATE	NOT RELATED	DRUG WITHDRAWN	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	腎嚢胞	20[redacted]-[redacted]-[redacted]	324	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	腰部脊柱管狭窄症	20[redacted]-[redacted]-[redacted]	325	.	N	MODERATE	NOT RELATED	DRUG WITHDRAWN	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	処置による疼痛	20[redacted]-[redacted]-[redacted]	372	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	瞼下痛	20[redacted]-[redacted]-[redacted]	372	26	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	食中毒	20[redacted]	392	8	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	靭帯捻挫	20[redacted]	414	74	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	坐骨神経痛	20[redacted]	459	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	小結節	20[redacted]	514	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	靭帯捻挫	20[redacted]	694	32	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	肉離れ	20[redacted]	8	18	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	37	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	高血圧	20[redacted]	77	117	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	ウイルス感染	20[redacted]	190	15	N	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	頭痛	20[redacted]	191	14	N	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	低血圧	20[redacted]	194	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	194	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	肺炎	20[redacted]	194	26	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	裂孔ヘルニア	20[redacted]	194	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	高血圧	20[redacted]	198	167	N	SEVERE	NOT RELATED	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	脊椎炎	20[redacted]	210	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	坐骨神経痛	20[redacted]	219	125	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	肺炎	20[redacted]	295	36	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	白内障	20[redacted]	496	16	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	眼瞼炎	20[redacted]	496	15	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	白内障	20[redacted]	529	47	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	坐骨神経痛	20[redacted]	611	57	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	611	57	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N

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 Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	椎間板障害	20[redacted]	614	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	ウイルス性上気道感染	20[redacted]	737	11	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	労作性呼吸困難	20[redacted]	766	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	貧血	20[redacted]	812	65	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	高コレステロール血症	20[redacted]	1120	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM		7[redacted]	F	WHITE OR CAUCASIAN	麦粒腫	20[redacted]	1191	141	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	痔核	20[redacted]	52	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	インフルエンザ様疾患	20[redacted]	75	2	N	SEVERE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	腹痛	20[redacted]	77	1	N	SEVERE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	歯膿瘍	20[redacted]	82	213	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	腹痛	20[redacted]	89	1	N	SEVERE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	水腎症	20[redacted]	94	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	胆嚢ポリープ	20[redacted]	94	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	腎膨大細胞腫	20[redacted]	94	153	Y	SEVERE	NOT RELATED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	99	148	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	高コレステロール血症	20[redacted]	120	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	腹部圧痛	20[redacted]	246	36	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	388	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	痔核	20[redacted]	442	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	痔核	20[redacted]	442	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	胃ポリープ	20[redacted]	442	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	584	9	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	UNITED STATES	AMG 785 210 MG SC QM					5[redacted]	F	WHITE OR CAUCASIAN	ウイルス性上気道感染	20[redacted]	653	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	PLACEBO Q3M	PLACEBO Q3M				5[redacted]	F	WHITE OR CAUCASIAN	腟脱	20[redacted]	124	2	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	PLACEBO Q3M	PLACEBO Q3M				5[redacted]	F	WHITE OR CAUCASIAN	腹圧性尿失禁	20[redacted]	124	2	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	PLACEBO Q3M	PLACEBO Q3M				5[redacted]	F	WHITE OR CAUCASIAN	高カルシウム尿症	20[redacted]	152	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	動悸	20[redacted]	1	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	筋骨格系胸痛	20[redacted]	15	150	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	血尿	20[redacted]	134	31	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	筋骨格痛	20[redacted]	141	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	蛋白尿	20[redacted]	155	11	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	腎嚢胞	20[redacted]	164	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	腎結石症	20[redacted]	164	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	胃炎	20[redacted]	301	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	脱水	20[redacted]	301	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	関節痛	20[redacted]	330	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	副鼻腔炎	20[redacted]	420	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	咳嗽	20[redacted]	420	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	頚髄神経根障害	20[redacted]	436	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	471	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	側腹部痛	20[redacted]	473	19	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	嘔吐	20[redacted]	473	19	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	悪心	20[redacted]	473	19	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	腎結石症	20[redacted]	477	15	Y	MILD	RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	血尿	20[redacted]	517	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	水腎症	20[redacted]	518	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	脾肉芽腫	20[redacted]	518	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	腎結石症	20[redacted]	518	16	N	MODERATE	NOT RELATED	DRUG WITHDRAWN	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	高カルシウム尿症	20[redacted]	577	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM		5[redacted]	F	WHITE OR CAUCASIAN	頚部痛	20[redacted]	66	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM		5[redacted]	F	WHITE OR CAUCASIAN	骨痛	20[redacted]	360	11	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM		5[redacted]	F	WHITE OR CAUCASIAN	浸潤性乳管癌	20[redacted]	1134	.	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM		5[redacted]	F	WHITE OR CAUCASIAN	高血圧	20[redacted]	1161	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM		5[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]	1165	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM		5[redacted]	F	WHITE OR CAUCASIAN	悪心	20[redacted]	1190	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM		5[redacted]	F	WHITE OR CAUCASIAN	不眠症	20[redacted]	1197	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM		5[redacted]	F	WHITE OR CAUCASIAN	好中球減少症	20[redacted]	1199	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	WHITE OR CAUCASIAN	動悸	20[redacted]	1	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	WHITE OR CAUCASIAN	非心臓性胸痛	20[redacted]	239	2	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	WHITE OR CAUCASIAN	副鼻腔炎	20[redacted]	450	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	WHITE OR CAUCASIAN	基底細胞癌	20[redacted]	540	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	WHITE OR CAUCASIAN	うつ病	20[redacted]	849	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	WHITE OR CAUCASIAN	唾液腺炎	20[redacted]	861	17	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	WHITE OR CAUCASIAN	上気道感染	20[redacted]	1084	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	WHITE OR CAUCASIAN	唾液腺炎	20[redacted]	1652	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	1687	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	5[redacted]	F	WHITE OR CAUCASIAN	悪性黒色腫	20[redacted]	2022	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	UNITED STATES	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	低ナトリウム血症	20[redacted]	184	2	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	悪心	20[redacted]	184	2	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	無力症	20[redacted]	184	2	Y	MILD	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED STATES	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	生殖器痛	20[redacted]	184	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	脱水	20[redacted]	184	2	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	顎痛	20[redacted]	225	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED STATES	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	頚部痛	20[redacted]	536	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	頭痛	20[redacted]	536	24	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	鼻閉	20[redacted]	610	52	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	677	.	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	PLACEBO	AMG 785 210 MG SC QM		6[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	49	.	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	PLACEBO	AMG 785 210 MG SC QM		6[redacted]	F	WHITE OR CAUCASIAN	動脈硬化症	20[redacted]	84	.	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	PLACEBO	AMG 785 210 MG SC QM		6[redacted]	F	WHITE OR CAUCASIAN	肺気腫	20[redacted]	84	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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	PLACEBO	AMG 785 210 MG SC QM		6[redacted]	F	WHITE OR CAUCASIAN	肺線維症	20[redacted]	84	.	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	PLACEBO	AMG 785 210 MG SC QM		6[redacted]	F	WHITE OR CAUCASIAN	季節性アレルギー	20[redacted]	109	.	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	PLACEBO	AMG 785 210 MG SC QM		6[redacted]	F	WHITE OR CAUCASIAN	頚部痛	20[redacted]	274	.	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	PLACEBO	AMG 785 210 MG SC QM		6[redacted]	F	WHITE OR CAUCASIAN	四肢痛	20[redacted]	683	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM		6[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	1135	11	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	PLACEBO	AMG 785 210 MG SC QM		6[redacted]	F	WHITE OR CAUCASIAN	肺炎	20[redacted]	1257	5	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	PLACEBO	AMG 785 210 MG SC QM		6[redacted]	F	WHITE OR CAUCASIAN	肺扁平上皮癌	20[redacted]	1269	.	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED STATES	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM		6[redacted]	F	WHITE OR CAUCASIAN	副甲状腺機能亢進症	20[redacted]	1438	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	腹痛	20[redacted]	57	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	皮膚病変	20[redacted]	95	72	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	156	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	悪心	20[redacted]	161	5	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	憩室炎	20[redacted]	161	19	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	腎嚢胞	20[redacted]	165	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	処置後挫傷	20[redacted]	183	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	憩室	20[redacted]	188	114	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	憩室炎	20[redacted]	188	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	そう痒症	20[redacted]	301	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	処置による疼痛	20[redacted]	301	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	悪心	20[redacted]	301	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	浮動性めまい	20[redacted]	301	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	傾眠	20[redacted]	302	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	嘔吐	20[redacted]	302	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	疲労	20[redacted]	302	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	頭痛	20[redacted]	305	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	注射部位炎症	20[redacted]	400	3	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	450	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	白内障	20[redacted]	465	167	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	引っかき傷	20[redacted]	514	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]	514	44	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	筋骨格痛	20[redacted]	514	12	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	913	10	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	尾骨骨折	20[redacted]	1224	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	意識消失	20[redacted]	1224	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	便秘	20[redacted]	1312	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	処置による疼痛	20[redacted]	1312	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	悪心	20[redacted]	1312	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	皮膚良性新生物	20[redacted]	1420	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	甲状腺の良性新生物	20[redacted]	1439	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	良性腺腫	20[redacted]	1463	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	痔核	20[redacted]	.	91	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	低血圧	20[redacted]	1788	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	処置による疼痛	20[redacted]	1788	15	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	外耳炎	20[redacted]	27	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	帯状疱疹	20[redacted]	187	17	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	胆石症	20[redacted]	364	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	節足動物咬傷	20[redacted]	416	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	紅斑	20[redacted]	551	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	異物感	20[redacted]	552	257	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]	659	12	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	腱炎	20[redacted]	671	199	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	腎不全	20[redacted]	729	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	甲状腺の良性新生物	20[redacted]	772	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N

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[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	憩室炎	20[redacted]	817	15	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	四肢痛	20[redacted]	1121	1	N	MODERATE	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	片頭痛	20[redacted]	1386	9	N	MODERATE	RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]	1476	2	N	MODERATE	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	インフルエンザ	20[redacted]	1552	6	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	1609	41	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	咳嗽	20[redacted]	1657	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	憩室炎	20[redacted]	1902	24	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	末梢静脈疾患	20[redacted]	2190	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	66	21	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	肺感染	20[redacted]	147	15	Y	MODERATE	NOT RELATED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	不安	20[redacted]	150	2	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	傾眠	20[redacted]	150	2	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	肝機能異常	20[redacted]	150	8	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	錯乱状態	20[redacted]	150	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	口腔内潰瘍形成	20[redacted]	153	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	肺感染	20[redacted]	230	19	Y	MODERATE	NOT RELATED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	頭痛	20[redacted]	230	7	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	消化不良	20[redacted]	236	7	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	肝機能検査異常	20[redacted]	238	5	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	297	20	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	360	12	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	消化不良	20[redacted]	363	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	痔核	20[redacted]	363	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	浮動性めまい	20[redacted]	365	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	アスパラギン酸アミノトランスフェラーゼ増加	20[redacted]	378	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	アラニンアミノトランスフェラーゼ増加	20[redacted]	378	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	口腔咽頭痛	20[redacted]	378	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	TPTD 20 UG SC QD					5[redacted]	F	WHITE OR CAUCASIAN	肺炎	20[redacted]	379	.	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	疲労	20[redacted]	42	.	N	MODERATE	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	歯膿瘍	20[redacted]	249	214	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	消化不良	20[redacted]	280	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	下痢	20[redacted]	296	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	インフルエンザ	20[redacted]	470	20	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	発疹	20[redacted]	485	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	膀胱瘤	20[redacted]	.	999	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	子宮脱	20[redacted]	728	921	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	動悸	20[redacted]	1119	79	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	ストレス	20[redacted]	1155	43	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	四肢痛	20[redacted]	1164	34	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	歯肉膿瘍	20[redacted]	1348	9	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	咽頭異常感覚	20[redacted]	1499	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]	1500	16	N	MILD	RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	咳嗽	20[redacted]	1501	16	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	呼吸困難	20[redacted]	1515	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	灼熱感	20[redacted]	1515	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	紅斑	20[redacted]	1515	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	頭痛	20[redacted]	1515	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]	1622	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	蕁麻疹	20[redacted]	1622	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	子宮脱	20[redacted]	1649	72	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	嘔吐	20[redacted]	1720	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	悪心	20[redacted]	1720	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	腹痛	20[redacted]	1720	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	蕁麻疹	20[redacted]	1995	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	54	9	N	MILD	RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	発疹	20[redacted]	59	2	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	外骨腫	20[redacted]	109	12	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	処置後血腫	20[redacted]	167	31	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	処置後挫傷	20[redacted]	168	30	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	大動脈硬化症	20[redacted]	401	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	415	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	476	14	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	510	24	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	534	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	不安	20[redacted]	574	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	関節痛	20[redacted]	580	44	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	痛風	20[redacted]	594	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]	601	41	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	体重減少	20[redacted]	605	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	滑液包炎	20[redacted]	605	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	うつ病	20[redacted]	610	31	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	上気道感染	20[redacted]	615	42	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	滑液嚢腫	20[redacted]	625	153	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	歯痛	20[redacted]	722	29	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	口腔粘膜紅斑	20[redacted]	734	31	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	非ホジキンリンパ腫	20[redacted]	777	.	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM				6[redacted]	F	WHITE OR CAUCASIAN	瘢痕痛	20[redacted]	788	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	浮動性めまい	20[redacted]	16	12	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	高コレステロール血症	20[redacted]	201	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	便秘	20[redacted]	315	87	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	脈拍欠損	20[redacted]	365	361	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	脈拍欠損	20[redacted]	365	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	377	8	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	485	22	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	悪心	20[redacted]	487	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	浮動性めまい	20[redacted]	630	732	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	足骨折	20[redacted]	843	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	発疹	20[redacted]	922	94	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	末梢性浮腫	20[redacted]	923	93	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	浮動性めまい	20[redacted]	1057	93	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	ウイルス性胃腸炎	20[redacted]	1085	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	ケトアシドーシス	20[redacted]	1085	3	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	1222	700	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	高血圧	20[redacted]	1274	29	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	1278	11	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	挫傷	20[redacted]	1300	31	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	1317	28	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	ウイルス性胃腸炎	20[redacted]	1365	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	霧視	20[redacted]	2176	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	心雑音	20[redacted]	2190	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	頭痛	20[redacted]	6	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	浮動性めまい	20[redacted]	40	4	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	血中カリウム増加	20[redacted]	40	4	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	頭痛	20[redacted]	61	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	皮膚疼痛	20[redacted]	154	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	四肢痛	20[redacted]	179	141	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	錯感覚	20[redacted]	212	149	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	313	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	腱痛	20[redacted]	318	352	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	足変形	20[redacted]	320	353	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	帯状疱疹	20[redacted]	431	17	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	皮膚乾燥	20[redacted]	491	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	尿失禁	20[redacted]	522	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	皮膚腫瘤	20[redacted]	558	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	筋痙縮	20[redacted]	628	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	血便排泄	20[redacted]	756	29	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	結腸癌	20[redacted]	785	54	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	処置による疼痛	20[redacted]	900	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	PLACEBO QM	PLACEBO QM	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	便秘	20[redacted]	902	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	四肢痛	20[redacted]	2	5	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	腹部不快感	20[redacted]	200	107	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	食欲減退	20[redacted]	200	231	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	上腹部痛	20[redacted]	261	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	貧血	20[redacted]	275	94	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	消化不良	20[redacted]	369	3	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	腹痛	20[redacted]	371	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	そう痒症	20[redacted]	372	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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]	CANADA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	437	14	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	裂孔ヘルニア	20[redacted]	567	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	発疹	20[redacted]	757	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	耳洗浄	20[redacted]	757	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	乳房腫瘤	20[redacted]	1022	33	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M			6[redacted]	F	WHITE OR CAUCASIAN	浸潤性乳管癌	20[redacted]	1055	.	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	眼の炎症	20[redacted]	28	359	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	不眠症	20[redacted]	146	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	嘔吐	20[redacted]	163	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	悪心	20[redacted]	163	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	処置後挫傷	20[redacted]	178	7	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	注射部位疼痛	20[redacted]	210	8	N	MODERATE	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	眼乾燥	20[redacted]	235	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	高血圧	20[redacted]	427	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	坐骨神経痛	20[redacted]	511	11	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	疲労	20[redacted]	550	2	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	鼻漏	20[redacted]	550	2	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	食欲減退	20[redacted]	583	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	616	137	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	結膜炎	20[redacted]	695	13	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	716	31	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	末梢性浮腫	20[redacted]	716	199	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	歯の障害	20[redacted]	825	8	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	915	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	消化不良	20[redacted]	1058	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	鼻出血	20[redacted]	1079	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	筋骨格痛	20[redacted]	.	84	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	1150	293	N	MILD	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	嘔吐	20[redacted]	1156	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	上気道感染	20[redacted]	1203	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	下痢	20[redacted]	1231	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	嘔吐	20[redacted]	1231	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	腹部不快感	20[redacted]	1231	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	上気道感染	20[redacted]-[redacted]-[redacted]	1239	30	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	認知障害	20[redacted]-[redacted]-[redacted]	1443	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	発熱	20[redacted]-[redacted]-[redacted]	1448	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	咳嗽	20[redacted]-[redacted]-[redacted]	1543	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	鼻漏	20[redacted]-[redacted]-[redacted]	1543	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	胆嚢炎	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	IV ANTIBIOTICS TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	腎機能障害	20[redacted]	.	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	貧血	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	うっ血性心不全	20[redacted]-[redacted]-[redacted]	1958	.	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	急性心筋梗塞	20[redacted]-[redacted]-[redacted]	1958	.	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	低マグネシウム血症	20[redacted]-[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	大腸菌性敗血症	20[redacted]-[redacted]-[redacted]	2061	32	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	急性心筋梗塞	20[redacted]-[redacted]-[redacted]	2061	.	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	クロストリジウム・ディフィシレ大腸炎	20[redacted]-[redacted]-[redacted]	2085	67	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	低血圧	20[redacted]-[redacted]-[redacted]	2100	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	注射部位紅斑	20[redacted]-[redacted]-[redacted]	1	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	筋緊張	20[redacted]-[redacted]-[redacted]	1	2247	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	便秘	20[redacted]	3	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	21	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	53	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	頭痛	20[redacted]	84	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	頭痛	20[redacted]	90	2158	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	便秘	20[redacted]	.	2152	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	ストレス	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	注射部位反応	20[redacted]	213	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	徐脈	20[redacted]	214	12	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	咳嗽	20[redacted]	.	43	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	299	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	第二度房室ブロック	20[redacted]	430	2	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	心タンポナーデ	20[redacted]	431	4	Y	LIFE THREATENING	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	肺炎	20[redacted]	432	19	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	.	1695	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	601	7	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	椎間板突出	20[redacted]	.	1512	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N

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]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	不眠症	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	体重減少	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	食欲減退	20[redacted]	.	154	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	.	1176	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	.	1146	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	単径ヘルニア	20[redacted]	1168	6	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	胃炎	20[redacted]	1169	1079	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	1214	10	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	関節痛	20[redacted]	.	903	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	末梢性感覚運動ニューロパチー	20[redacted]	1349	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	蕁麻疹	20[redacted]	1	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	そう痒症	20[redacted]	2	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	悪心	20[redacted]	2	31	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	皮膚刺激	20[redacted]	2	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	脱毛症	20[redacted]	2	62	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	振戦	20[redacted]	.	.	Y	MILD	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N

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[redacted]	AUSTRIA	AMG 785 140 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	鍯感覚	20[redacted]	34	.	Y	MILD	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	鼻炎	20[redacted]	59	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	鼻炎	20[redacted]	66	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	鼻炎	20[redacted]	76	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 140 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	鼻炎	20[redacted]	86	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	筋骨格痛	20[redacted]	.	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	蕁麻疹	20[redacted]	.	58	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	口腔咽頭痛	20[redacted]	3	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	四肢痛	20[redacted]	3	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	外骨腫	20[redacted]	9	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	肩回旋筋腱板症候群	20[redacted]	9	824	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	軟骨疾患	20[redacted]	9	824	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	胆石症	20[redacted]	26	2129	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	頭痛	20[redacted]	30	2125	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	鼻炎	20[redacted]	40	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	筋緊張亢進	20[redacted]	47	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	59	.	N	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	110	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	後天性涙腺炎	20[redacted]	121	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	適用部位反応	20[redacted]	179	3	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	白内障	20[redacted]	267	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	帯状疱疹	20[redacted]	268	5	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	354	1801	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	帯状疱疹	20[redacted]	438	8	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	腹痛	20[redacted]	455	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	筋骨格痛	20[redacted]	563	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	結膜炎	20[redacted]	585	1570	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	眼の炎症	20[redacted]	787	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	限局性感染	20[redacted]	813	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	季節性アレルギー	20[redacted]	814	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	肩回旋筋腱板症候群	20[redacted]	831	2	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	口腔ヘルペス	20[redacted]	901	8	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	腱炎	20[redacted]	943	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	上顆炎	20[redacted]	1006	2	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	消化不良	20[redacted]	1140	10	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	外傷性血腫	20[redacted]	1234	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	1234	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	皮膚炎	20[redacted]	1254	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	下痢	20[redacted]	1289	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	顎痛	20[redacted]	1341	16	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	歯瘻	20[redacted]	1345	12	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	嘔吐	20[redacted]	1372	9	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	ビタミンD欠乏	20[redacted]	1422	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	鉄欠乏	20[redacted]	1422	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	失神	20[redacted]	1434	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	抜歯	20[redacted]	1610	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	睡眠障害	20[redacted]	1640	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	胆道仙痛	20[redacted]	1640	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	AUSTRIA	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	胆嚢炎	20[redacted]	1667	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	91	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	159	1087	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	関節痛	20[redacted]	159	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	340	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	435	.	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	膝関節形成	20[redacted]	477	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	不整脈	20[redacted]	529	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	回転性めまい	20[redacted]	529	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	赤血球増加症	20[redacted]	529	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	541	22	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	胃炎	20[redacted]	671	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	食道炎	20[redacted]	671	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	体重減少	20[redacted]	677	147	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	胆石症	20[redacted]	697	32	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	坐骨神経痛	20[redacted]	776	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	小結節	20[redacted]	1111	32	N	MILD	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	1246	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	1424	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	椎間板突出	20[redacted]	1664	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	2152	11	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	2178	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	筋骨格痛	20[redacted]	218	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	乳房石灰化	20[redacted]	481	31	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	735	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	高血圧	20[redacted]	741	34	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	薬疹	20[redacted]	774	32	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	発疹	20[redacted]	1058	46	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	発疹	20[redacted]	1119	29	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	白内障	20[redacted]	1127	112	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	白内障	20[redacted]	1127	98	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	痔核	20[redacted]	1253	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	発疹	20[redacted]	1275	232	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	1431	52	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	1431	43	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	歯膿瘍	20[redacted]	1487	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	関節炎	20[redacted]	1543	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	末梢性浮腫	20[redacted]	1547	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	1655	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	体重減少	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	疲労	20[redacted]	1824	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	副甲状腺機能亢進症	20[redacted]	1826	220	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	甲状腺の良性新生物	20[redacted]	1889	157	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	胸部不快感	20[redacted]	1889	10	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	腎嚢胞	20[redacted]	1889	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	呼吸困難	20[redacted]	1897	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	便秘	20[redacted]	2045	23	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	処置による疼痛	20[redacted]	2045	9	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	痔核	20[redacted]	2045	23	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	肛門出血	20[redacted]	2045	23	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	血栓性痔核	20[redacted]	2045	23	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	N
[redacted]	BELGIUM	ALN 70 MG PO QW					6[redacted]	F	WHITE OR CAUCASIAN	胃潰瘍	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW					6[redacted]	F	WHITE OR CAUCASIAN	胆管炎	20[redacted]	.	56	Y	SEVERE	NOT RELATED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	BELGIUM	ALN 70 MG PO QW					6[redacted]	F	WHITE OR CAUCASIAN	高コレステロール血症	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW					6[redacted]	F	WHITE OR CAUCASIAN	そう痒症	20[redacted]	108	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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[redacted]	BELGIUM	ALN 70 MG PO QW					6[redacted]	F	WHITE OR CAUCASIAN	大腸菌性菌血症	20[redacted]	108	40	N	SEVERE	NOT RELATED	DRUG WITHDRAWN	MEDICATION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW					6[redacted]	F	WHITE OR CAUCASIAN	昏睡	20[redacted]	108	1	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BELGIUM	ALN 70 MG PO QW					6[redacted]	F	WHITE OR CAUCASIAN	肝膿瘍	20[redacted]	108	.	N	SEVERE	NOT RELATED	DRUG WITHDRAWN	NO ACTION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW					6[redacted]	F	WHITE OR CAUCASIAN	咳嗽	20[redacted]	227	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	出血性素因	20[redacted]	55	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	外陰部腟カンジダ症	20[redacted]	62	164	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	丹毒	20[redacted]	129	97	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	体重増加	20[redacted]	183	988	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	咳嗽	20[redacted]	224	27	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	224	27	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	咳嗽	20[redacted]	419	239	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	419	49	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	467	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	高尿酸血症	20[redacted]	467	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	ぶどう膜炎	20[redacted]	503	155	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	丹毒	20[redacted]	648	10	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	口腔咽頭痛	20[redacted]	755	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	咳嗽	20[redacted]	755	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	丹毒	20[redacted]	1076	16	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	1163	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	副鼻腔炎	20[redacted]	1532	31	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	咳嗽	20[redacted]	1532	31	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	1532	31	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	咳嗽	20[redacted]	1787	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	挫傷	20[redacted]	1787	12	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	胃腸管癒	20[redacted]	1975	102	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	胃腸管癒	20[redacted]	1975	122	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	5[redacted]	F	WHITE OR CAUCASIAN	咳嗽	20[redacted]	2128	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M				7[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	483	1	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	278	16	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	313	37	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	肛門癌	20[redacted]	386	.	Y	LIFE THREATENING	NOT RELATED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	便秘	20[redacted]	66	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	悪心	20[redacted]	66	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	上腹部痛	20[redacted]	147	92	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	気管炎	20[redacted]	238	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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[redacted]	BELGIUM	AMG 785 70 MG SC QM					6[redacted]	F	WHITE OR CAUCASIAN	脳虚血	20[redacted]	273	.	Y	SEVERE	NOT RELATED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	85	7	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	便秘	20[redacted]	144	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	上腹部痛	20[redacted]	158	48	N	MILD	RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	上腹部痛	20[redacted]	273	13	N	MILD	RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	神経過敏	20[redacted]	363	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	上腹部痛	20[redacted]	367	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	高コレステロール血症	20[redacted]	406	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	450	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	咽頭炎	20[redacted]	541	9	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	557	11	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	うつ病	20[redacted]	571	164	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	体重減少	20[redacted]	571	345	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	肛門の炎症	20[redacted]	719	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	過敏性腸症候群	20[redacted]	729	6	Y	MILD	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	うつ病	20[redacted]	735	.	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N

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]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	歯肉炎	20[redacted]-[redacted]-[redacted]	967	30	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	齲歯	20[redacted]-[redacted]-[redacted]	967	30	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	高血圧	20[redacted]-[redacted]-[redacted]	1028	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]-[redacted]-[redacted]	1126	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	腱鞘炎	20[redacted]-[redacted]-[redacted]	1159	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	上腹部痛	20[redacted]-[redacted]-[redacted]	1428	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	回転性めまい	20[redacted]-[redacted]-[redacted]	1942	151	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	起立性低血圧	20[redacted]-[redacted]-[redacted]	2	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	中心性肥満	20[redacted]-[redacted]-[redacted]	8	23	Y	MILD	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	横隔膜ヘルニア	20[redacted]-[redacted]-[redacted]	16	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	胃食道逆流性疾患	20[redacted]-[redacted]-[redacted]	16	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	表在性静脈炎	20[redacted]-[redacted]-[redacted]	16	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	静脈炎	20[redacted]-[redacted]-[redacted]	16	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	頭痛	20[redacted]-[redacted]-[redacted]	16	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	肺塞栓症	20[redacted]-[redacted]-[redacted]	20	11	Y	LIFE THREATENING	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	胃潰瘍	20[redacted]-[redacted]-[redacted]	22	29	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	深部静脈血栓症	20[redacted]	29	29	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	116	107	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	高血圧	20[redacted]	147	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	300	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	高コレステロール血症	20[redacted]	390	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	インスリン抵抗性	20[redacted]	405	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	うつ病	20[redacted]	665	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位疼痛	20[redacted]	1126	4	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位疼痛	20[redacted]	1126	4	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1188	4	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1188	4	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1244	3	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1244	3	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1307	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1307	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	1394	22	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	歯膿瘍	20[redacted]	1406	10	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	1456	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	靭帯捻挫	20[redacted]	1456	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]	1476	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	坐骨神経痛	20[redacted]	1522	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	抜歯	20[redacted]	1608	31	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	PLACEBO Q3M	PLACEBO Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	1973	10	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	動悸	20[redacted]	1	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻炎	20[redacted]	78	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	副鼻腔炎	20[redacted]	104	11	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	脂肪腫	20[redacted]	177	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	回転性めまい	20[redacted]	208	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	疲労	20[redacted]	208	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	頭痛	20[redacted]	208	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	胸痛	20[redacted]	342	93	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	咽頭炎	20[redacted]	378	9	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	578	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	関節損傷	20[redacted]	631	20	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	高コレステロール血症	20[redacted]	640	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	上気道感染	20[redacted]	647	9	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	静脈瘤	20[redacted]	693	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	副鼻腔炎	20[redacted]	769	10	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	818	9	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	平滑筋腫	20[redacted]	854	35	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	緑内障	20[redacted]	1035	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	尺骨骨折	20[redacted]	1099	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	手首関節骨折	20[redacted]	1099	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	1204	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	関節痛	20[redacted]	1204	65	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	1215	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	眼瞼炎	20[redacted]	1372	50	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	緑内障	20[redacted]	1372	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	坐骨神経痛	20[redacted]	1379	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]	1478	2	N	MILD	RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	1513	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	歯修復	20[redacted]	1937	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位疼痛	20[redacted]	1	2	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	頭痛	20[redacted]	1	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	9	7	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	84	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	322	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	インフルエンザ様疾患	20[redacted]	333	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	過敏性腸症候群	20[redacted]	410	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	大腸ポリープ	20[redacted]	427	40	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	嚢胞	20[redacted]	708	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	805	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	846	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	関節滲出液	20[redacted]	937	154	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位疼痛	20[redacted]	1100	2	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位疼痛	20[redacted]	1100	2	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	1145	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1156	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1156	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	1180	7	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1219	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1219	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1248	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1248	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1276	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1276	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	節足動物咬傷	20[redacted]	1279	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1304	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1304	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1339	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1373	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	注射部位そう痒感	20[redacted]	1401	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	1425	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	そう痒症	20[redacted]	1430	1	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	1453	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	インフルエンザ	20[redacted]	1472	3	N	MILD	RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	抜歯	20[redacted]	1718	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	1811	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	2108	9	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	大腸腺腫	20[redacted]	2145	34	Y	MILD	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	一過性脳虚血発作	20[redacted]	6	29	Y	SEVERE	NOT RELATED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	白内障	20[redacted]	10	257	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	うつ病	20[redacted]	25	106	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	不眠症	20[redacted]	25	106	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	便秘	20[redacted]	25	215	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	疼痛	20[redacted]	25	31	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	高コレステロール血症	20[redacted]	25	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	51	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	筋痙縮	20[redacted]	222	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	362	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	頭痛	20[redacted]	33	2	N	MILD	RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	回転性めまい	20[redacted]	120	33	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	高コレステロール血症	20[redacted]	181	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	353	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	384	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	腹痛	20[redacted]	391	17	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	大腸ポリープ切除	20[redacted]	516	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	憩室	20[redacted]	516	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	587	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	641	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	879	16	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	上腹部痛	20[redacted]	906	2	Y	MILD	NOT RELATED	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	滑液包炎	20[redacted]	1022	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	1086	7	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	節足動物咬傷	20[redacted]	1302	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	歯修復	20[redacted]	1319	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	インフルエンザ様疾患	20[redacted]	1476	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	憩室炎	20[redacted]	1487	27	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N

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]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	老人性難聴	20[redacted]	1488	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻乾燥	20[redacted]	1488	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	歯痛	20[redacted]	1858	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	失神寸前の状態	20[redacted]	1871	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	1991	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	尿失禁	20[redacted]	157	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	基底細胞癌	20[redacted]	392	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	アルツハイマー型認知症	20[redacted]	.	.	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	糖尿病	20[redacted]	1062	15	Y	MILD	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	1062	3	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	不安	20[redacted]	181	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	坐骨神経痛	20[redacted]	694	136	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	末梢性浮腫	20[redacted]	694	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	高コレステロール血症	20[redacted]	760	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]	812	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	1143	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	粘膜乾燥	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	1577	328	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	咽頭炎	20[redacted]	1633	13	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	1850	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	処置による疼痛	20[redacted]	1905	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	ウイルス性心膜炎	20[redacted]	8	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	インフルエンザ	20[redacted]	31	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	低血圧	20[redacted]	31	47	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	40	21	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	咽頭炎	20[redacted]	78	17	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	胃炎	20[redacted]	184	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	白内障手術	20[redacted]	221	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	244	12	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	線維筋痛	20[redacted]	366	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	放屁	20[redacted]	380	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	軟骨損傷	20[redacted]	614	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	軟骨損傷	20[redacted]	687	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	歯膿瘍	20[redacted]	805	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N

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]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	無力症	20[redacted]	822	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	嘔吐	20[redacted]	1114	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	悪心	20[redacted]	1114	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	遺尿	20[redacted]	1311	865	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	咳嗽	20[redacted]	.	86	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	高血圧	20[redacted]	1520	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	挫傷	20[redacted]	1835	67	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	筋骨格痛	20[redacted]	1835	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	1835	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	橈骨骨折	20[redacted]	1846	.	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	うつ病	20[redacted]	2007	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	回転性めまい	20[redacted]	2052	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	関節痛	20[redacted]	2052	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	47	7	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	329	9	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	409	10	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	貧血	20[redacted]	601	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	609	12	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	669	11	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	714	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	727	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	尿路感染	20[redacted]	897	7	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	1032	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	1093	7	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	1362	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	1523	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	軟便	20[redacted]	1779	56	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	胃炎	20[redacted]	1820	127	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	食道炎	20[redacted]	1820	127	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	下痢	20[redacted]	1854	93	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	肺炎	20[redacted]	1939	9	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	うつ病	20[redacted]	1947	110	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	7[redacted]	F	WHITE OR CAUCASIAN	消化管運動障害	20[redacted]	1947	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				7[redacted]	F	WHITE OR CAUCASIAN	便秘	20[redacted]	3	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				7[redacted]	F	WHITE OR CAUCASIAN	発熱	20[redacted]	4	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				7[redacted]	F	WHITE OR CAUCASIAN	嘔吐	20[redacted]	18	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				7[redacted]	F	WHITE OR CAUCASIAN	発熱	20[redacted]	18	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				7[redacted]	F	WHITE OR CAUCASIAN	舌障害	20[redacted]	36	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				7[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	555	11	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				7[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	604	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				7[redacted]	F	WHITE OR CAUCASIAN	筋骨格痛	20[redacted]	679	.	N	MILD	NOT RELATED	DRUG WITHDRAWN	NO ACTION TAKEN	N

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]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				7[redacted]	F	WHITE OR CAUCASIAN	マイコバクテリウム・カンサシイ感染	20[redacted]	704	.	Y	MILD	NOT RELATED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	関節周囲炎	20[redacted]	186	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	高コレステロール血症	20[redacted]	191	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	坐骨神経痛	20[redacted]	459	73	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	子宮瘤	20[redacted]	.	354	Y	MILD	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	排尿困難	20[redacted]	.	354	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	直腸瘤	20[redacted]	.	354	Y	MILD	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	白内障	20[redacted]	668	132	N	MILD	NOT RELATED	DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	血腫	20[redacted]	697	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	697	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	DENOSUMAB 60 MG Q6M			7[redacted]	F	WHITE OR CAUCASIAN	失見当識	20[redacted]	838	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	腹痛	20[redacted]	22	20	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	消化管壊死	20[redacted]	25	1	Y	MILD	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	便秘	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	歯膿瘍	20[redacted]	378	16	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	虚血性大腸炎	20[redacted]	635	9	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 140 MG SC Q3M	AMG 785 140 MG SC Q3M	PLACEBO			8[redacted]	F	WHITE OR CAUCASIAN	尿意切迫	20[redacted]	906	10	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	乳癌	20[redacted]	51	90	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	四肢痛	20[redacted]	140	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	消化不良	20[redacted]	636	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	耳鳴	20[redacted]	902	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	関節周囲炎	20[redacted]	1227	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	四肢痛	20[redacted]	1536	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	気道感染	20[redacted]	1952	65	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	2068	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	2107	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	AMG 785 210 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	靭帯捻挫	20[redacted]	2107	22	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	肺感染	20[redacted]	.	35	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	裂孔ヘルニア	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	肩回旋筋腱板症候群	20[redacted]	338	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	脳出血	20[redacted]	338	1	Y	MILD	NOT RELATED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	338	1	Y	MILD	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	鎖骨骨折	20[redacted]	338	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	頭蓋骨骨折	20[redacted]	338	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	顔面骨骨折	20[redacted]	338	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	高血圧	20[redacted]	338	40	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	創傷	20[redacted]	721	10	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	721	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	創傷	20[redacted]	875	11	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	875	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	1041	.	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	ALN 70 MG PO QW	AMG 785 140 MG SC QM	PLACEBO			7[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	1070	1	Y	MILD	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	聴力低下	20[redacted]	28	30	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	インフルエンザ	20[redacted]	51	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	耳感染	20[redacted]	125	9	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	四肢痛	20[redacted]	134	18	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	134	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	末梢性浮腫	20[redacted]	148	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	複合性局所疼痛症候群	20[redacted]	201	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	脱毛症	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	大腸ポリープ	20[redacted]	541	1	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	回転性めまい	20[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	咽頭炎	20[redacted]	729	16	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	手掌紅斑	20[redacted]	732	4	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	BELGIUM	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	白内障	20[redacted]	801	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	気管支炎	20[redacted]	80	46	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	出血性膀胱炎	20[redacted]	129	16	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	唾液腺炎	20[redacted]	152	13	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	胸部不快感	20[redacted]	.	94	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	疲労	20[redacted]	247	51	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	気道感染	20[redacted]	289	10	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	皮膚新生物切除	20[redacted]	329	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N

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[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	インフルエンザ	20[redacted]-[redacted]-[redacted]	356	14	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	錯感覚	20[redacted]-[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	慢性閉塞性肺疾患	20[redacted]-[redacted]-[redacted]	454	14	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	脳血管発作	20[redacted]-[redacted]-[redacted]	458	1	Y	MILD	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	鼻出血	20[redacted]-[redacted]-[redacted]	463	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	性交困難	20[redacted]-[redacted]-[redacted]	504	78	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM				6[redacted]	F	WHITE OR CAUCASIAN	外陰腟真菌感染	20[redacted]-[redacted]-[redacted]	537	45	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	無力症	20[redacted]-[redacted]-[redacted]	22	.	N	MILD	NOT RELATED	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	高血圧	20[redacted]-[redacted]-[redacted]	22	.	N	MILD	NOT RELATED	DRUG WITHDRAWN	NO ACTION TAKEN	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	頚部痛	20[redacted]-[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	高コレステロール血症	20[redacted]-[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	関節周囲炎	20[redacted]-[redacted]-[redacted]	197	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	白内障	20[redacted]-[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	黄斑変性	20[redacted]-[redacted]	.	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BELGIUM	TPTD 20 UG SC QD					7[redacted]	F	WHITE OR CAUCASIAN	冠動脈疾患	20[redacted]-[redacted]-[redacted]	268	.	Y	MILD	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	末梢腫脹	20[redacted]-[redacted]-[redacted]	15	74	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	不随意性筋収縮	20[redacted]-[redacted]-[redacted]	212	.	N	MODERATE	RELATED	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	肺炎	20[redacted]-[redacted]-[redacted]	376	25	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	帯状疱疹	20[redacted]-[redacted]-[redacted]	492	112	N	SEVERE	NOT RELATED	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	N

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]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	腹痛	20[redacted]	492	112	N	SEVERE	NOT RELATED	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	膣分泌物	20[redacted]	.	60	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	.	882	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	1173	13	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	処置後便秘	20[redacted]	1185	2	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	消化不良	20[redacted]	1185	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	処置による嘔吐	20[redacted]	1186	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	便秘	20[redacted]	1188	60	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	処置による疼痛	20[redacted]	1188	61	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	消化不良	20[redacted]	1188	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	1258	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	嘔吐	20[redacted]	1309	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	浮動性めまい	20[redacted]	1309	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	そう痒症	20[redacted]	1400	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	腹痛	20[redacted]	1478	2	N	MODERATE	RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	悪心	20[redacted]	1479	2	N	MODERATE	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]	1482	5	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	肺炎	20[redacted]	1918	27	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	聴覚障害者	20[redacted]	1927	14	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	不眠症	20[redacted]	1930	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	不眠症	20[redacted]	1932	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	処置による疼痛	20[redacted]	2038	8	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	消化不良	20[redacted]	2038	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	8[redacted]	F	WHITE OR CAUCASIAN	処置後便秘	20[redacted]	2039	2	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	32	13	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	頻尿	20[redacted]	44	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	151	61	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	305	48	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	紅斑性皮疹	20[redacted]	401	318	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	靭帯捻挫	20[redacted]	469	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	外陰腟乾燥	20[redacted]	646	701	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	高血圧	20[redacted]	675	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	682	37	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	885	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	900	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	加齢黄斑変性	20[redacted]	.	838	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	1114	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	末梢冷感	20[redacted]	1123	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	歯周病	20[redacted]	1177	10	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	浮動性めまい	20[redacted]	1202	32	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	下肢静止不能症候群	20[redacted]	1238	19	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	そう痒症	20[redacted]	1419	29	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻咽頭炎	20[redacted]	1533	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	そう痒症	20[redacted]	1549	10	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	流涙増加	20[redacted]	1591	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	鼻漏	20[redacted]	1591	15	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	膀胱炎	20[redacted]	1592	7	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	新生血管加齢黄斑変性	20[redacted]	1788	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 140 MG SC QM	AMG 785 140 MG SC QM	PLACEBO	AMG 785 210 MG SC QM	ZOLEDRONIC ACID	6[redacted]	F	WHITE OR CAUCASIAN	脳血管発作	20[redacted]	1856	.	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	悪心	20[redacted]	2	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	頭位性回転性めまい	20[redacted]	11	82	N	MILD	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	高血圧	20[redacted]	117	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	関節痛	20[redacted]	278	57	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	関節腫脹	20[redacted]	278	57	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	注射部位疼痛	20[redacted]	391	3	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	インフルエンザ	20[redacted]	460	15	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	橈骨骨折	20[redacted]	546	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	EMERGENCY ROOM VISIT	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	交通事故	20[redacted]	719	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	皮膚擦過傷	20[redacted]	719	32	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	筋骨格痛	20[redacted]	719	32	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	関節痛	20[redacted]	719	32	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	筋痙縮	20[redacted]	771	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	脂漏性角化症	20[redacted]	771	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	筋骨格痛	20[redacted]	1029	252	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	ウイルス性胃腸炎	20[redacted]	1096	5	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	背部痛	20[redacted]	1295	44	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]	1349	6	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	鼠径部痛	20[redacted]	1430	8	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	日光角化症	20[redacted]	1462	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	関節痛	20[redacted]	1472	505	Y	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	聴力低下	20[redacted]	1564	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	異常感覚	20[redacted]	1714	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	変形性関節症	20[redacted]	1795	283	Y	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	平衡障害	20[redacted]	1898	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	肺気腫	20[redacted]	1912	.	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 70 MG SC QM	AMG 785 70 MG SC QM	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	7[redacted]	F	WHITE OR CAUCASIAN	関節リウマチ	20[redacted]	1912	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	中足骨痛	20[redacted]	13	56	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	関節脱臼	20[redacted]	34	91	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	スピゲリウスヘルニア	20[redacted]	120	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N

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[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	レジオネラ菌性肺炎	20[redacted]	148	34	Y	SEVERE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	筋肉痛	20[redacted]	246	133	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	ヘルニア修復	20[redacted]	254	1	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	四肢痛	20[redacted]	569	105	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	転倒	20[redacted]	569	1	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	関節痛	20[redacted]	611	63	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	四肢痛	20[redacted]	768	1067	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	ウイルス感染	20[redacted]	790	16	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	軟骨損傷	20[redacted]	.	173	N	MILD	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	湿疹	20[redacted]	892	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	歯痛	20[redacted]	1102	62	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	齲歯	20[redacted]	1102	62	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	OTHER	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	関節痛	20[redacted]	1130	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	関節痛	20[redacted]	1130	.	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	インフルエンザ	20[redacted]	1152	11	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	胃腸炎	20[redacted]	1198	8	N	MILD	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	DENMARK	AMG 785 210 MG SC Q3M	AMG 785 210 MG SC Q3M	DENOSUMAB 60 MG Q6M	AMG 785 210 MG SC QM	NO INTERVENTION	6[redacted]	F	WHITE OR CAUCASIAN	節足動物咬傷	20[redacted]	1367	4	N	MODERATE	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN	N